MACHINERY SAFETY
RISK ASSESSMENT

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Productmanagement „Industrial Safety & Motion Control Sensors“

May 2021

REMARKS TO THIS WEBINAR

- This webinar will be recorded!

- If you would like to receive the **presentation** and / or the **recording** afterwards, we ask for your **consent in accordance with the GDPR**!

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MACHINE DIRECTIVE 2006/42/EG
ANNEX I

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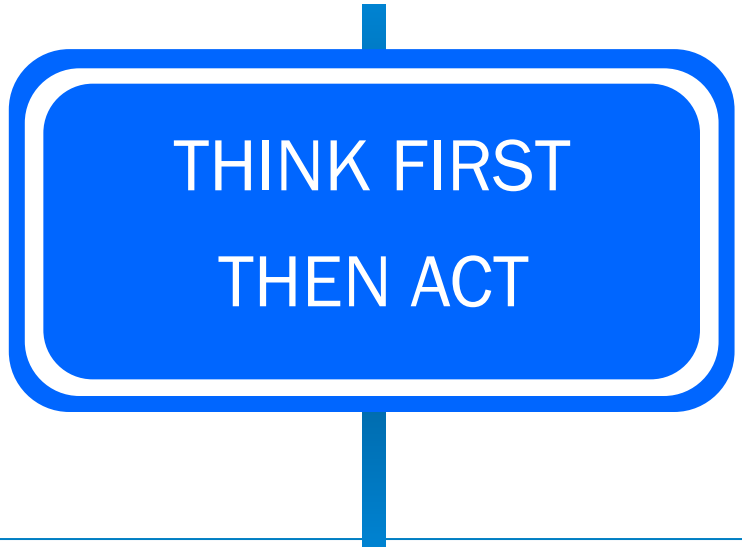
General Principles:

1.) The **manufacturer** of machinery 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



METHODOLOGY FOR SAFE MACHINES

The manufacturer is obliged:

- To assess the risks associated with his machine

RISK ASSESSMENT

- and to construct the machine based on the results of the risk assessment

RISK REDUCTION

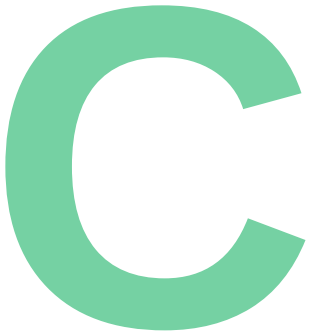
STRUCTURE OF THE SAFETY STANDARDS

A-type standards - basic safety standards

- Which basic principles must be taken into account in the development and design of machines?

B-type standards - generic safety standards

- What are the default values for safety-relevant parameters?

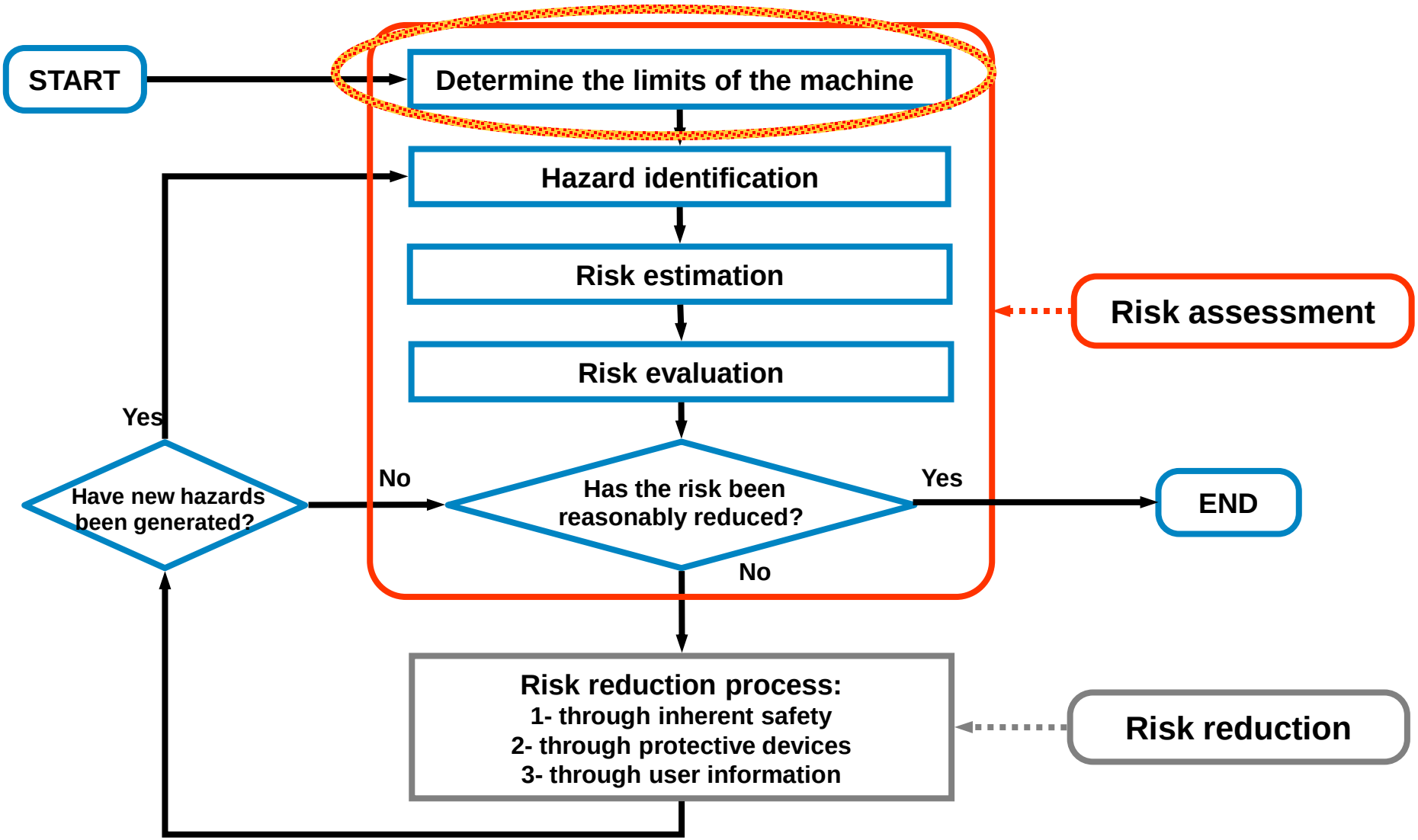


C-type standards - machine safety standards

- Development and design specifications for machinery (groups) taking into account general experience and the “state of the art”

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

RISK ASSESSMENT AND RISK REDUCTION
EN ISO 12100



RISK ASSESSMENT
EN ISO 12100

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1. Determine the limits

Spacial limits:	Range of movement, space requirements, air pollution
Use limits:	Intended use, reasonably foreseeable misuse, ...
... during the life phases:	Construction, transport, commissioning deployment and use: operation, cleaning, maintenance, dismantling, removal, disposal
Time limits:	Service life, wear and tear parts, consumption

2. Identify hazards...

... Crushing, shearing, electrocution, poisoning, burning, ...

