

Risk Assessment – Basic Principle of Operation of Securer Machines and Machinery in the European Union

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Machines, machinery, risk assesment.

ABSTRACT

Machines and machinery determine the daily routine in many enterprises. Those persons working with and at the certain machines mustn't suffer from a physical damage. Therefore the European Union (EU) outlined a coherent preventive security concept for machinery. The essential regulations of the EU rules for safety and health requirements were laid down by the Parliament and the European Council of the EU in the Machinery Directive 2006/42/EC. The harmonized European Standards (ES) developed by the standardization body CEN are intended to implement these essential safety and health requirements comprised in the Annex. These requirements have to be met by the manufacturer due to the principle of the risk assessment in the design and construction processes; moreover they have to be specified within EC conformity declaration and technical documentation of the machines.

1. European Legal Basis of Machinery Directive on Security

The role of the European Union (EU) is to provide a harmonized development of the economics within the Union, higher stability, a sustainable growth of the standard of living and closer relations between and among member states which are all interconnected and furthermore to achieve this goal it is necessary to establish a common market and a gradual convergence of economical policies of member states. The main tasks are the following ones: removal of trade barriers, enforcement of free movement of goods and services, enforcement of free movement of capital as well as cooperation in the field of social issues.

The consolidated version of the EU-Treaty /1/ under the Article 114(ex 95 EC Treaty) adopted measures for the coordination of laws, regulations and administrative provisions of the EU member states and furthermore for the establishment and operation of the European internal market. The essential requirement in the fields of health, security, environment and consumer protection policies was to provide a high quality security and as follows a high quality product security.

To put a product into service which is called " machine " the EU-Machinery Directive 2006/42/EC /2/ has to be applied. Due to this directive member states are obliged to provide security and health protection of all persons mainly of all operators and users of the machinery taking into consideration the issue of risks. To remove trade barriers it is necessary to approximate different warranted quality – and- security requirements on machinery in each member state. The Machinery Directive was comprehensively implemented into the national standards (common security principle on the Euro-

pean internal market). The manufacturers of the machines are obliged as well to carry out their own daily routine in compliance with this Machinery Directive.

For the technical implementation of the essential Regulations of the EU rules for safety and health requirements on design and construction of the machinery, determined in the Annex I, the harmonized European Standards (Es) have to be applied. As soon as the harmonized standards were published in the Official Journal of the EU and consequently implemented into the national standards of at least one member state, they resolved the issue of conformity presumption. The security standards of machinery are grouped as follows /3/:

- **Type-A- Standards** (Basic Safety Standards) specify basic concepts and general design principles that can be applied to all types of machines;

- **Type-B- Standards** (Group Safety Standards) specify safety standards or a type of protective device that can be applied to a fairly wide range of machine groups:

- **Type-B1-standards** are related to specific safety aspects such as safe distances, surface temperature or noises.

- **Type-B2- standards** are related to safety-related devices, e.g. two-hand control, locking systems, pressure sensitive protective devices, guard locking system;

- **Type-C- Standards** (Individual Product Safety Standards) specify detailed safety requirements for a specific machine or a group of machines. (e.g. mechanical presses, industrial robots).

Beside the Machinery Directive the other European harmonized Directives of Machinery Safety can be relevant as well.

- **Directive on equipment and protective systems for use in potentially explosive atmosphere 94/9/EC /4/,**

- **Pressure Equipment Directive 97/23/EC /5/,**

- **EMC Directive harmonized standards 2004/108/EC /6/.**

The European legal basis for machinery safeguard was complemented by the Article 153 EU-Treaty/1/ (ex 137 ECT). The main issue concerns the gradual approximation of rules for safety and health of employees at work by improvement of both working conditions and environment, social protection of employees, provision of employees' information and consultation,, equal opportunities for men and women on the labour market and equal treatment at the workplace. To provide

safety at machine use the following directives are mainly relevant::

- **EC- Framework Directive – safety and health at work 1989/391/EWG/7/,**

- **Directive – the use of work equipment 2009/104/EC /8/.**

Also these directives have to be implemented into the national law of member states. In comparison with the directives under the Article 114 EUT these contain only minimum specifications which could be complemented by any other requirement in each member state.

