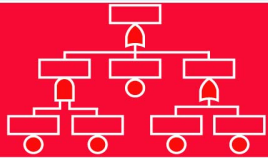

The EU Machinery Directive

Marvin Rausand

Department of Production and Quality Engineering
Norwegian University of Science and Technology
marvin.rausand@ntnu.no



EU Directives

Legislation

Free movement

The new method

Types of directives

Benefits

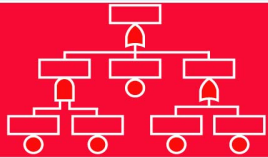
Stand. org.

Machinery dir.

Annexes

Standards

EU Directives



European legislation

EU Directives

Legislation

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Types of directives

Benefits

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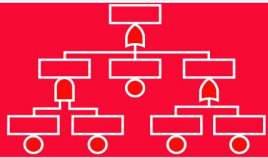
Machinery dir.

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The legislation in the European Union (EU) builds on:

- Regulations
- Directives
- European (EN) Standards



The EU open market requires

EU Directives

Legislation

Free movement

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Benefits

Stand. org.

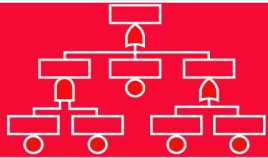
Machinery dir.

Annexes

Standards

- Free movement of
 - Goods
 - Persons
 - Services
 - Capital

- To obtain free movement of goods, we have to remove business barriers like:
 - Physical barriers (controls at national borders)
 - Technical barriers (national safety requirements)
 - Fiscal (financial) barriers (taxes)



The new method

- EU Directives
- Legislation
- Free movement
- The new method**
- Types of directives
- Benefits
- Stand. org.
- Machinery dir.
- Annexes
- Standards

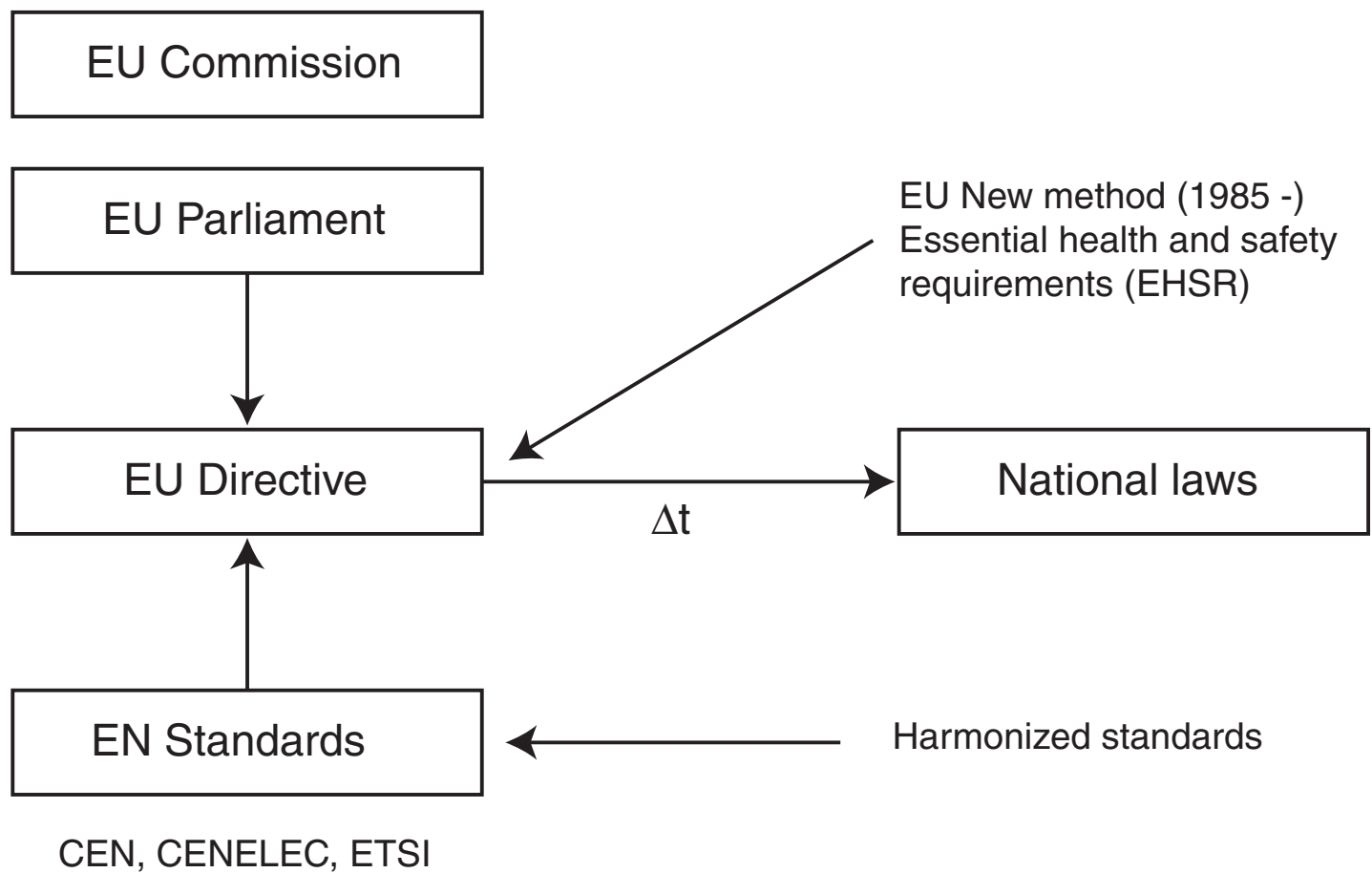
- Directives give basic requirements to safety, health, and the environment (SHE) (- and do not contain technical specifications)
- Technical specifications are given in harmonized standards
- It is up to the user whether or not she wants to comply with the standards
- Products that are made according to harmonized standards are assumed to comply with the directive's "Essential health and safety requirements" (EHSR)