3. Risk assessment/risk evaluation

... Severity of harm, presence in the hazardous area, probability, ...

4. Select measures

... design, technical, warnings, operating instructions, ...

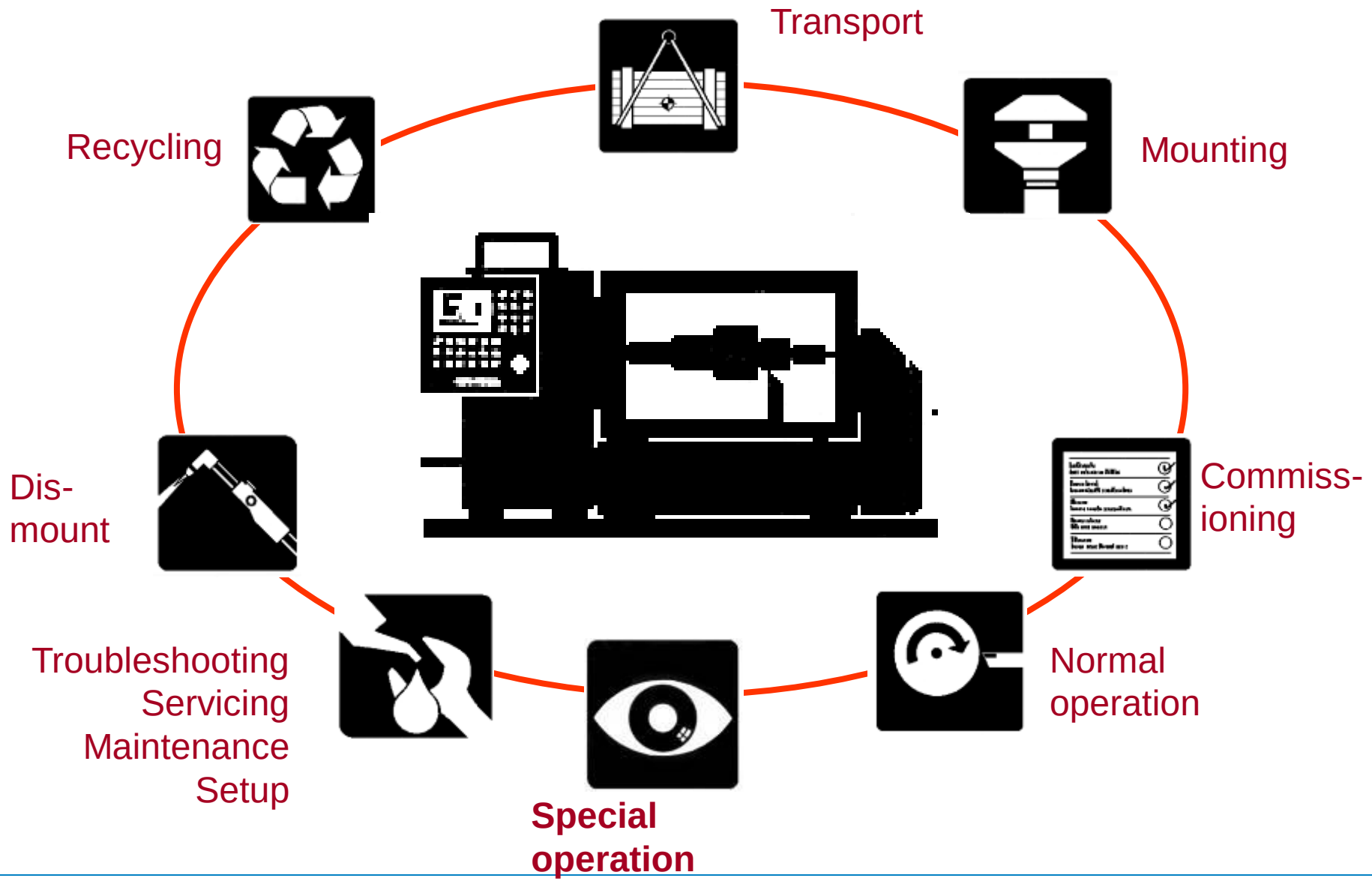
5. Determine residual risks

(check effectiveness of protective measures, validation)

6. Take additional measures

(Points 2 - 6 are to be applied to all limits and life phases mentioned under 1.)
(Points 4 - 6 are to be repeated until the residual risk has been reduced to an acceptable level)

RISK ASSESSMENT
LIFE PHASES OF MACHINERY TO BE CONSIDERED



RISK ASSESSMENT
LIFE PHASES AND TASKS

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LIFE PHASES

- Construction
- Transport, mounting, installation
- Commissioning
- Adjustment, teach-in, programming or process change *
- Operation/special operation
- Cleaning
- Troubleshooting
- Servicing/maintenance
- Decommissioning, disassembly and - if it affects safety - disposal

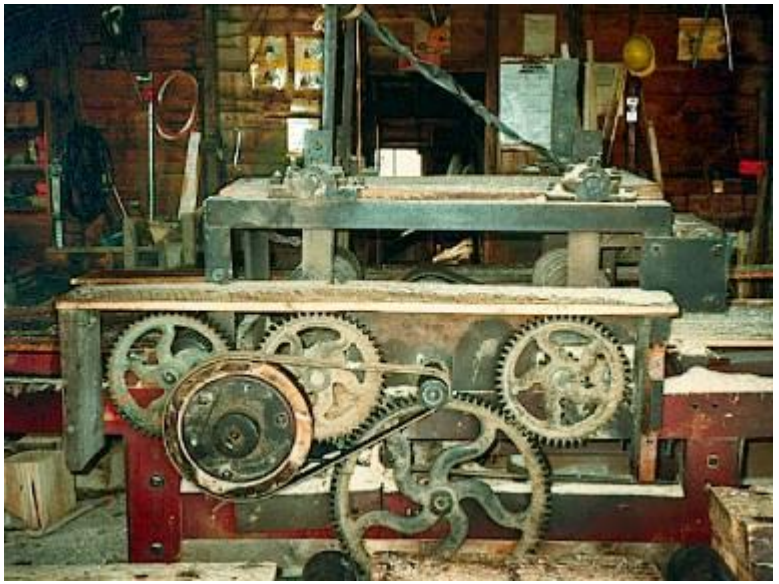
TASKS (examples)

- Adjustment
- Testing
- Teach-in/programming
- Process/tool changeover
- Commissioning
- Loading/material transportation
- Unloading/product removal
- Stopping the machine
- Stopping in an emergency
- Restarting after a material jam
- Restart after a fault
- Troubleshooting and rectification by the operator
- Cleaning, care
- Maintenance

