

Annex 6

Risk analysis for machinery

1. SCOPE

This instruction applies to performing a risk analysis for the design of machinery.

2. INTRODUCTION

The Machinery Directive requires that safety measures should be carefully documented in a so-called construction file. The core idea behind this file is that the design decisions relating to security must be substantiated and recorded accurately.

In this regard, carrying out a systematic risk assessment is essential: it provides a basis for good design decisions associated with security.

Moreover, such a risk assessment provides evidence to competent authorities that the designer / builder has fulfilled its legal obligations and demonstrated “good workmanship”. Security measures taken must be accounted for for a period of 10 years.

However, while requiring that a risk assessment be performed, the Machinery Directive does not state how it should be performed. It is therefore the aim of this document to provide for an example of a systematic risk assessment of machinery. Be it for the design of a new machine or a part thereof or for the modification of equipment or parts thereof.

Methodologies mentioned are typically based on the harmonized standard EN ISO 12100:2011.

3. CONCEPT OF RISK ASSESSMENT AND RELATED CONCEPTS

3.1. DEFINITIONS

3.1.1. *Machine (directive):*

- An assembly of linked parts or components
- At least one of which can move
- Joined together for a specific application

3.1.1. Endangered (EN ISO 12100: 2011): a source for injury or damage to health. The danger can be latent (potential) (physical phenomenon) or acute (actually).

3.1.2. Risks (EN ISO 12100: 2011): A combination of the likelihood of injury or damage to health and the severity of the possible injury or potential damage to health in a dangerous situation: $\text{risk} = \text{probability} \times \text{impact}$.

3.1.3. Danger zone (EN ISO 12100: 2011) is the area in and / or around machinery in which a person is exposed to a health risk.

3.2. THE CONCEPT OF RISK ASSESSMENT (EN ISO 12100 : 2011)

It is intended to assist designers and safety experts in determining the most appropriate measures so that they can achieve the highest possible level of security.

3.3. PREVENTION PRINCIPLES (MACHINERY DIRECTIVE ANNEX 1)

When choosing the most appropriate solution, the following principles should be applied, in the order given:

1. Exclude or minimize risks
2. Take the necessary protection against risks that can not be excluded
3. Inform users of residual risks present due to any shortcomings of the protective measures adopted, indicate whether any particular training is required and indicate that personal protective equipment should be used.

3.4. TEAMWORK

A risk assessment is always carried out in a team. A team has the advantage to make a more objective assessment of the product and benefit from the experiences of others. The team is made up as much as possible multidisciplinary.

It is also advisable to perform a risk assessment at an early stage of the design mogelijk. A second formal assessment can happen when a working model or prototype is manufactured.

4. ROADMAP FOR CARRYING OUT A RISK ASSESSMENT OF MACHINES

4.1. GENERAL

A risk assessment of a machine examines the manifest latent dangers manifest and the risks they may induce. A specific method has been developed to support the Machinery Directive. This is described in the harmonized European standards EN ISO 12100: 2011

In this approach, the following phases are identified in the risk assessment:

Step 1 :

- collect information and define the limits of the machine (problem definition)

Step 2 :

- identify the latent hazards related to the machine (identification of latent dangers)

THEN FOR EACH IDENTIFIED LATENT DANGER:

Step 3 :

- Estimate the associated risks (risk assessment)
- Evaluate the risk (risk assessment)
- Determine whether the machine is sufficiently safe

IF THE MACHINE IS NOT SUFFICIENTLY SECURE:

Step 4 :

- Take measures to eliminate the latent danger or reduce the risk (risk reduction) and if necessary redo the risk assessment.

In Figure 1, (p. 4), these steps are shown schematically.