2. Definition of “MACHINE” and “MACHINERY”

The term “*machine*” is determined in details in the Machinery Directive (MD) /2/. According to this definition the machinery is „an assembly of linked parts or components, at least one of which moves and which are joined together, intended for loading “. In this Directive not only the individual machines but also the machine groups are specified and they are divided into completed machines and partly completed machinery. (→Article 2 MD).

A “*partly completed machinery*” is an assembly “*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 construction*”. As an example can be the machine control systems or loading - feeding facility.

A “*machinery*” is an assembly of machines, resp. partly completed machines” proving the following compulsory relations :

- **production** – technical relation i.e. the particular machine or partly completed machinery is assembled with the goal of a common production function as a common product and having a common overall control including al related equipment used in the operation e.g. assembly system in the automobile industry.,

- **security** – technical relation i.e. the particular machine or the partly completed machines are functionally linked, so that the operation of any machine or partly completed machine with other machines or partly completed machines have to cooperate, moreover a risk assessment is required for all of them and in case of any risk or hazard all these system parts must be kept in a safe condition.

3. Machine risk Assessment

The risk is assessed from the multiplication of

probability of adverse events occurrence (e.g. injury) and from the extent of damage (from small injury up to a fatal injury). The risk therefore can be defined as follows:

$$R[\frac{s}{t}] = W[\frac{E}{t}] \cdot S[\frac{s}{E}]$$

R – risk [severity of potential damage in a given time period]

W – probability of occurrence [frequency of adverse events in a given time period]

S – extent of damage [severity of potential damage per event]

The manufacturer of the machine has to take into consideration many aspects of the risk assessment including the preventive hazard estimation which could occur either at completed machinery or partly completed machinery, furthermore he/she has to focus on its analysis (risk analysis) and its assessment (risk assessment) and moreover on risk reduction or elimination of the risk (risk elimination) aimed at designing and constructing a securer machine. The risk assessment comprises therefore the following steps according to EN ISO 12100 /9/

– **Risk analysis** – (determination of the limits of the machinery which includes its intended use, identification of hazards and estimation of risks for each potential hazardous situation)

– **Risk assessment** – qualitative and quantitative assessment and evaluation of potential risks and hazardous situations associated with the machine.

The identification of risks and potential hazards associated with the machines in different operating conditions is to be carried out applying the relevant Machinery Safety Standards → C-Standards (e.g. EN 12417 machine tools /10/). These standards comprise the occurring risks (mechanical hazard through crushing, splashing of liquids under excessive pressure) in different hazardous situations associated with the machine use (e.g. machine tools, hydraulic systems). All these listed aspects have to be taken into consideration and evaluated by the constructor of the machine.

The result of the risk assessment process has to determine the necessity of the risk reduction. Applying a risk index it is enabled to identify different risk levels (e.g. three) and consequently the protective measures for risk reduction can be identified (Fig.1).

$$R = S \cdot (W I + W II + W III)$$

R = Risk index

(1) **S** = extent of damage

Extent of injury or damage to health		Rate of occurrence
S1	= no injuries	1
S2	= small injuries	2-3
S3	= moderate injuries	4-6
S4	= fatal injuries	7-8
S5	= death	9-10

(2) **W I** + **W II** = probability of occurrence

Frequency and duration of exposition to hazard (W I)		Rate of occurrence
W1	= rarely	1
W2	= frequently more than 1 □ per shift)	2
Probability of occurrence of hazardous situation (WII)		Rate of occurrence
W3	= low (almost improbable)	1
W4	= medium (permanently probable)	3
W5	= high (very probable)	5
Probability of avoiding or limiting harm by a person at risk		Rate of occurrence
W6	= probable	1
W7	= probable under specific conditions	2
W8	= improbable	3

(3) Levels of risk and risk measures

Risk index	0 -24	25 -42	43 - 100
Risk evaluation	Low risk	Medium risk	High Risk

Fig. 1: Determination of risk levels for assessing the required measures for machine risk reduction. /11/

The measures required for each significant type of hazard are specified in compliance with EN ISO 12100/9/ according to "three-level process" (example Fig. 2):

– level 1: Inherently safe (safe design) measures

The risk can be eliminated by choosing the appropriate design elements of the machine, e.g. reduction of sharp edges and corners, secure design of machine elements.