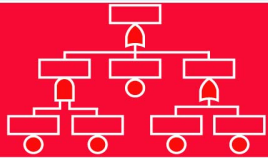
The "new approach" was created to overcome the difficulties of the "old approach", which lead to highly technical and complex directives.



New method directives

- EU Directives
- Legislation
- Free movement
- The new method**
- Types of directives
- Benefits
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- Machinery dir.
- Annexes
- Standards





Two main types of directives

EU Directives

Legislation

Free movement

The new method

Types of directives

Benefits

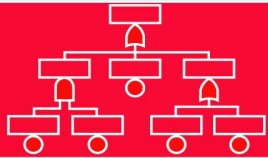
Stand. org.

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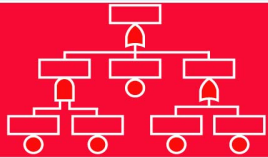
- Business barrier directives (100A) (e.g., the Machinery Directive). These directives are also called “maximum directives”
- Minimum directives (118A) (e.g., the Environmental Impact Assessment (EIA) Directive, and the Seveso II Directive)



Benefits of product directives

- EU Directives
- Legislation
- Free movement
- The new method
- Types of directives
- Benefits**
- Stand. org.
- Machinery dir.
- Annexes
- Standards

- Before, manufacturers had to comply with multiple conflicting national compliance systems
- A product that complies with the requirements can be sold in all member countries in EU/EEA
- The required activities may result in safer products and/or enhanced manufacturing processes



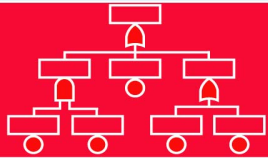
Standards organizations

- EU Directives
- Legislation
- Free movement
- The new method
- Types of directives
- Benefits
- Stand. org.**
- Machinery dir.
- Annexes
- Standards

The EU standards are developed by:

- CEN (Comité Européen de Normalisation)
- CENELEC (Comité Européen de Normalisation Electrotechnique)
- ETSI (European Telecommunication Standards Institute)

A total of approximately 750 standards will “support” the Machinery Directive.



EU Directives

Machinery dir.

Directive

Objectives

Stakeholders

What is machine

Interchangeable eq.

Safety components

Machines?

