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WHITE PAPER

Risk assessments made easy

Basic information and practical tips for execution

All machinery manufacturers are obliged to carry out a risk assessment to determine the applicable health and safety requirements that apply to their machinery, and to design their machinery accordingly. In some cases, a risk assessment may also be mandatory for machine operators. This white paper sets out the way in which the requirements of the Machinery Directive can be easily satisfied.

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1. Introduction

All manufacturers that produce machinery and plants and wish to sell them on the European Market are obliged by the Machinery Directive to carry out a **risk assessment**.
For operators, the hazard assessment is the central element of Occupational Health and Safety, and must be completed by the operator independently. Under certain circumstances, however, as outlined below, the machine *operator* may also be obliged to carry out a risk assessment.

The risk assessment is a process that requires adherence to a defined system and that can, at least in part, be quite complex. To complicate matters, the requirements can change, perhaps as the result of new policies or technical innovations. The use of software tools and the involvement of external specialists – whether occasionally or to accompany the process throughout – can make the process much easier. In addition, safety experts can also offer tips on how requisite protective measures can be integrated into the machine in a way that is cost efficient and that supports productivity. By following the right approach, the risk assessment can help to enhance employee safety and bring economic benefits.

This White Paper provides a clear, brief outline of the legal basis and prescribed process steps, clarifies the application of standards and explains how the new generation of collaborative robot systems should be taken into account in the risk assessment. In addition, it also outlines how support from software tools and external service providers, such as the **tec.nicum** division of the Schmersal Group, can help.

2. Legal basis

The risk assessment is required by law and is consequently not a voluntary activity by a company. It is mandatory in accordance with the Machinery Directive 2006/42/EC in order to issue a Declaration of Conformity for a machine. The Declaration of Conformity is a prerequisite for affixing the CE marking. A CE marking is, in turn, mandatory for bringing a machine onto the market in the European Economic Area. The Machinery Directive states the following: 'The machinery manufacturer [...] must ensure that a risk assessment is carried out in order to determine the health and safety requirements that apply to the machinery. The machinery must then be designed and constructed taking into account the result of the risk assessment.'

With the conformity assessment procedure, the manufacturer determines conformity of the machinery with all requirements of the Machinery Directive 2006/42/EC, in particular with the fundamental health and safety requirements. This proof is provided by compiling technical documentation, whereby there is no detailed specification regarding the form and layout of the documentation. While this technical documentation must be made available to the competent national authorities on request, the machinery manufacturer is not obliged to pass it on to customers. This is because the risk assessment could contain considerable technical expertise that the manufacturer wishes to protect. It is worthwhile for the manufacturer to prepare thorough, detailed documentation, especially for the prevention of liability risks. Manufacturers and/or distributors of machinery and plants will have to deal with product safety law, warranty and product liability law and perhaps even criminal law in the event of a safety-related product defect.

3. When is a risk assessment obligatory for the *operator* of machinery?

The machinery fleet operated by production companies is frequently changing, sometimes as a result of expansions and modernisations. Within these changes, the question then arises as to whether a ‘significant change’ has occurred. If it has, the machine operator who made the ‘significant change’ becomes the manufacturer and must therefore take into account all directives and any standards relating to machine safety that apply to a machine manufacturer. As a consequence, a risk assessment must be carried out for the related changes and a conformity assessment procedure must be followed that results in the renewed CE marking of the machine. This may, in some circumstances, mean that additional measures need to be implemented to achieve conformity.

According to an interpretation paper published in April 2015 by the German Federal Ministry for Labour and Social Affairs (BMAS) with the participation of the German Federal Institute for Occupational Safety and Health (BAuA), whether or not a change is significant is determined by whether or not there is a new hazard. If this hazard leads to a new or elevated risk, then it is a significant change.

In addition, the operator also becomes the manufacturer if it has assembled several complete and/or incomplete machines into an overall machine or interlinked them to form a plant. These terms are also referred to in the Machinery Directive:
The essential characteristic of an ‘incomplete machine’ is that it is unable to fulfil a specific function. ‘Interlinked machines’ or ‘machine plants’ satisfy the criteria for ‘assemblies of machinery’ if they form a production-related link and a safety-related link, through either

a) the (spatial) arrangement

b) the common production objective (joint manufacture of a specific product) or

c) a joint, higher-level functional control system.