*: particularly relevant for production-related operation of machinery

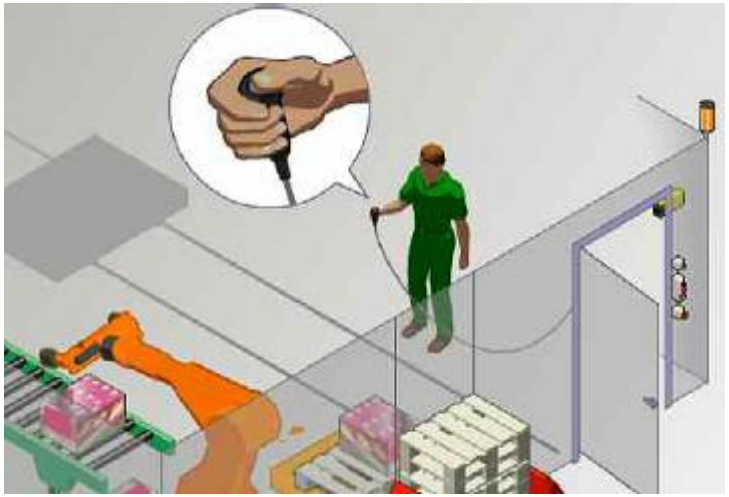
RISK ASSESSMENT
LIMITS OF THE MACHINE – SPACE, TIME AND OTHER LIMITS

- Spacial limits
  - Space requirements and range of movement
  - Operator interaction
  - Power supply
- Time limits
  - Service life of the machine and components
  - Recommended maintenance intervals.
- Other limits
  - Ambient conditions
    (temperatures, indoor or outdoor use, moisture, weather,
    direct sunlight, dust, ex-atmosphere, etc.)
  - Required cleanliness
  - Materials used and substances processed

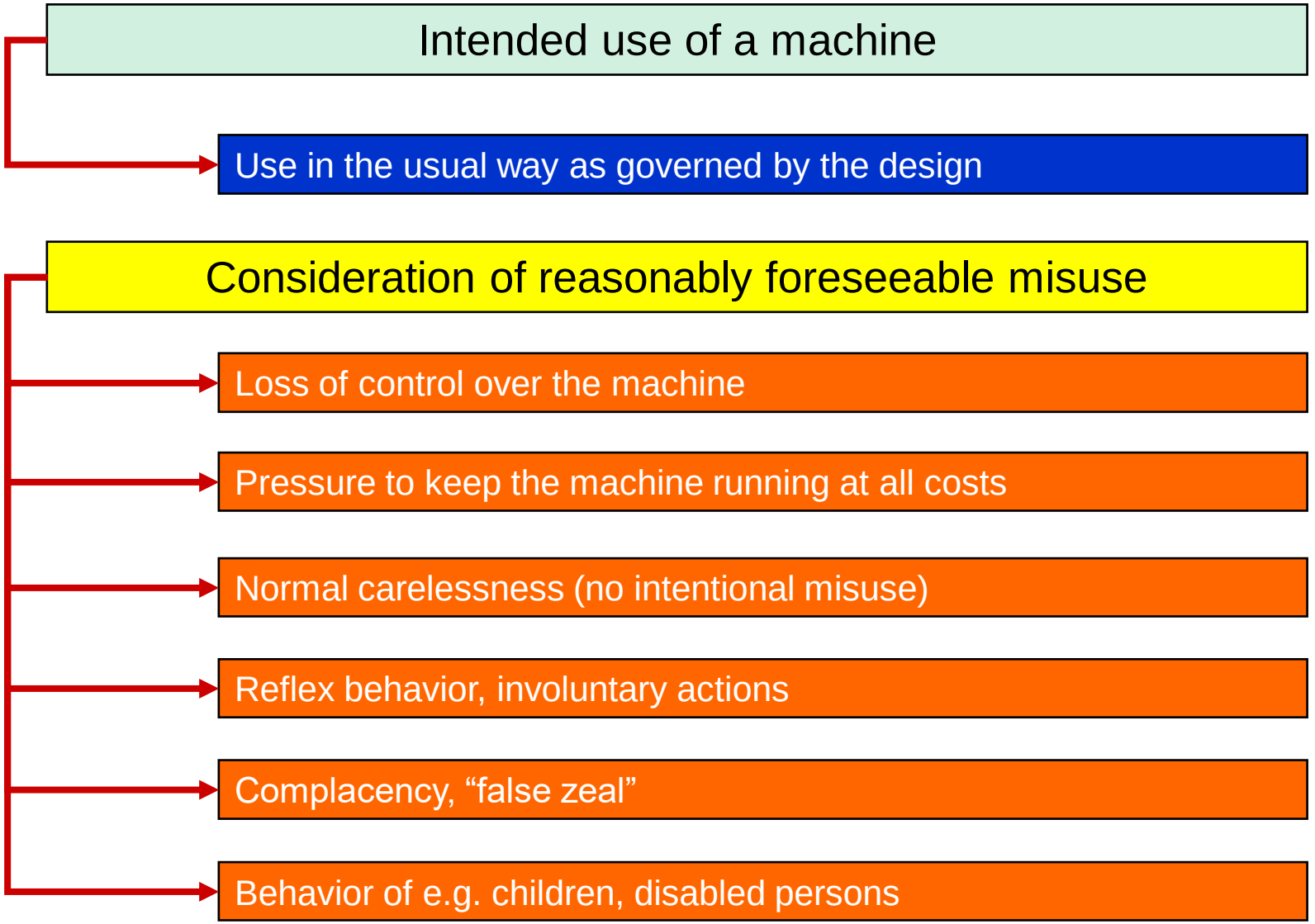


covers the intended use **and** the (reasonably) foreseeable misuse (must be taken into account!)

- Operating modes of the machine
- Number and timing of operator interventions and procedures
- Use of the machine (e.g. industrial, non-industrial, household use)
- Persons who operate the machine and their physical abilities
- Education and experience of users, required training or instruction:
  - Operators
  - Maintenance personnel, technical personnel
  - Apprentices
  - Public use
- Foreseeable exposure of other persons
  - other workstations nearby
  - other employees nearby
  - External personnel (service providers)
  - Visitors (possibly also children)



USE OF THE MACHINE
INTENDED – REASONABLY FORESEEABLE MISUSE



IDENTIFYING HAZARDS

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Hazards should be identified during the risk analysis:

▪ Mechanical hazards	Crushing, shearing, cutting, catching, drawing in, stabbing, pushing, ...
▪ Electrical hazards -	Burns, electric shock, ...
▪ Thermal hazards	Burns, scalds, frostbite, ...
▪ Noise hazards	Loss of hearing, consciousness, balance, ...
▪ Vibration hazards	Discomfort, physical injury, ...
▪ Radiation hazards	Skin/eye damage, genetic damage
▪ Hazards due to substances	Poisoning, infections, explosions
▪ Ergonomic hazards	Discomfort, fatigue, stress
▪ Working environment	Slipping, falling, suffocation

▪ Combinations of the above hazards

IDENTIFYING HAZARDS
EXAMPLES (EN ISO 12100)