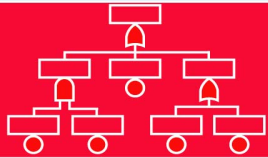
Requirements

Own use

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The EU Machinery Directive



The Machinery Directive

EU Directives

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Requirements

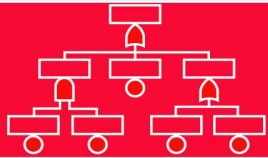
Own use

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Standards

- The first Machinery Directive, 89/392/EEC, was approved in 1989
- The current version is 98/37/EEC - approved in 1998
- A new version, 2006/42/EC was approved in 2006 - and will enter into force in 2008

The revised directive 2006/42/EC does not introduce any radical changes compared with 98/37/EC but aims to consolidate the achievements of the Machinery Directive in terms of free circulation and safety of machinery while improving its application.



Objectives of the Directive

EU Directives

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Objectives

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Requirements

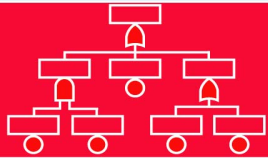
Own use

Annexes

Standards

The objectives of the Machinery Directive are:

- To ensure free circulation of machinery on the internal market
- To ensure a high level of protection of users and other exposed persons against risk
- To ensure safety by design



Stakeholders

EU Directives

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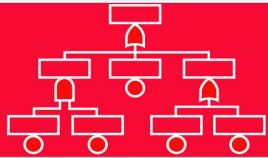
Annexes

Standards

The main parties that should be interested in the EU Machinery Directive are:

- Producers
- Importers
- Users

of machinery products



What is a machine?

EU Directives

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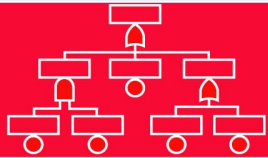
Requirements

Own use

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- An assembly of linked parts or components, at least one of which moves, with the appropriate actuators, control and power circuits, etc., joined together for a specific application, in particular for the processing, treatment, moving or packaging of a material
- An assembly of machines which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole



Interchangeable equipment

EU Directives

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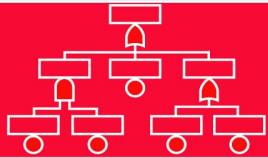
Requirements

Own use

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- Interchangeable equipment modifying the function of a machine, which is placed on the market for the purpose of being assembled with a machine or a series of different machines or with a tractor by the operator himself in so far as this equipment is not a spare part or a tool



Safety components

EU Directives

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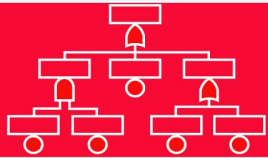
Requirements

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- A *safety component* is a component, provided that it is not interchangeable equipment, which the manufacturer or his authorized representative established in the Community places on the market to fulfill a safety function when in use and the failure or malfunction of which endangers the safety or health of exposed persons.



Are these machines?

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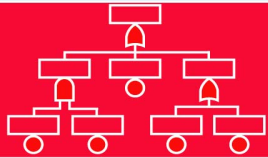
Requirements

Own use

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- An office chair?
- A wheelchair?
- An outboard motor?
- A food processing plant?
- A power station?
- An oil refinery?



What is a machine?

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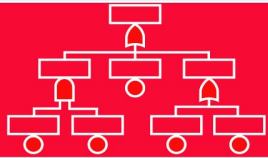
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Standards

The following “machines” are exempted from the scope of the Machinery Directive:

- Manually powered machinery (except for lifting)
- Machinery for medical use, used in direct contact with patients
- Special equipment for use in fairgrounds and/or amusement parks
- Steam boilers, tanks and pressure vessels
- Machinery used for nuclear purposes
- Firearms
- Seagoing vessels
- Agricultural and forestry tractors
- and so on

A complete list of excluded machinery is found in Article 1, para. 3 of the Directive.