In this sense, a simple emergency-stop link is not considered a safety-related link or ‘assembly of machinery’.

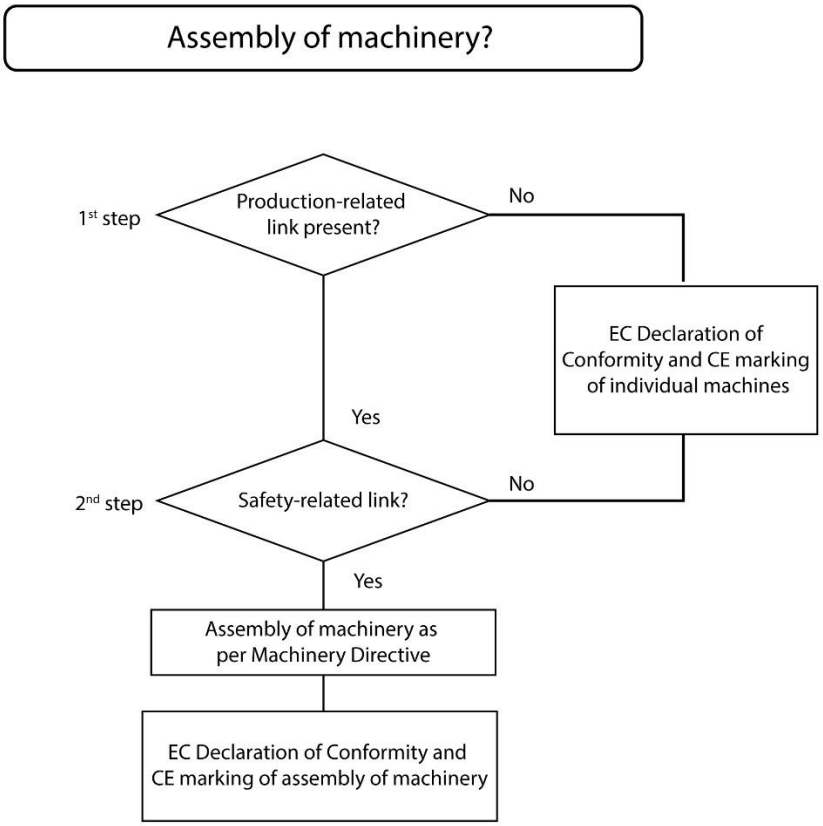

Figure: German Federal Institute for Occupational Safety and Health (BAuA)

4. Start at the beginning – the right time for a risk assessment

A risk assessment should not be carried out only once a new machine has been fully assembled. To begin with, the Machinery Directive stipulates that a machine must be 'designed and constructed taking into account the results of the risk assessment'. Secondly, the obligatory three-stage process for risk reduction (see point 5.5.) requires 'inherently safe design' as the primary solution model. This can, however, only be achieved in the planning phase. Thirdly, once the machine has been constructed, it is often no longer possible to identify design errors (e.g. incorrectly selected parts). Fourthly, dangers that are only identified at the end of the design process can usually only be eliminated or minimised with increased technical and financial outlay.
It is, therefore, worthwhile to consult machinery safety specialists during the planning stage for a new machine or plant – e.g. an external service provider. They offer a neutral and unbiased view and can provide tips on how safety solutions can best be designed to be as cost efficient as possible and ensure that they do not restrict plant availability and productivity during later operation.

Furthermore, the risk assessment is not a one-off process that simply needs to be ticked off on a list, but rather an 'iterative' process to support the design, i.e. it is a process that needs to be repeated several times and until the risks have been sufficiently eliminated or minimised.
Any retrofit or conversion of a machine may, however, result in certain safety functions or parts of the safety concept needing to be revised, in which case the risk assessment will need to be adapted or supplemented.