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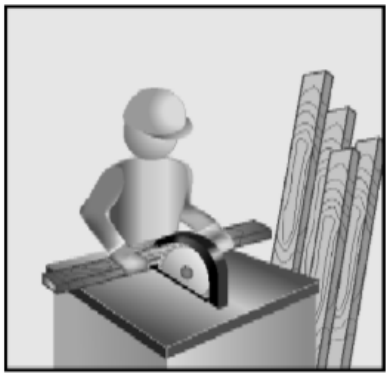
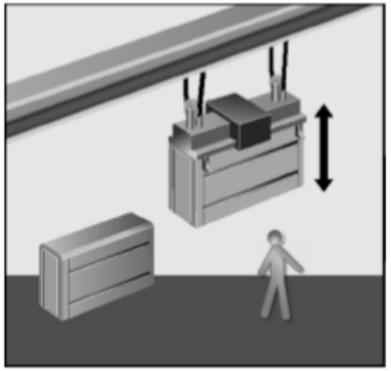
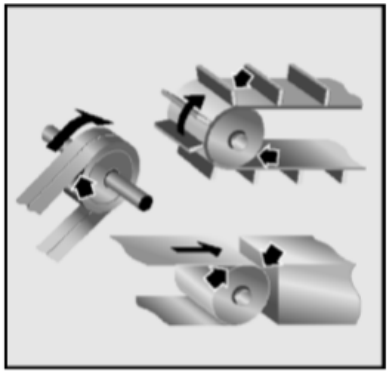
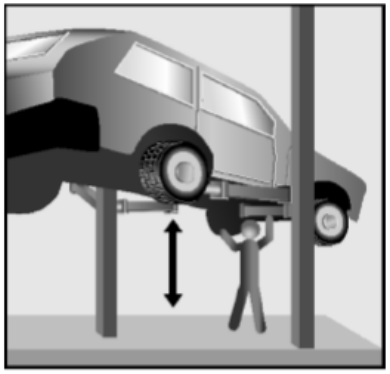
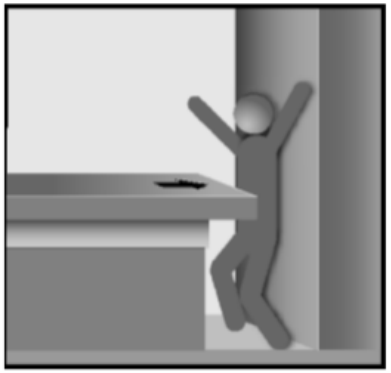
	**Origin** cutting parts **Potential consequences** – cutting – severing		**Origin** falling objects **Potential consequences** – crushing – impact
	**Origin** moving elements **Potential consequences** – crushing – impact – shearing		**Origin** moving elements (three examples) **Potential consequences** – drawing-in – friction, abrasion – impact
	**Origin** gravity, stability **Potential consequences** – crushing – trapping		**Origin** approach of a moving element to a fixed part **Potential consequences** – crushing – impact

IDENTIFYING HAZARDS
EXAMPLES (EN ISO 12100)

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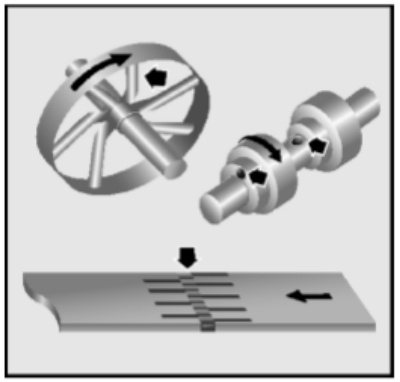
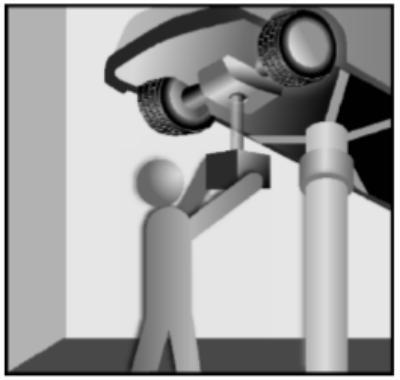
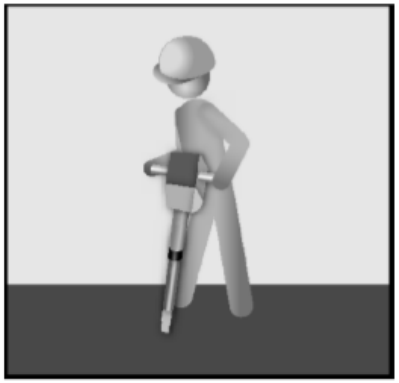
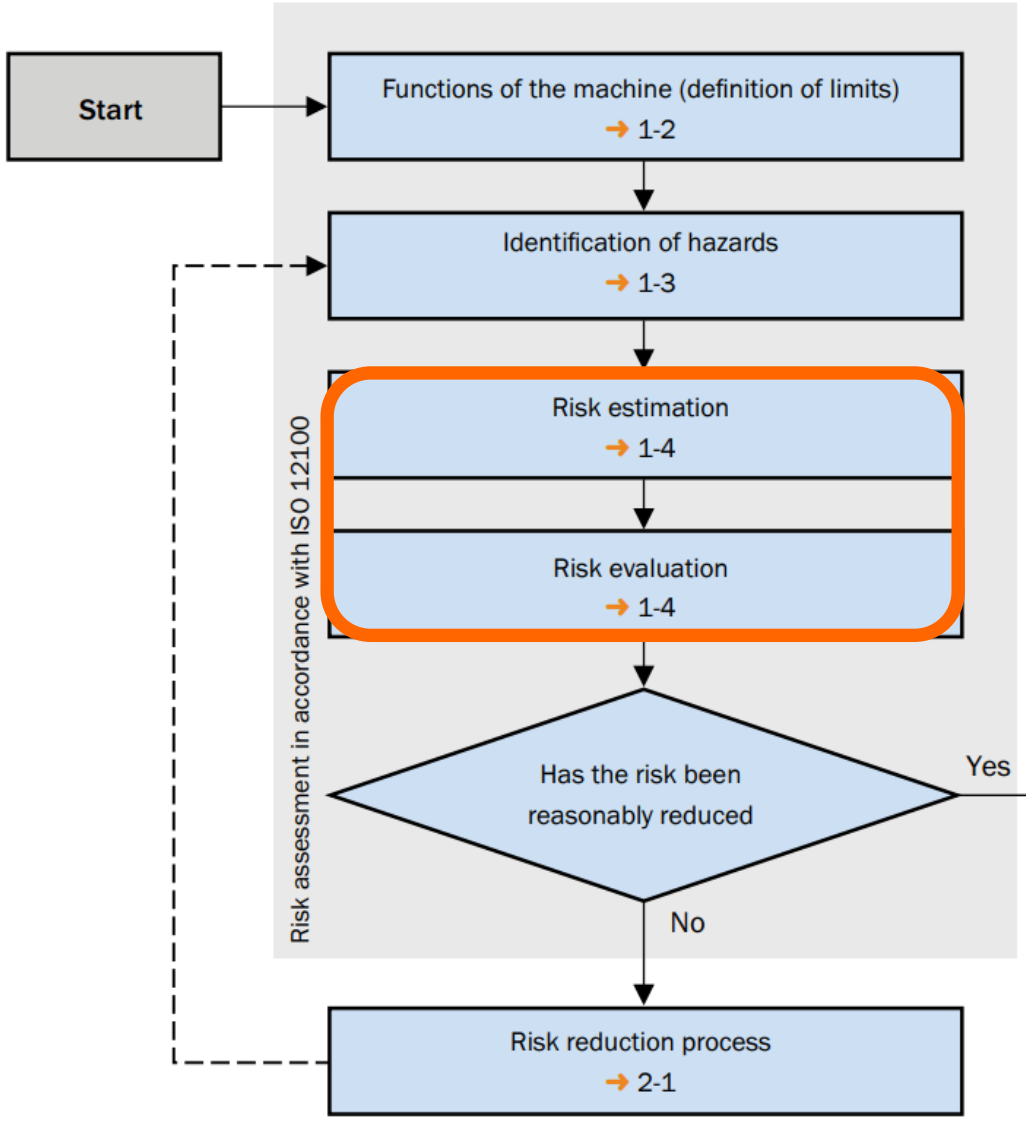
	**Origin** rotating or moving elements (three examples) **Potential consequences** – severing – entanglement		**Origin** moving elements **Potential consequences** – crushing – friction, abrasion – impact – severing
	**Origin** live electrical parts **Potential consequences** – electric shock – burn – puncture – scald		**Origin** objects or materials with a high or low temperature **Potential consequences** – burn
	**Origin** vibrating equipment **Potential consequences** – osteo-articular disorder – vascular disorder		**Origin** noisy manufacturing process **Potential consequences** – fatigue – hearing impairment – loss of awareness – stress