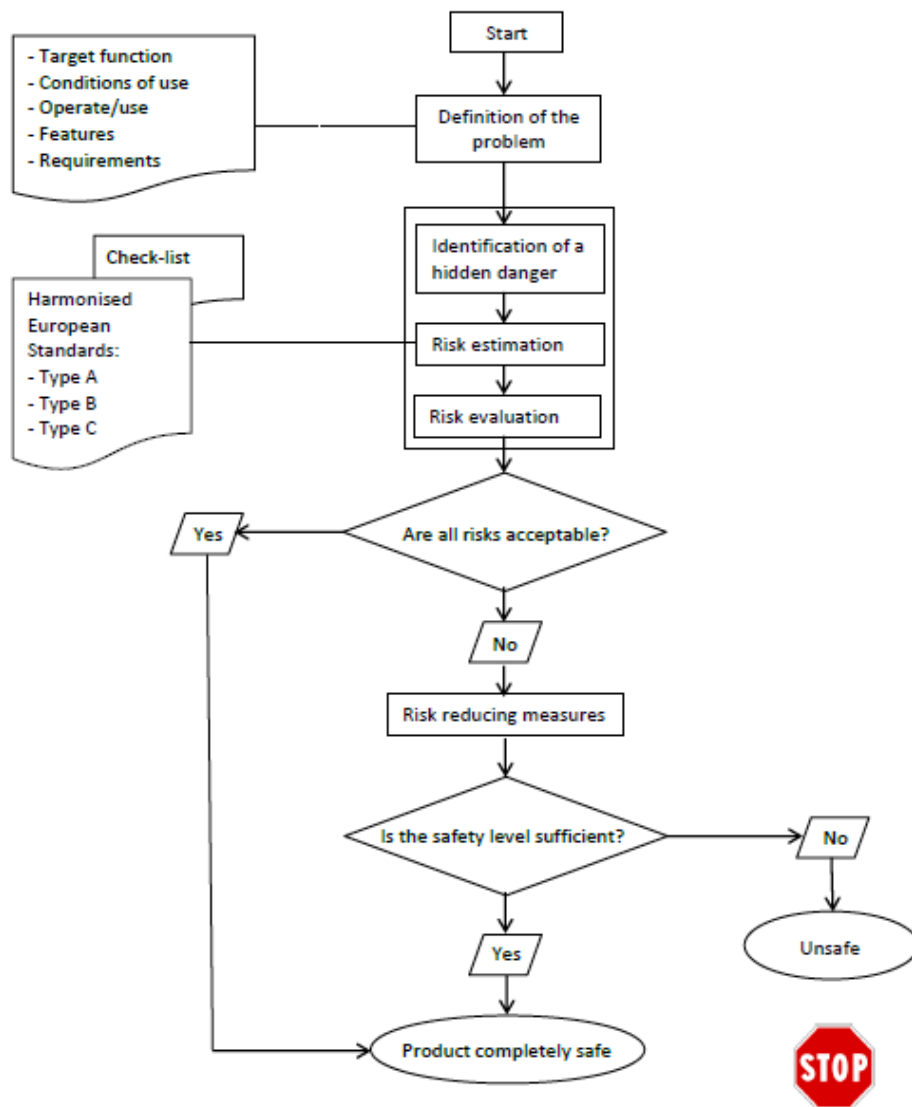


Figure 1: Schematic representation of the steps for carrying out a risk assessment of machines

4.2. STEP 1: COLLECTING INFORMATION + LIMITS OF THE MACHINE

4.2.1. Collecting information

In this phase information is collected, that may be useful for the determination of the hazards and risks associated with the use of the machine (see “below checklist”).

CHECKLIST OF POTENTIALLY USEFUL INFORMATION FOR THE PURPOSE OF CARRYING OUT A RISK ASSESSMENT (PARTIALLY DERIVED FROM EN1050: 1996)

- The machine itself
- Relevant European directives (essential requirements relating to the design and construction of the machine)
- Relevant harmonized European standards and other normative documents
- Specifications of the limits of the machine (using time, dimensions)
- Drawings
- Calculations
- Process Operations (process flow diagrams)
- Accident Data (historical data)
- (People with) user experience with a similar machine
- Images such as photos and videos
- Details of the construction of the machine used, materials to be processed or produced (MSDS)
- Feedback from users
- Information about user groups such as specialists, consumers, children, the elderly and disabled
- Complaints Register and reliability data
- Proprietary checklists
- Machine-specific literature
- Information relating to the environment in which the machine is intended to function (eg, high / low temperatures, “clean room” / contaminated area, away / busy area, weather conditions, electromagnetic radiation, potentially explosive atmosphere)