Requirements

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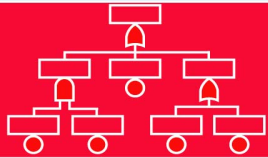
Own use

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Standards

The manufacturer or his representative, resident in the EU is responsible for the following:

- To carry out a hazard assessment to analyze all of the risks related to the machinery and if required apply measures to reduce these
- To ensure that the machinery conforms to the relevant essential health and safety requirements
- To draw up an EU declaration of conformity/incorporation and affix a CE mark
- To draw up a technical file



Machines for own use

EU Directives

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Interchangeable eq.

Safety components

Machines?

Requirements

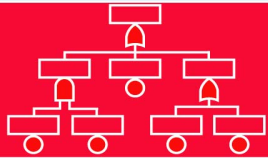
Own use

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Standards

The Machinery Directive also applies for companies producing machines for own use.

Para: 8.7: “... The same obligations shall apply to any person assembling machinery or parts thereof or safety components of various origins or constructing machinery or safety components for his own use.”



EU Directives

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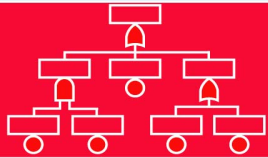
Conformity

Notified body

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Annexes to the Machinery Directive

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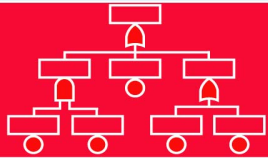
Conformity

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Standards

- I Essential health and safety requirements (EHSR) relating to the design and construction of machinery and safety components
 - II Contents of the declaration of conformity
 - III CE conformity marking
 - IV “Dangerous” machines and safety components - that need a special procedure
 - V EC declaration of conformity
 - VI EC type-examination
 - VII Criteria for notification of bodies
- (The above titles are abbreviated)



Contents of Annex I

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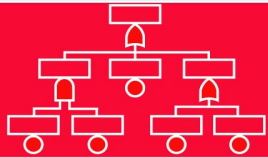
Notified body

Eight steps

Standards

Annex I defines the essential health and safety requirements (EHSR) the machines must fulfil. Annex I has the following chapters:

- EHSR (general)
- EHSR for certain categories of machinery
- EHSR to offset the particular hazards due to the mobility of machines
- EHSR to offset the particular hazards due to lifting operations
- EHSR for machinery intended for underground work
- EHSR to offset the particular hazards due to lifting or moving of persons



Example of EHSR in Annex I

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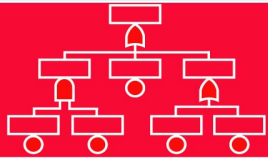
Standards

1.2.1 Safety and reliability of control systems

Control systems must be designed and constructed so that they are safe and reliable, in a way that will prevent a dangerous situation arising. Above all they must be designed and constructed in such a way that:

- They will withstand the rigors of normal use and external factors
- Errors in logic do not lead to dangerous situations

Comment: This is an example of an EHSR that needs to be elaborated and specified in a standard.



Example of EHSR in Annex I

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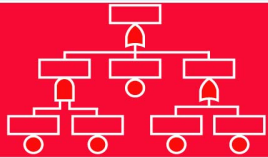
Eight steps

Standards

1.7.3 Marking

All machinery must be marked legibly and indelibly with the following minimum particulars:

- Name and address of manufacturer
- The CE marking (as specified in Annex III)
- Designation of series or type
- Serial number (if any)
- The year of construction



The CE mark

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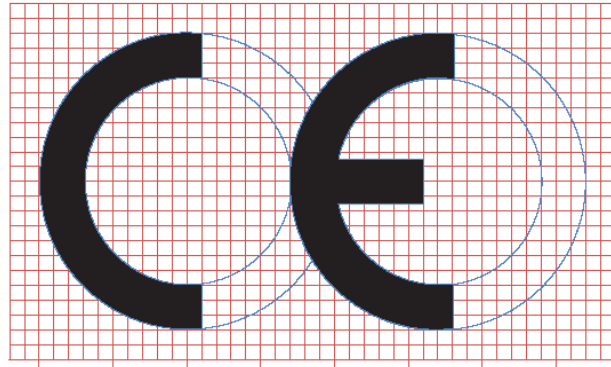
Conformity

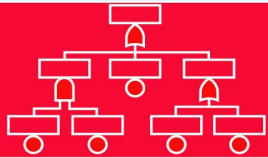
Notified body

Eight steps

Standards

CE is an abbreviation for Communauté Européenne being the French way of saying European Community.