RISK ASSESSMENT
EN ISO 12100



What is a risk?

Hazard = risk?

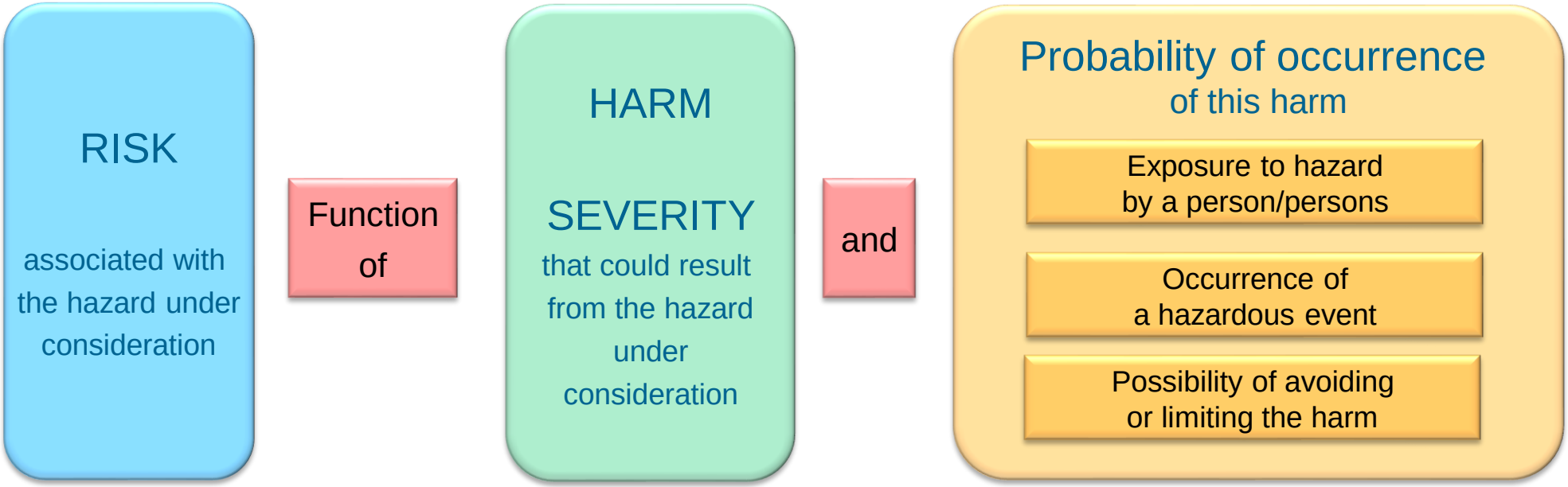
How can I assess the risk correctly?

What exactly is a serious injury?

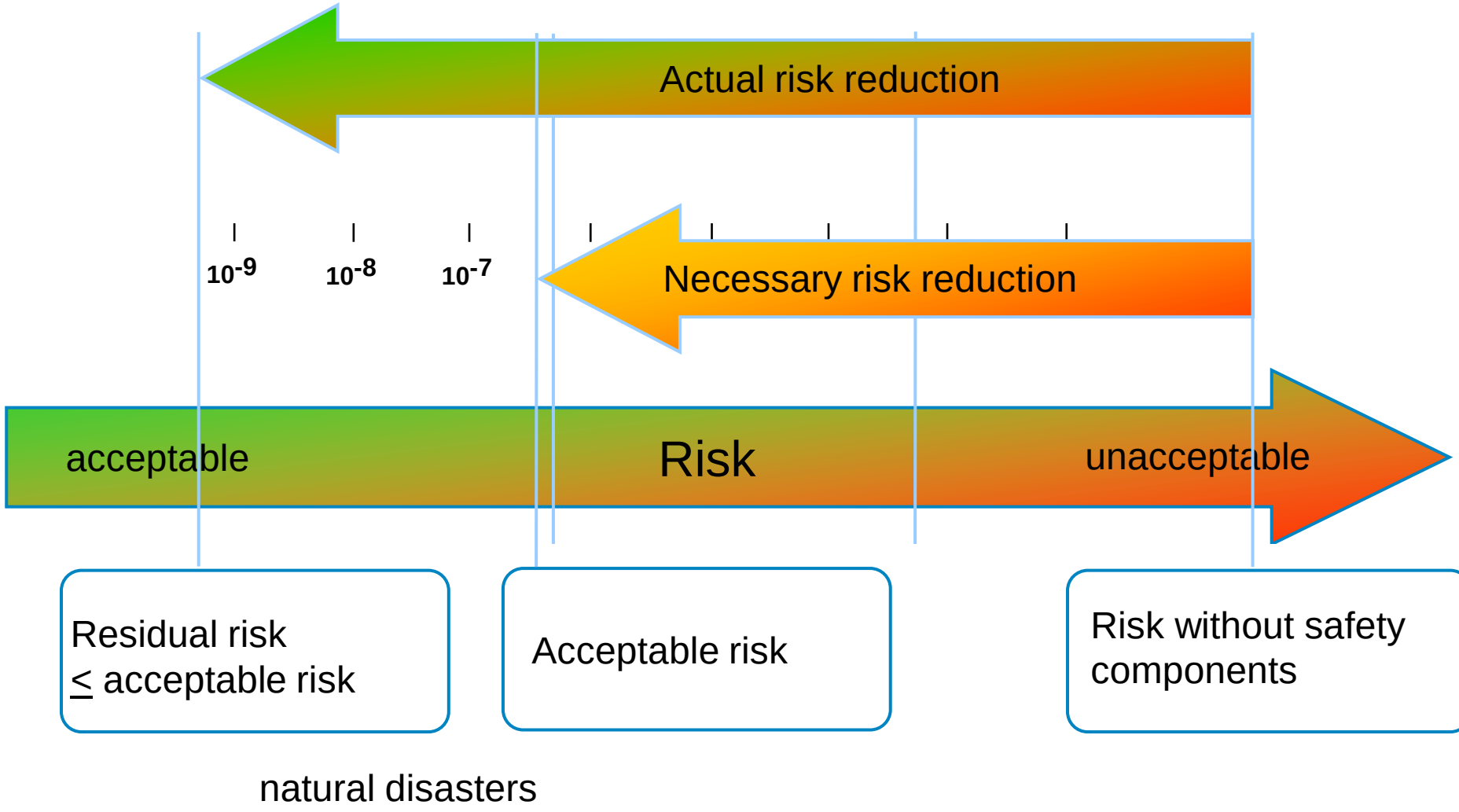
What is frequent?