5. Risk assessment process steps

The risk assessment is carried out in five process steps:

1. Establishing the limits of the machine
2. Identifying hazards or hazardous situations that may emerge from the machine
3. Evaluating the risk
4. Risk evaluation in order to determine whether risk reduction is required
5. Eliminating the hazards or risk reduction

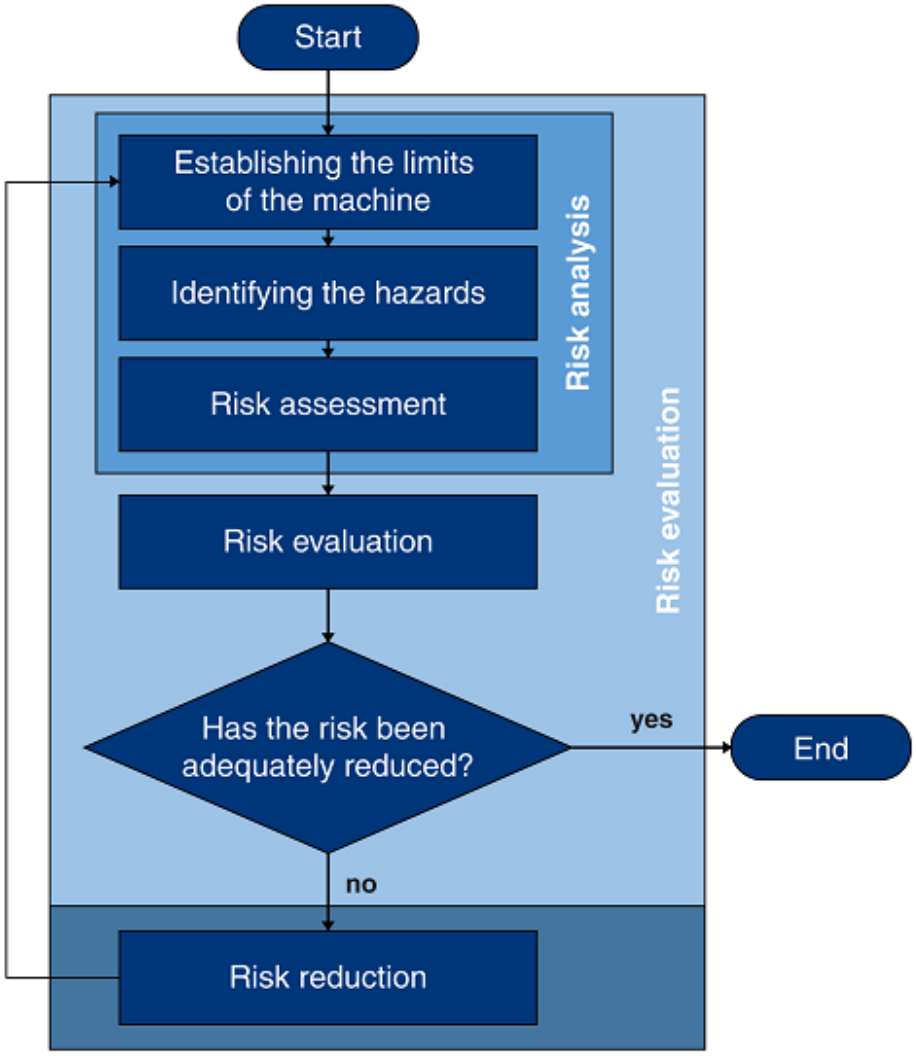

Figure: Risk assessment and risk reduction process steps

Source: German Federal Institute for Occupational Safety and Health (BAuA)

5.1. Establishing the limits of the machine

The risk assessment begins with the identification of the limits of a machine, whereby four areas have to be considered:

I. Limits of use (area of application, intended use, operating modes such as assembly, servicing, maintenance, etc.)

II. Spatial limits (space requirement, movement ranges and safety distances, man-machine interface, etc.)

III. Time limits (service life, maintenance intervals) and

IV. Other limitations (e.g. types of energy, properties of the materials to be processed, recommended minimum and maximum temperatures)

5.2. Identification of hazards and hazardous situations

The identification of hazards is the most crucial step in any risk assessment. Only once a hazard has been identified can measures be taken to reduce the associated risk. Checklists in Appendix B to DIN EN ISO 12100 are a valuable tool for identifying hazards (e.g. falling objects, moving parts, laser beams) and hazardous situations (e.g. working near moving parts, working in noisy environments, performing tasks such as assembly, maintenance, troubleshooting that could lead to a hazardous situation). In principle, however, the risk assessment should be carried out as a team activity, with members of the team coming from different parts of the company – different perspectives and alternative points of view have often proved to be extremely useful.