Foreseeable misuse

EU Directives

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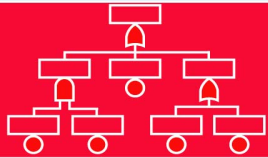
Conformity

Notified body

Eight steps

Standards

Annex I, para. 1.2.2 c): “When designing and constructing machinery, and when drafting the instructions, the manufacturer must envisage not only the normal use of the machinery but also uses which could reasonably be expected”



Examples of “dangerous” machines in Annex IV

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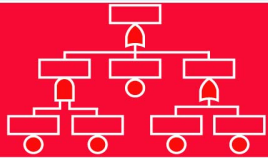
Notified body

Eight steps

Standards

- Circular saws
- Band saws
- Portable chain-saws
- Presses
- Planing machines for woodworking
- Machines for manufacture of pyrotechnics
- and so on

The above list is abbreviated - see Annex IV for a complete list.



Instructions handbook

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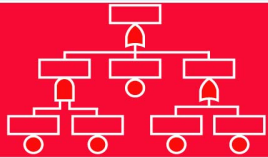
Eight steps

Standards

The required contents of the instructions handbook is listed in Annex I, para. 1.7.4

- Foreseen use of the machinery
- Workstations likely to be occupied by operators
- Instructions for safe:
 - ➡ putting into service
 - ➡ use
 - ➡ handling
 - ➡ assembly, dismantling
 - ➡ adjustment
 - ➡ maintenance (service and repair)
- Training instructions (if necessary)
- and so on

See Annex I for details



Technical file

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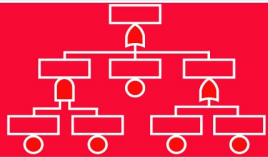
Conformity

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Eight steps

Standards

- An overall drawing of the machinery together with drawings of the control circuits
- Full detailed drawings, accompanied by any calculation notes, test results, etc. required to check the conformity of the machinery with the essential safety requirements
- A list of:
 - The EHSRs
 - Applicable harmonized standards
 - Other standards used
 - Other technical specificationsthat were used when the machinery was designed
- A description of methods adopted to eliminate hazards presented by the machinery



Technical file (cont.)

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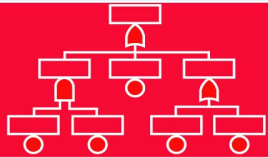
Notified body

Eight steps

Standards

- Any technical report or certificate obtained from a competent body or laboratory (optional)
- A copy of the instruction for the machinery
- For series manufacture, the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of the Directive

The documentation shall be retained and kept available for up to ten years from the time of last manufacture of the machinery.



Declaration of conformity

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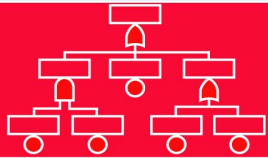
Eight steps

Standards

After performing a critical design review, making changes to the product design that will minimize risks of harm, and compiling the “Technical file,” the manufacturer may affix the CE marking and prepare a “Declaration of conformity.”

The Declaration must identify:

- Who you are
- What product it refers to
- What directives are involved
- What standards are applicable
- Where test results can be found
- Who is responsible in your company



Notified body

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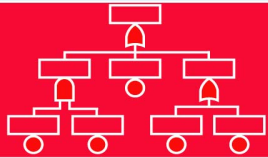
Conformity

Notified body

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Standards

- A notified body must be located within the geographical bounds of EU/EEA
- An approval by a notified body located anywhere in the EU/EEA is valid throughout the EU/EEA



Eight steps

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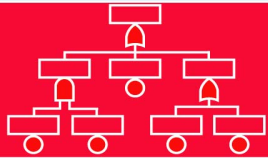
Conformity

Notified body

Eight steps

Standards

- Does the Machinery Directive apply?
- Do other legislations apply?
- Who is responsible?
- Hazard analysis
- Principles of safety requirements
- Use European standards for details
- Documentation
- Declaration and CE Mark



EU Directives

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Standards

Types of standards

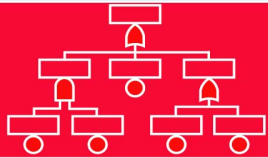
Examples

Design strat.