When exactly can I evade a hazard?

The level of risk is a function of the
harm severity and probability of occurrence



EVALUATING THE RISK



SCRAM METHOD IN 3 LEVELS

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“Scalable Risk Analyses and Evaluation Method”

RISK ESTIMATION
PROCEDURE

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How

do I choose the parameters correctly?

associated with the hazard under consideration

Start	HARM SEVERITY	Exposure to hazard	Harm avoidance	Probability of occurrence O1	O2	O3
	S1	-	-	0	0	0
	S2	-	A1	0	0	1
			A2	0	1	2
	S3	F1	A1	1	2	3
			A2	2	3	4
		F2	A1	3	4	5
			A2	4	5	6
	S4	F1	A1	5	6	7
			A2	6	7	8
		F2	A1	7	8	9
			A2	8	9	10
				Risk		

- Severity of harm — negligible/slight/serious/severe
- Frequency — seldom/frequent
- Avoidability — possible/hardly possible
- Probability of occurrence — low/medium/high

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RISK	Level 1	Level 2	Level 3
	Harm severity	Injury level	
		Effect duration	
	Exposure to hazard	Need for access	
		Exposure duration	
		Exposure frequency	
		Persons exposed	
	Harm avoidance	Operator skills	
		Avoidance experience	
		Risk awareness	Operator information
			Direct hazard perception
			Warning (indirect hazard perception)
		Avoidance possibility	Physical ability
			Hazard appearance or speed
			Surrounding space (allowing avoidance)
			Other circumstances
	Probability of occurrence	Risk comparison	
		System reliability	
		Accident history	
		Damage to health probability	

AGREED DEFINITIONS

S1 = negligible	minor injuries such as scratches and smaller bruises requiring first aid;
S2 = slight	reversible injuries, such as lacerations, stitches, and bruises requiring medical attention;
S3 = serious	more severe but healing injuries, such as broken limbs, or non-healing injuries with no significant impact on normal life (e.g. loss of a fingertip or toe);
S4 = severe	Death, very severe non-healing injuries that have a significant impact on normal life, such as loss of limbs.

EXPOSURE TO HAZARD - FREQUENCY/DURATION

AGREED DEFINITIONS

F1 = low	Twice or less per work shift *and* less than 15 min cumulated exposure per shift;
F2 = high	more than twice per shift *or* more than 15 min cumulated exposure per shift.

AVOIDABILITY OF HARM
AGREED DEFINITIONS

A1 = avoidable *(possible under certain conditions)*	There are certain conditions that allow the avoidance of harm; such as skilled workers, slow movements, infrequent intervention, low-complexity processes, no sudden or unexpected movements with high acceleration;
A2 = not avoidable *(nearly impossible)*	Avoidance is nearly impossible due to the lack of indication or awareness of the hazardous situation, high complexity processes, and/or the effect of routine on hazard awareness

PROBABILITY OF THE HAZARD OCCURRING
AGREED DEFINITIONS

O1 = low	Machine malfunctions (including the control system), jams, or malfunctions due to the properties of the materials jam, or inappropriate human behavior are seldom.
O2 = medium	Machine malfunctions (including the control system), jams, or malfunctions due to the properties of the materials jam, or inappropriate human behavior are foreseeable.
O3 = high	Machine malfunctions (including the control system), jams, or malfunctions due to the properties of the materials jam, or inappropriate human behavior have to be expected with certain regularity.

RISK INDEX - DERIVATION OF PL_R

ISO/TR 22100-2:2014, SECTION 4.2

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Severity	Exposure	Avoidance	Occurence ÷	Occurence O1	Occurence O2	Occurence O3
S1	÷	÷		0	0	0
S2	F0	÷	0 / 1			
	F1/F2	A1		0	0	1
		A2		0	1	2
S3	F0	÷	1			
	F1	A1		1	2	3
		A2		2	3	4
	F2	A1		3	4	5
		A2		4	5	6
S4	F0	÷	1			
	F1	A1		5	6	7
		A2		6	7	8
	F2	A1		7	8	9
		A2		8	9	10
			Risk index			