The exact information required varies from product to product and will often depend on factors such as:

- the type of machine
- the degree of innovativeness (comparable machine already made in the past?)
- the technologies / techniques (hydraulics, pneumatics, electronics, automatic control systems, equipment, etc ...)
- the phase of development in which the machine is during the execution of the risk assessment

4.2.2. Machine limits

In this phase, the limits of the machine must also be defined. In other words, delimiting how the machine is to be used, as well as how the machine should not be used. “Use” must be understood in a broad sense, ie use from “cradle to grave” is to be taken into consideration.

Important factors in this respect are :

- the nature and characteristics of the machine
- the nature and characteristics of the products that are processed with the machine
- the manner in which the machine is used
- the operating environment of the machine
- the type of user(s)
- the working methods throughout the various life phases of the machine
- factors related to how the machine should be used or how the machine should not be used (reasonably foreseeable misuse; dangerous abuse, failure modes and their consequences)

These factors are particularly important if the machine is to work in conjunction with other machines (when the machine is built into a larger whole), or if the manufacturer believes that insufficient understanding of the user - no matter what stage of life of the machine - can lead to dangerous situations.

Figure 2 considers the various life stages of a machine. This figure can be used in identifying the specific hazards that may occur among the various user conditions during packaging, transportation, installation, use, maintenance, cleaning and destruction of the machine.