5.3. Risk assessment

An assessment of the risks must be carried out for each hazard identified (how high is the risk?). Based on this, the need for action to reduce the risk must be identified in the risk assessment. Risk assessment is an extremely difficult step and there are a wide range of methods available.[1)]

5.4. Risk evaluation

Where the previous step was about assessing the risk in terms of the extent of the damage and the likelihood of occurrence, the next part involves a decision: is the risk tolerable or are risk reduction measures required?

5.5. Eliminating the hazards or risk reduction

When eliminating hazards or reducing the risks of these hazards, the Machinery Directive 2006/42/EC specifies a mandatory three-stage approach:

I. Inherently safe design

II. Technical protective measures

III. User information

The inherently safe design can actually only be achieved at the design and development stages, since these are protective measures which either completely eliminate hazards or at least reduce them by altering the design or operational characteristics of the machinery without the use of separating or non-separating protective equipment. This step is carried out first because inherent protective measures appear to be most effective, while technical protective measures could be bypassed.

The technical protective measures offer a wide choice of separating or non-separating protective devices – such as safety fences or safety light grids – which can be designed and used according to the type of hazard. User information includes acoustic or visual warning signals as well as warning notices, operating instructions and labels indicating residual risks.

6. Application of standards

Standards can be helpful when carrying out a risk assessment and to help make the process more straightforward. This is because they outline, in a practical manner, the technology or processes that designers can use to meet the requirements of a directive.

Type A standards are fundamental safety standards, which deal with basic concepts of machine safety, design principles and general aspects that can be applied equally to all machines. The relevant type A standard for the risk assessment is DIN EN ISO 12100:2010, which contains a clear overview of the requisite process steps as well as the important individual aspects. For example, it lists potential sources of danger and/or hazards with clear illustrations (see also point 5.2. in this White Paper: 'Identification of hazards').

Type B standards deal with specific safety aspects or a certain type of safety equipment that can apply to a whole range of machines. Furthermore, type B standards are subdivided into type B1 and type B2 standards. Type B1 standards deal with specific safety aspects (e.g. safety clearances and approach speeds), while type B2 standards deal with specific safety equipment (e.g. two-hand controls or locking devices).

Type C standards are machine-specific standards that deal with all safety-related aspects of a specific type of machine. Type C standards provide excellent support when carrying out risk assessments, as they provide a number of different points for attention, such as:

- The definition of the limits of the machine
- The hazardous areas that frequently occur on the machine
- A list of significant hazards
- Solution specifications for risk reduction

The application of type C standards does not, however, release the machine manufacturer from its obligation to carry out the risk assessment. The manufacturer must still check whether or not the standard(s) that has/have been applied cover all dangers that could be caused by the machine and whether or not suitable protective measures have been put in place to cover the dangers. If a danger

is not covered by a standard, the manufacturer must carry out a comprehensive risk assessment for that specific danger. If the content of a standard is implemented in full, the manufacturer can claim what is known as ‘presumption of conformity’. In terms of product liability law, this results in reverse onus, which means that in the event of an accident, the manufacturer does not have to prove that the machine was safe, rather it must be proven to the manufacturer that the machine was or is unsafe.