PL_r (ISO13849-1)
a
b
c
d
e

S1 acc. to EN ISO 13849-1

S2 acc. to EN ISO 13849-1

RISIK REDUCTION

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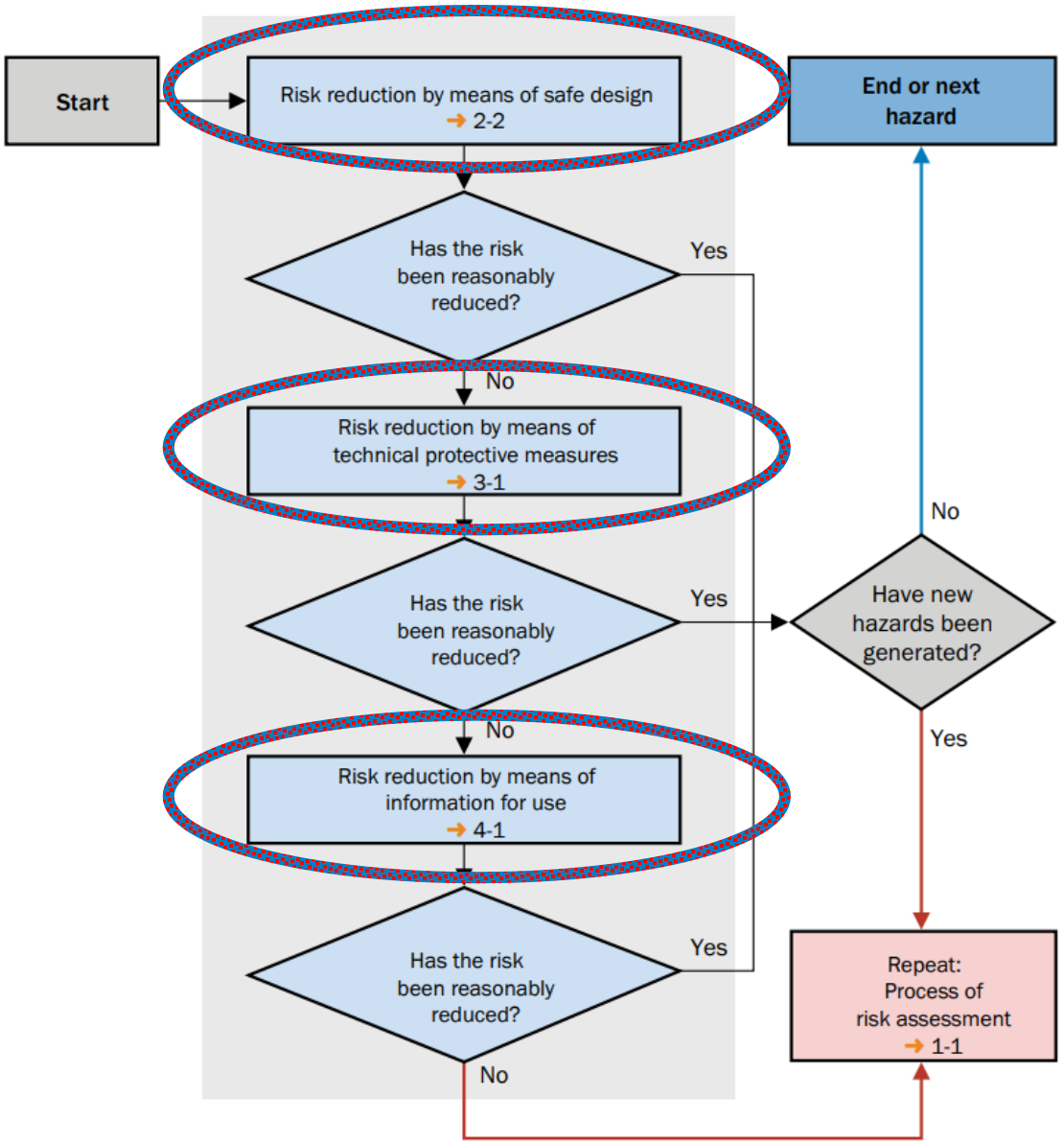
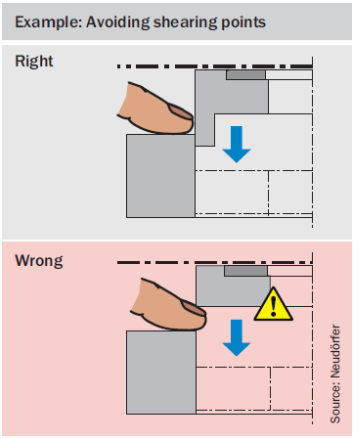
RISK REDUCTION
3 STEP METHOD ACCORDING TO EN ISO 12100



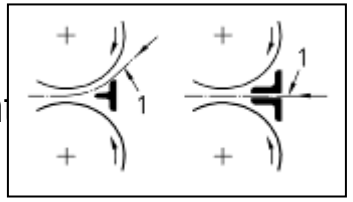


RISK REDUCTION
MANDATORY: 3–STEP METHOD (EN ISO 12100)

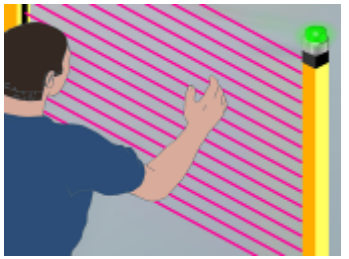
The Machinery Directive requires the safe design of machinery

The machine designer must adhere to the following procedure and sequence:

- Safe design: elimination or minimization of residual risks as far as possible (in safety in the design and construction of the machine)



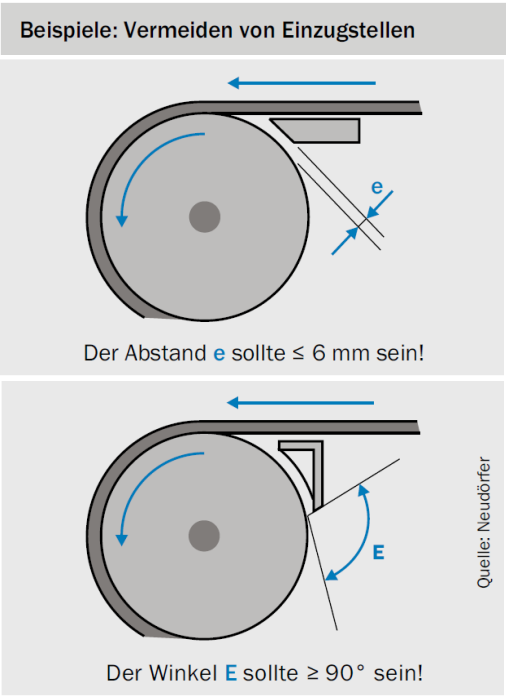
- Take the necessary protective measures in relation to risks that cannot be eliminated

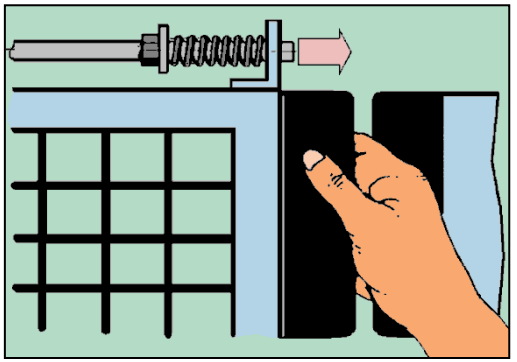


- Inform users of the residual risks due to any shortcomings in the protective measures adopted.Note any special training or induction and protective equipment that may be required