– level 2: Technical and additional protective measures

When the conclusion of rational judgement is that the inherently safe design approach cannot eliminate the source of hazard e.g. relative movement between the workpiece and tool at the machine, a separable or non-separable guarding facility or a safeguarding device must be used for human protection.

– level 3: Providing information to users

When the conclusion of rational judgement is that the inherently safe design and technical and additional protective measures are not sufficient for elimination of existing risks, "it is requirable to inform the user about the residual risks at the machine" either by (e.g. warnings and cautions) or in user manual (e.g. application of personal protective equipment).

Both the results of the risk assessment and the protective measures on risk reduction have to be documented.

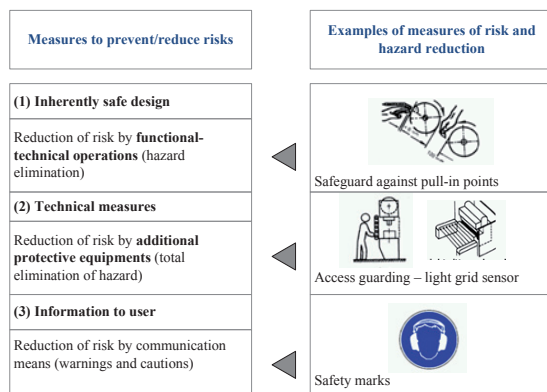


Fig. 2: Levels of risk reduction as a result of risk assessment.

The risk assessment in the European economical environment is the basis for all legally required activities concerning the process of putting a machine into service (and it concerns both complete machinery and partly completed machinery). The manufacturer /authorized representative of a ma-

chine has to confirm, that the particular machine meets all requirements of the EU rules for safety and health comprised in the Machinery Directive /2/ and this machine was manufactured in compliance with other relevant EU- Directives. Fig. 3 presents an overview of all required processes at putting a machine into service.

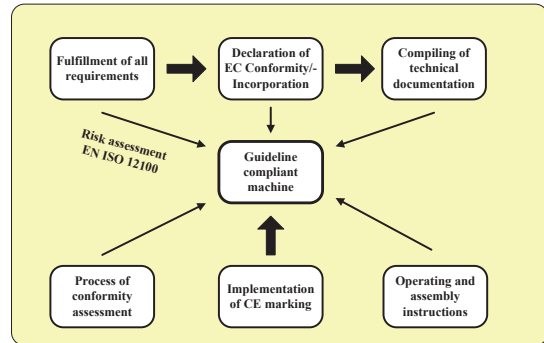


Fig. 3: Activities carried out in the process of putting a machine into service (Overview of manufacturer's duties).

Fulfillment of requirements: All the principles and requirements related to machine use according to Annex I EU Directive 2006/42/EC/2/ have to be specified and by the iterative process of risk assessment and risk reduction the protective measures of risk reduction have to be determined throughout the foreseeable lifetime of the machinery, including the phases of transport, assembly, dismantling, disabling and scrapping.

EC – Declaration of conformity of the machinery: The Declaration of Conformity (DC) determines the process in which the manufacturer declares that the ready-to-use machine which has been put into service fulfils all relevant safety and health requirements (Annex II A, 2006/42/EC) /2/.

The Declaration of Incorporation comprises the same requirements as the DC but it concerns the partly completed machines (section 2) highlighting the requirement that the partly completed machinery must not be put into service until the final machinery into which it is to be incorporated has been declared in conformity with the provisions of this Directive (Annex II B, 2006/42/EC) /2/.

Technical Documentation: In case of the completed machines (Annex VII A, 2006/42/EC) /2/, resp. partly completed machines (Annex VII B, 2006/42/EC) /2/ the manufacturer is obliged to compile a technical documentation /2/, which

comprises the enhancement to the user interface and the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, where appropriate, the indication of the residual risks.