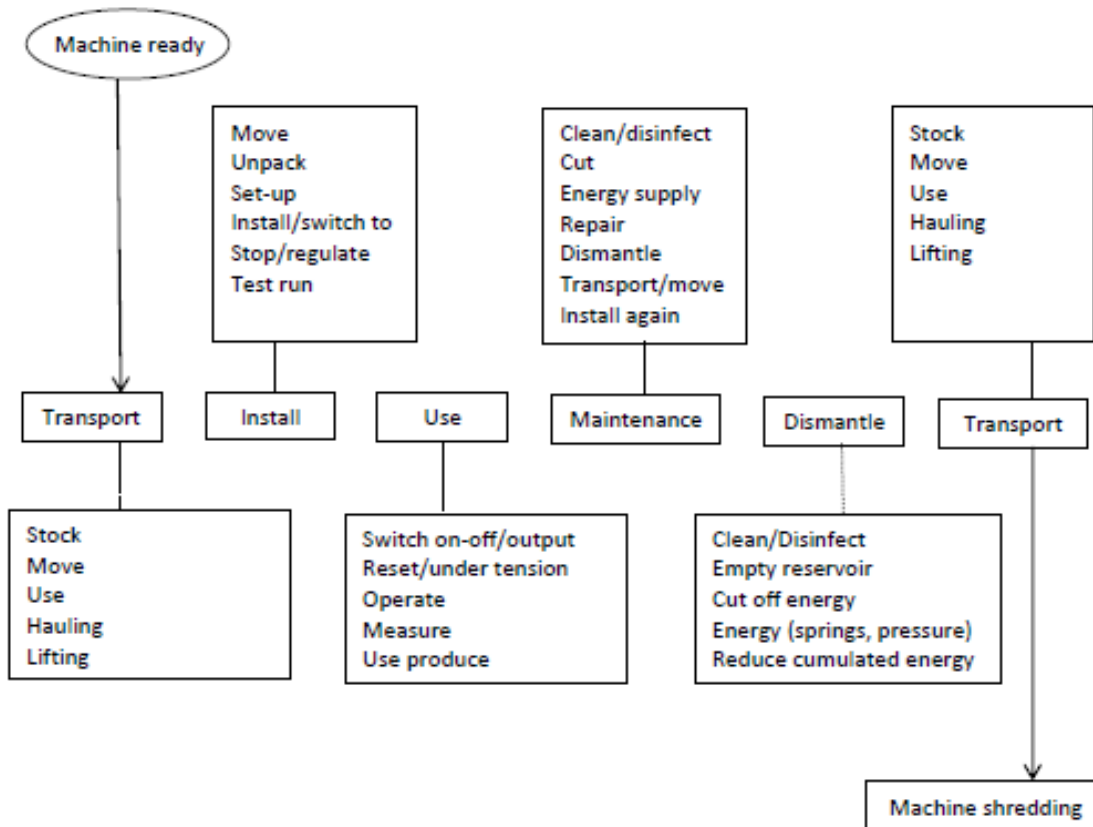


Figure 2: Life stages of a machine

4.3. STEP 2: IDENTIFICATION OF LATENT DANGERS

Once the limits of the machine have been determined, the next step is identification of latent hazards. The purpose of this phase is to create a comprehensive list of latent hazards and their potential effects on exposed persons.

4.3.1. Latent Dangers

Identifying latent hazards is often the most difficult step in the process of risk assessment.

It is therefore advised to make use of checklists in this process.

4.3.2. Consider situations

The situations in which the latent dangers are addressed, should be involved in the analysis. A latent danger is perhaps relevant only under certain circumstances. For example, a rotating shaft can be dangerous only when a screen has been removed or when the shaft is mounted improperly, inadequately lubricated or has not been properly balanced.

After determining the various hazards that may be caused by the machine, the designer must try to foresee all situations where these hazards may result in injury or damage to health.

1. Acts of persons for all phases of the life of the machine:

- Construction
- Transport and Commissioning
 - Compile, install,
 - Adjust
- Use
 - Set up, programming or changing process
 - Operation
 - Cleaning
 - Detection of defects
 - Maintenance
- Decommissioning, demolition and; as far as safety is compromised, removal

2. The possible operating states of the machine:

- The machine performs the intended function (normal operation)
- the machine does not perform the intended function (fault), for various reasons, including:
 - Variation of a property of or a size of the processed material, or of the workpiece
 - Failure of one or more of its components
 - External effects (eg, shock, vibration, electromagnetic magnetic fields)

- An error or defect in the design (eg software errors)
- Failure of power supply
- Unability to regain control of the machine by the operator (Particularly in portable machines)

3. Foreseeable cases of misuse of the machine could be:

- foreseeable incorrect behavior resulting from ordinary negligence, but not from intentional abuse of the machine
- reflex behavior of a person at fault, fortuitous event, defect etc. while using the machine
- wrong behavior by taking the “path of least resistance” in the execution of a task
- for some machines (especially machines for non-professional use), foreseeable behavior of certain groups of people, such as children and the disabled

A common error is that a latent danger is ignored, because it is assumed that a taken (or to take) measure “neutralizes” the latent danger. An example is the assumption that enclosure is sufficient to take away a dangerous situation. Although enclosure can be an effective measure when the machine is in “normal operation”, it may be necessary in other operating conditions that the shield is removed (for example during maintenance or overhaul); the operator can then in fact be exposed to the dangerous situation.

4.3.3. Documenting latent dangers

When capturing the identification of latent hazards, it should always be kept in mind that records must remain understandable for a period of 10 years. A good description should therefore include the following:

- the nature of the hazard itself
- the place in / on / at the machine where the danger occurs
- the situation / circumstances where the risk is manifested
- the nature of the injury that may result from the latent danger
- the use phase in which the risk is relevant

4.4. STEP 3: Risk Assessment

The third step of the risk assessment process is the risk assessment itself. In this step, the risk is determined corresponding to an identified latent hazard or hazardous situation. The identified risk determines whether, and if so what action should be taken against the latent danger.

4.4.1. The risk factors

The harmonized European standards established in support of the Machinery Directive provide a more systematic approach to assessing risk. In these standards, risk is considered as a function of the seriousness of the possible injury on one hand, and of the probability that this lesion is actually happening on the other hand. These standards also describe in more detail four factors that must be considered for risk assessments.