Risk assessment

Risk elements

Standards related to the Machinery Directive



Standards related to the Machinery Directive

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Types of standards

Examples

Design strat.

Risk assessment

Risk elements

A-Standards

Design principles and methods for all machinery

B₁-Standards

Aspects of safety valid for a wide range of machinery

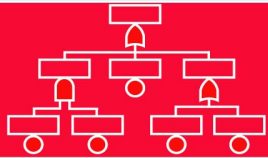
B₂-Standards

Aspects of safety devices valid for a wide range of machinery

C-Standards

Safety of one category of machinery

The use of standards is not obligatory. Conformity with the Essential health and safety requirements (EHSR) of the directives may also be demonstrated directly.



Examples of standards

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Standards

Types of standards

Examples

Design strat.

Risk assessment

Risk elements

A-Standards

EN 292 (Basic machine safety issues)

EN 1050 (Risk analysis)

B₁-Standards

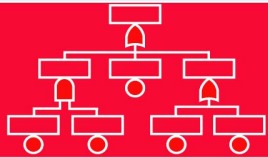
EN 294 (Safety distances to avoid that parts of the human body are endangered)

B₂-Standards

EN 418 (Emergency stop equipment)

C-Standards

EN 1218 (Safety requirements related to wood treatment machinery)



EN, national and ISO standards

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Design strat.

Risk assessment

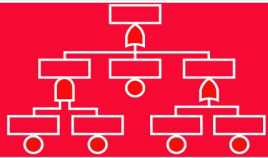
Risk elements

When EN standards are issued, they are (normally) published as national standards, for example:

- EN 292-1 \Rightarrow NS-EN 292-1 in Norway, and BS-EN 292-1 in Britain.

Many EN standards are now transformed into international standards, for example:

- EN 292-1 \Rightarrow ISO 12100-1
- EN 1050 \Rightarrow ISO 14121



Strategy for risk reduction

EU Directives

Machinery dir.

Annexes

Standards

Types of standards

Examples

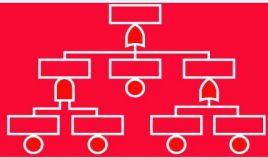
Design strat.

Risk assessment

Risk elements

The designer shall take the following actions: (ISO 12100-1/EN 292-1)

- Specify the applications and limitations of the machine
- Identify the hazards and evaluate the risk
- If possible, remove the hazards or reduce the risk as far as possible
- Implement barriers and/or safety functions against the residual risks
- Inform and warn the user against residual risks
- Consider other required actions



Strategy for risk reduction

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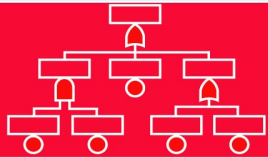
Design strat.

Risk assessment

Risk elements

When describing the application(s) of the machine, we have to consider:

- Potential incorrect use resulting from carelessness and foreseeable misuse (e.g., children's use of the machine)
- Reflex actions of operators when failures of the machine occur
- Expect that the simplest way to carry out actions is selected by the users of the machine
- Consider actions by special users like disabled, children, and so on.



Proposed risk assessment methods

EU Directives

Machinery dir.

Annexes

Standards

Types of standards

Examples

Design strat.

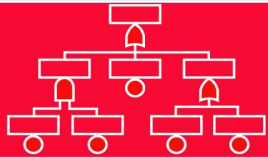
Risk assessment

Risk elements

The following methods are proposed in ISO 14121 (EN 1050):

- Preliminary hazard analysis (PHA)
- What-if analysis
- Failure modes and effects analysis (FMEA)
- Fault simulation for control systems
- MOSAR
- Fault tree analysis (FTA)
- Delphi technique

A detailed list of relevant hazards is provided in Annex A of ISO 14121



Elements of risk

- EU Directives
- Machinery dir.
- Annexes
- Standards
- Types of standards
- Examples
- Design strat.
- Risk assessment
- Risk elements**