Assessment of conformity: Its aim is to confirm that the ready-to-use machinery fulfils all relevant requirements specified in the Machinery Directive 2006/42/EC /2/. There are the following processes to be carried out:

- **internal checks at the manufacturing of the machine (Annex VIII, 2006/42/EC),**
- **EC-type-examination procedure (Annex IX, 2006/42/EC) carried out by a „notified body,, –in the EU proved examination body for the machinery in compliance with Annex IV, 2006/42/EC – “hazardous machines” ,**
- **full quality assurance (Annex X, 2006/42/EC) at design, construction, final product inspection and testing of the machines by a “notified body” (LEHDER /12/).**

CE-marking (Comunante Europeene): The administrative symbol confirms for supervisory authorities of member states that the ready –to use machine complies with the requirements of the Directive of Conformity. (Annex IV, 2006/42/EC /2/). The prerequisite for that is that the machine complies with the related safety and health requirements , furthermore the Declaration of Conformity and the Assessment of Conformity as well as the technical documentation have to be submitted.

Operating and assembly instructions: The Operating and assembly instructions have to be elaborated for the ready-to-use machines by the manufacturer. They comprise the related instruction manual of the machine and the foreseeable risks are indicated.

Assembly instructions have to be written for partly completed machines including a description of the conditions which must be met with a view to correct incorporation in the final machinery, so as

not to compromise safety and health of employees.

Putting machines into service (completed machines and partly completed machines) in the EU is enabled only by complying with the requirements of the related Directive. 2006/42/EC /2/ .

The elaboration of the EU Declaration of Conformity, technical documentation as well as the usage of the CE Marking iare allowed only due to accomplished risk assessment of the particular machine. The above listed documents as well as the CE-Marking are highly crucial for the potential user of the machine.

4. Secure Operation of Machines

Due to the documents provided by the manufacturer of the machine (section 3) the indicated residual risks have to be identified by all persons (employees and users) operating a machine. Before using the machine the user/operator has to take actions to secure additional protective measures, e.g. provision and use of personal protective equipments.

Moreover, the operator of the machine has to accomplish a risk assessment for the particular workplace in advance to start-up. These kinds of risks can be caused by working environment, shipping company and under certain condition also workplace specific factors. As a consequence the operator is obliged to carry out the following tasks:

- **choice of securer machines (where appropriate compare different variants),**
- **determination of both additional protective measures due to information provided by the machine manufacturer and the risk assessment of the machine operator. To specify the amount of workplace specific risks the risk graph can be applied. (Fig. 1) and Fig. 4 highlights how to identify the urgent need of taking protective measures for the machine operator .**

(3) Levels of risk and inevitable measures

Risk index	0 -24	25 -42	43 - 100
Risk	Low risk	Moderate risk	High risk
	Specific organisational and personal measures	Common protective measures required	Higher level of protective measures required

Fig. 4: Urgent need of taking protective measures by machine operator /11/.

– **Determination of required tests, maintenance and repair work of the machines and meeting dates (deadline),**
– **Instructing and training of workers / operators in safety machine operation. The required document for the machine operator is the operating instruction which has to be elaborated according to operating manual provided by the manufacturer and workplace specific risk assessment provided by the machine operator . (Fig. 5).**

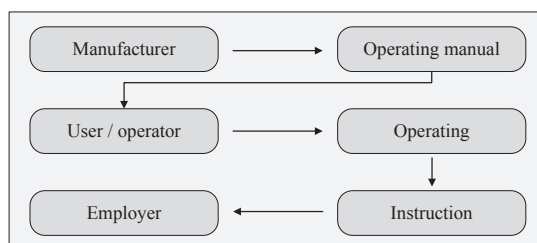


Fig. 5: Information chain for operating manual use by machine operator.

5. Conclusion

If the protective measures taken by the manufacturer of a particular machine and the related workplace specific protective measures taken by the machine operator due to risk assessment are in interaction then a secure machine and machinery operations can be confirmed. (Fig. 6).

Issues concerning the importance of quality management in the process of the design and construction of securer machines mainly in connection with the assessment of conformity /12/.

Protective measures to be carried out by designer		
o Reduction of risk by functional-technical operations (inherently safe design)	o Protective equipments o Safe control systems (technical and additional protective measures)	o Operating manual o Warnings, cautions (information to user)
⇒ <u>Elimination of hazard</u>	⇒ <u>Total elimination of hazard</u>	⇒ <u>Attention to risk</u>
	Additional protective equipments	Operating instructions Education /Training Application of personal protective equipments Monitoring
Protective measures to be carried out by user		

Fig. 6: Protective measures for machines taken by the manufacturer and the operator.

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