These four factors are (see fig. 3):

- the severity of the possible injury (E)
- the frequency and duration of exposure of individuals to the considered situation (B)
- the probability that the considered dangerous event takes place (W)
- the lack of possibilities for hazard mitigation (G), that is to say the lack of possibilities to avoid or minimize injury

These factors should be considered for each latent danger identified in step 2 (see figure 1 on page 4). The harmonized European standard for risk assessment (EN ISO 12100: 2011) provides the following information about the risk factors:

The risk associated with a particular situation or technical process is derived from a combination of the following elements:

1: Extent of possible damage

- the volume can be estimated by taking into account the following:

a. the nature of what is being protected:

- persons
- business
- environment

b. the severity of injury or damage to health:

- Light (effects usually resolve)
- Heavy (effects do not usually remedy)
- deadly

c. extent of damage (for each machine)

- Limited to one person
- Relative to more people

2: Probability: the probability of the occurrence of a damage, can be estimated by taking into account:

- Frequency and duration of exposure, can be deducted from:

a. the need for access to the danger zone (eg for normal operation, maintenance or repair)

b. the nature of the access (for example for manual feed of materials)

c. the time spent in the danger zone

d. the number of persons to have access

e. the frequency of access

- Probability of a dangerous situation occurs, be deducted from:

a. reliability and other statistical data

b. accident history

c. data on health damage

d. comparison of risks (see 8.3) Note: The occurrence of a hazardous event can have a technical or human cause

• Possibilities to avoid or limit damage, distract from:

a. the manner in which the machine is operated

- By experienced persons
- Inexperienced persons
- Unmanned

b. the speed with which a hazardous event occurs:

- All of a sudden
- Fast
- Slowly

c. risk awareness:

- By general information
- By direct observation
- By indicators

d. human possibilities to avoid or limit damage (Eg reflex, agility, possibility of escape)

- Possible
- Under certain conditions
- Impossible

e. by practical experience and knowledge:

- Of the machine
- Of a known similar machine
- No experience

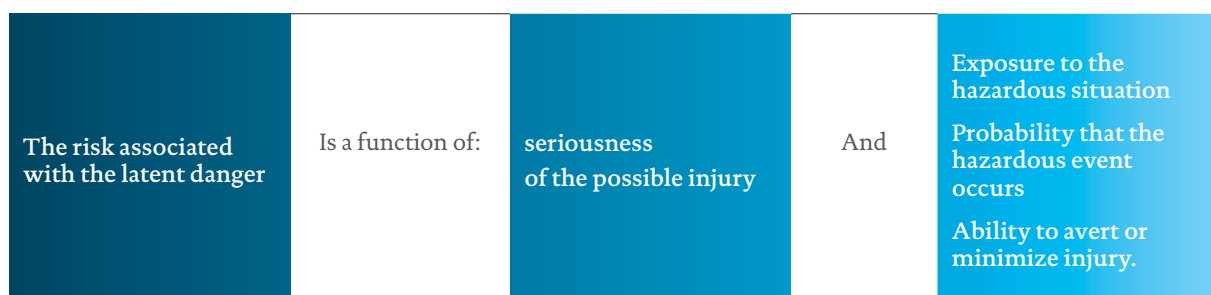


Figure 3: Risk factors and determination

4.4.2. QUANTIFYING RISKS

Risk estimation is usually a subjective activity. There are quantitative methods, which will be calculated in detail as regards the size and nature of the risk. This is usually done by coupling a number to a risk factor, and via a mathematical formula combining these factors with each other. The result is a number that is a measure for the risk. It is also possible to turn off the risk factors in a diagram, from which the risk value can be derived graphically.

Although risk assessments are quantitative for the sake of clarity and analysis, it should be kept in mind that resulting risk values are always based on a subjective evaluation. It is therefore important to assign an absolute value to such a specific risk value.

To that end, it is especially useful to compare risks in relation to each other, so that they can be assigned relative priority. For each identified potential risk factors, the value of E, B, W and G are determined.

E	Degree of severity of the possible injury
1 =	<u>Light</u> (usually reversible)
2 =	<u>Severe</u> (usually irreversible)
3 =	<u>Death</u>
B	Frequency and duration of exposure of individuals to latent danger
1 =	<u>Rare</u> to fairly often
2 =	<u>Frequent</u> to continuous
W	Probability that the hazardous event occurs
1 =	<u>Low</u> (so unlikely that it can be assumed that the event does not occur)
2 =	<u>Medium</u> (it is likely that it takes place once in the life of the machine)
3 =	<u>High</u> (it is likely that it happens quite frequently)
G	Opportunities to evade the danger or to minimize injury
1 =	<u>Possible</u> under certain circumstances
2 =	<u>Hardly possible</u>

A useful tool for assessing risks is called “risk graph” (see fig. 4). The risk graph is a concept in which the relationship between the four risk factors is shown.