7. Risk assessment for collaborative robots

The number of robot workstations has increased rapidly in recent years. Increasingly, these are robots that work directly with humans, with no fixed guards in place. These collaborating robot systems also fall under the scope of the Machinery Directive 2006/42/EC. The risk assessments for these robots, known as cobots, do not differ fundamentally from those of other machines and robot systems in terms of the procedure that must be followed.[2)] The principal standards applicable to industrial robots are EN ISO 10218-1 and 10218-2. Collaborative robots were, however, fairly uncommon in 2011 when these standards were published, and the standards are currently incomplete. Consequently, the International Organization for Standardization (ISO) published guidelines in 2016 in the form of the technical specification ISO/TS 15056, which deals with the safety aspects of human/robot collaboration and which will be integrated into ISO 10218 in the coming years. In particular, this technical specification takes into account the performance and force limitation which allows these robots to operate without a safety fence being in place. The robot systems are designed so that in the event of contact, e.g. between parts or the robot or robot tool and people, biomechanical limit values are never exceeded (force, pressure). These limit values are based on the latest research on the determination of pain onset waves and are listed in Appendix A to ISO/TS 15066. A risk assessment must measure whether or not these are adhered to; special measuring systems are also now available for this purpose. In the event that limit values are exceeded, protective measures must be put in place, e.g. by modifying the design of the robot to include padding on the robot arms or spring-mounted grippers.[3)]

8. Use of software tools for the risk assessment

Software tools offer good support for practical execution of the multi-stage process of the risk assessment, especially when assessing complex plants or machines with multiple potential hazard points. The software guides the user through the risk assessment systematically. It provides different checklists and shows, at a glance, which tasks are outstanding or which danger areas have not yet been dealt with. In addition, the software applications also provide a sound basis for compiling the requisite documentation. Most are characterised by simple, intuitive operation, which means that prior software training is not required. A range of providers are available, each with its own version.

tec.nicum has also developed its own software application for risk assessments – the RSK tool. It is a leaner program than others available on the market, and enables more efficient risk assessment processes. At the same time, the RSK tool is extremely flexible and is easy to adapt to individual customer preferences. Furthermore, it is a practical tool that has been fully customised to the needs of technicians. The user interface is available in nine languages – German, English, French, Italian, Spanish, Chinese, Dutch, Swedish and Portuguese) so that final documentation can be generated in multiple languages in a standardised format and design without significant effort – a huge benefit, especially for companies with branches in different countries.

tec.nicum experts offer use of the RSK tool as an option, and are happy to carry out the risk assessment with other software tools currently available on the market, depending on customer requirements.

9. Support from external service providers

Many companies do not regard functional machine safety – particularly the legal and normative aspects – as one of their core competences, and consequently, they often lack the specialists they need. In the age of 'Lean Management' or at times of 'order overload', internal personnel resources can often be lacking. These companies are advised to seek the support of external service providers when it comes to risk assessments.

tec.nicum, a business division of the Schmersal Group, offers a modular package of services, and companies can choose from the following services according to their needs:

- tec.nicum qualifies companies' specialist personnel so that they can carry out risk assessments independently. In addition, the tec.nicum academy offers seminars at different training locations or on-site at customers' premises.
- tec.nicum experts can be consulted as needed at different phases of the risk assessment. In addition, flexible hourly allotments can also be agreed, for use by customers as required. tec.nicum employees can provide support to customers either on-site or remotely by phone or over the internet.
- tec.nicum experts carry out the complete risk assessment, including the formulation of recommendations for action and corrective measures as well as all requisite documentation.
- In addition to risk and hazard assessments, tec.nicum also offers safety evaluations of individual machines as well as consultancy on specific safety issues.

One of **tec.nicum's USPs** is its product and manufacturer neutrality; they advise and evaluate independently, and develop safety solutions objectively. This also means that they obtain,

install and commission products that are not necessarily part of the Schmersal product range.
tec.nicum experts are certified as Functional Safety Engineers by TÜV Rheinland and are professional, experienced specialists in the field of safety technology. They form a global network, allowing companies with branches in other countries to call upon their services globally – always with the same quality standards.

Further information: www.tecnicum.com

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Comments:

1) The report entitled
   'Risk assessment in mechanical engineering', published by the German Federal Institute for Occupational Safety and Health, offers a good overview of the methods used for risk assessment.
2) See DGUV Information 11/2015: Collaborative robot systems.
3) Further information and a table of limit values can be found in DGUV Information 11/2015: Collaborative robot systems.

Photo, page 1: Shutterstock, figures pages 6 and 8: German Federal Institute for Occupational Safety and Health