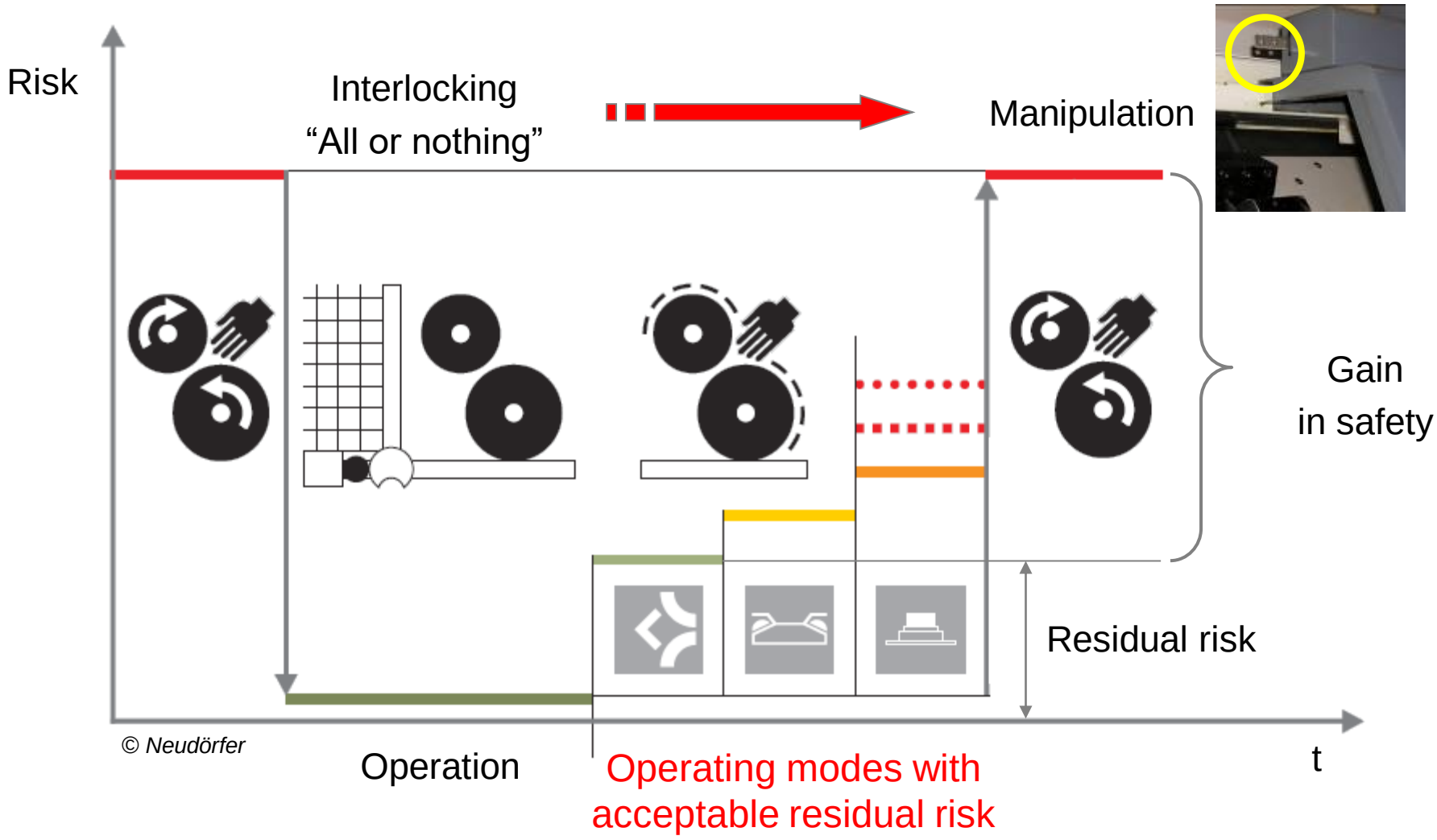
INHERENT SAFETY BY DESIGN

- Measures against component failure
  - Design for the specific application
  - Use appropriate technologies
  - Use fail-safe components
  - Redundancy
- Design measures
  - Suitable geometric design
  - Prevent access
  - Comply with safety distances
- Energetic measures
  - Limit the effective energy
  - Interrupt the force flow
  - Targeted deformation of machine parts





USE OF OPERATING MODES



SUMMARY

- The manufacturer of a machine is obligated to carry out a risk assessment
- An initial risk assessment should already be carried out in the design phase of the machine
- The basic safety standard is EN ISO 12100
- Risk assessment and risk reduction are part of an iterative process
- Risk = harm severity x probability of occurrence
- The limits of the machine in all life phases must be considered
- Foreseeable misuse is an important component
- Risk reduction involves a 3-step process

SUMMARY

- SCRAM = Scalable Risk Analysis and Evaluation Method
- Methodology of estimating the risk
- “More precise” than the risk graph in EN ISO 13849-1
- From the risk index according to SCRAM, you can derive the PLr according to EN ISO 13849-1

SUMMARY

- Risk reduction based on a 3-step method …
- Risk reduction to an acceptable level of risk
- Inadequate or impractical risk reduction encourages manipulation
- Protective devices are divided into two general groups: physical and non-physical

MACHINE SAFEGUARDING EVALUATION
SERVICE DESCRIPTION

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Objective: Identifying the safety status of a machine*)

- In times of ever-faster product changes, **production systems** are subject of constant **changes and adjustments**
- Machine users and their safety personnel are faced with the **challenge of ensuring the safety** of their machines when they are **modified, changed or linked together**

(MSE) Machine safeguarding evaluation service...

- ...offers an overview of the current **safety status** of the machine
- ...helps to **determine the protective measures**, necessary to comply with legal requirements
- ...has globally defined and **harmonized content**
- ...is a **worldwide applicable** standardized service
- ...**foundation** for an **effective** and **economic safeguarding concept** for machines and plants

*) Does not replace the manufacturers **risk assessment**; other risks than mechanical or electrical might occur

MACHINE SAFEGUARDING EVALUATION
GENERAL TASKS

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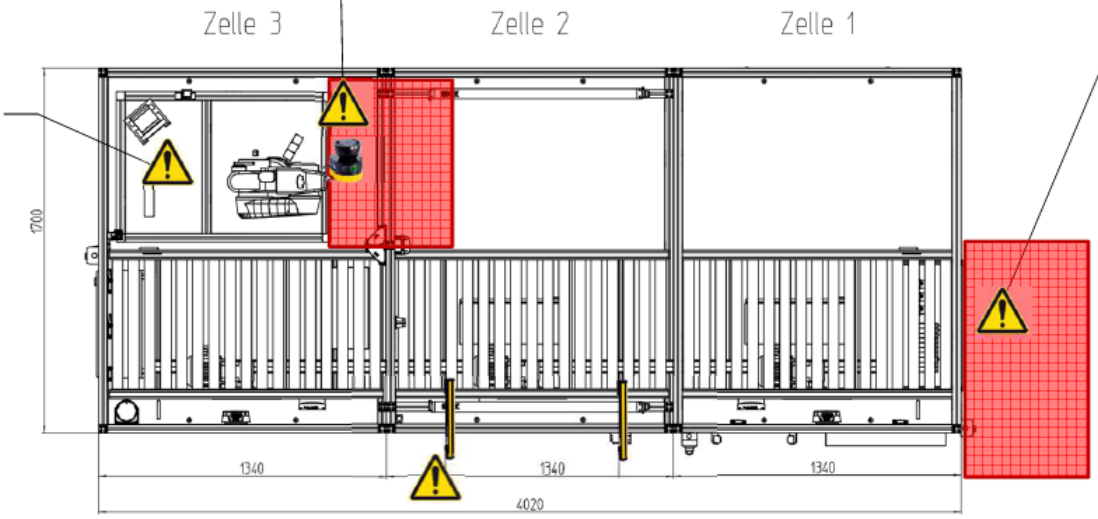
- **Recommendation for improvements of existing protective measures** ②
- **Recommendation of measures for non-safeguarded hazards** ③
- **Identification of elec. and mech. hazards with risk estimation and PLr estimation** ①



- **Functional test of existing protective devices** ④
- **Audited report** ⑤

MACHINE SAFEGUARDING EVALUATION
FOLLOW ON SERVICES

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MSE follow-up services for implementation of machine safety measures

- **Safety concept**
  - Compilation of the safety functions
  - Selecting the type and qty of the safety components based on the identified safety level
- **Safety design (software & hardware)**
  - Plausibility check of the safety concept
  - Compilation of the SRP/CS design
    - Selecting the specific safety components
    - PLr verification (e.g. with SISTEMA)
  - Compilation of the interconnect drawings
    - ePlan, hydraulic and pneumatic plans, etc.
  - Compilation/ programming of the SRASW
  - Documentation of safety design
    - Compilation of the design matrix
- *Installation* **& Commissioning**
- **Verification & validation**
  - Based on the design matrix





MANY THANKS FOR YOUR ATTENTION

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