Note: The risk graph presented in figure 4 is derived from EN 1050 (now repealed). As the EN ISO 12100: 2011 does not object against this, it could be used further.

By following the arrows, and columns that correspond to the determined values of the factors E, B, and W G, one find a position in the matrix of the risk graph. At this place there is a number which is a value for the relative size of the risk.

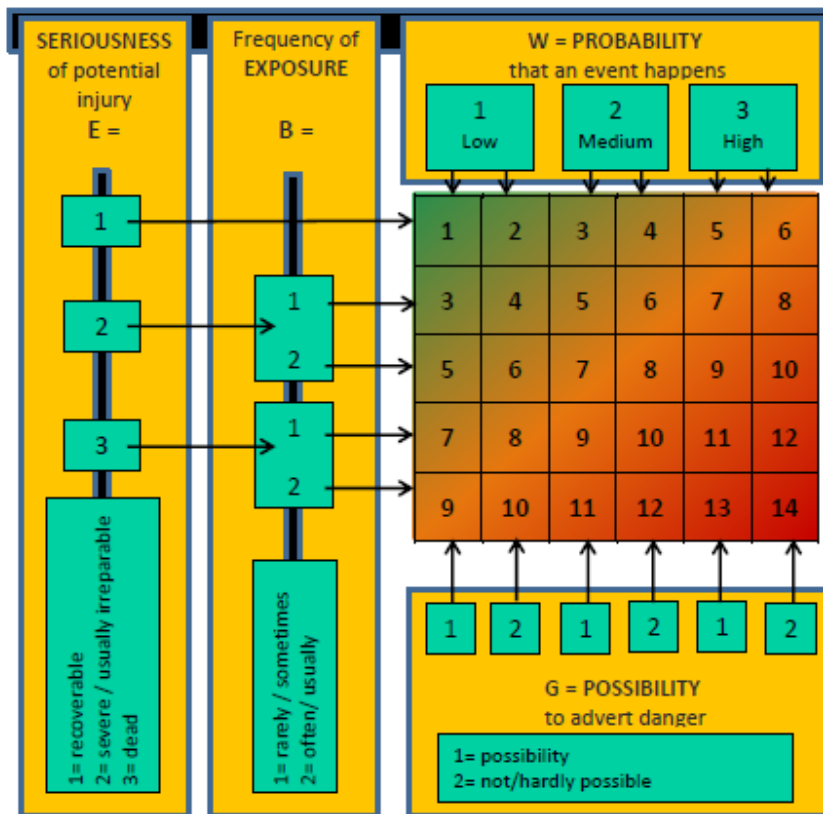


Figure 4: The risk graph

For each potential hazard or hazardous situation, the factors E, B, W and G are to be determined - possibly after extensive discussion - and to be recorded.

If the risk assessment is carried out by a group of people then it is important to record all critical remarks and considerations that led the final value adopted. It is often experienced that the discussion itself is more valuable than the final risk number assigned, because it allows a deeper insight into risks linked to the machine.

In all cases, one should aim at removing a risk entirely, preferably by removing the latent danger (see principles of prevention 2.4)

The risk score is a tool for determining priorities for risk reduction measures and can be used to defend how funds should be spent. In this context it is important to realize that when a risk can be reduced by a simple, inexpensive measure

In summary, for each latent latent danger - which has been identified in the previous step - a preliminary assessment of associated risks is to be made. The estimates must be sufficient to allow the next step (evaluating the risk).

4.4.3. RISK ASSESSMENT

After latent hazards were identified and associated risks assessed (either qualitative or quantitative), risks must be evaluated to determine whether the residual risk, ie the risk that remains after security measures have been taken, is or not acceptable. “Acceptable” indicates that a satisfactory level of safety is achieved.

A possible classification acceptability is next.

R	Meaning	P	Timing
11-14	Very High risk	0	Immediate
8-10	High risk	1	Within 3 months
5-7	Average risk	2	Within 6 months
1-4	Low Risk	3	Within 1 year

In all cases, it should be kept in mind that the values are relative and are not absolute. There are no general rules that state whether a risk is acceptable or not, even for single machines.

However, values derived from the risk assessment allow for giving priorities to higher risks in view of risk reduction. This does not mean that high-risk is by definition unacceptable.

4.5. STEP 5: RISK

4.5.1. General

There will be very few machines that have satisfactory safety in their basic versions. For most machines, one or more risks will be reduced either by eliminating some latent dangers, or by applying security measures.

In the selection of risk-reduction measures, the following must be taken into account:

- the mandatory order in which those should occur according to Annex 1 of the Machinery Directive

and furthermore with

- the size of the risk
- the technical feasibility of measures and
- the economic feasibility of measures

Risk reduction is not part of risk assessment, but both issues can not be dealt with separately in most cases. Risk reduction is a “feedback loop” in which corrective action is taken before a new assessment is made to determine whether adequate safety has been achieved.

4.5.2. Measures under Annex I, Article 1.1.2b of the Machinery Directive

Each risk deemed unacceptable should be reduced to an acceptable level. The Machinery Directive imposes a mandatory hierarchy of measures (Annex I, Article 1.1.2b) (see also principles of prevention)

These measures are described in detail in the harmonized standard EN ISO 12100: 2011. In the diagram “risk” (Figure 5), the method to follow is illustrated.

4.5.3. Inherently safe design

In the first place, risk should be as far as possible eliminated by the design. This premise is logical: if there is no latent danger, the risk is removed. Following design measures can be implemented separately or in combination:

- removal of latent hazards as much as possible by appropriate design choices
- reduction of as many risks as possible by appropriate design choices
- limitation of the exposure of individuals to latent dangers by minimizing the need to enter danger zones

4.5.4. Additional measures and provisions

The manufacturer shall verify whether the safety of his machine can be further enhanced by the inclusion of additional provisions.

EN292-2 mentions in paragraph 6 the following measures:

- facilities for emergencies such as:
 - applying one or more emergency stops
 - creating escape routes
 - allowing manual operation (after an emergency stop)
- equipment, systems and measures to increase safety, including:
 - facilities for service and maintenance on the machine
 - opportunities to disconnect the machine (and shut it down) from its energy source (s)
 - facilities for the safe handling of the machine and / or its heavy components
 - facilities for safe entering of danger zones
 - arrangements for increasing the stability of the machine and its elements
 - resources to trace errors, to diagnose and / or correct them

4.5.5. Screening measures

Risks can be reduced by the application of barriers. In legislation, such barriers are clearly subordinated to design measures. The Machinery Directive provides in Annex I, 1.4.2 and 1.4.3, respectively basic requirements for barriers and protective devices.

4.5.6. Information

The remaining risks must be reduced to an acceptable level by providing information. The Machinery Directive clearly indicates that these measures should not compensate for structural defects.

EN ISO 12100: 2011 provides several opportunities to reduce remaining risks by providing information:

- warning signs
- markers, icons, and texts
- accompanying documents

4.5.7. Fill-Journal “Risk”

Using the sheet “Risk” potential risk mitigation measures can be identified. Several columns are made for:

- intrinsically safe design versions (“Bill”)
- risk reduction by taking blocking action (“construction”) and
- risk reduction by providing information and (possibly) use of personal protective equipment (“PPE / Information”)

For each identified risk alternative and / or additional solutions can be recorded. These can be of use in the event of subsequent design changes.

After the preventive measures were established the “residual risk” must be assessed again. If this is not acceptable, additional measures have to be provided.

ACCEPTABLE RISK

Purpose: elimination of all risks.

However, if a residual risk > 4 would be and for some reason it can not be reduced, then this should be justified and documented in detail in the risk analysis. (whom why, how ...)

Then the document should be frozen and written permissions are removed.

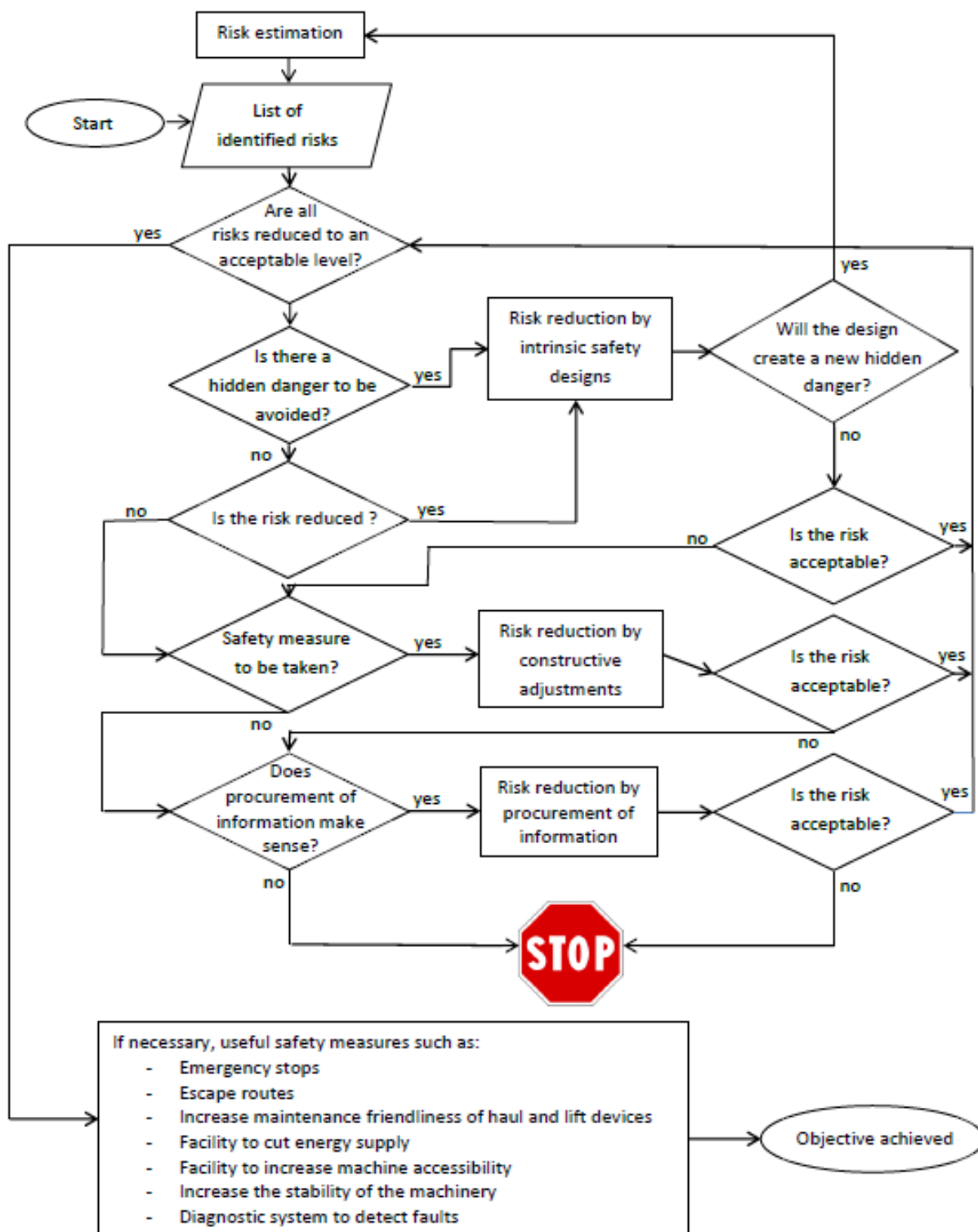


Figure 5: Diagram risk

RISK ESTIMATES ACCORDING EN ISO 13849

If the risk reduction measures consist of technical measures (eg emergency stop, light curtain, limit switch, safety PLCs ...) the risk assessment for the identified latent hazards should be carried out again by means of the risk graph of the EN ISO 13849.