



Ministry of Labour, Employment,
Occupational Training and Social Dialog

Ministry of Agriculture, Agrifood and
Forestry

Technical Guide dated 18 November 2014 Relative to Modifications to Machinery in Service

Subject: This technical guide presents the notion of "modification" as applied to machinery in service, and the rules that employers shall take into consideration when performing such an operation. It also indicates the prevention principles and procedures recommended in order to preserve or improve the safety of machinery.

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Summary: The machinery used in companies is frequently modified by the user for many reasons: to adapt the machinery to production and work organisation requirements, assemble it with other machinery, improve the level of safety, extend a production line, and so on. Given the lack of any specific text concerning machinery modification operations in the European regulation, this technical guide provides the necessary information on the notion of "modification". It also reiterates the regulatory objectives with regard to risk prevention relative to the use of machinery. Lastly, it presents the recommended procedures to apply to modification operations.

Keywords: modification of machinery in service, typology of modifications, examples of modifications, risk prevention and assessment approach, regulatory objectives relative to the use of machinery, legal and technical frames of reference.

Introduction

There are many reasons why users make modifications to machinery in service: to adapt the machinery to production and work organisation requirements, assemble it with other machinery, improve the level of safety, extend a production line, and so on.

The purpose of this guide is to detail the notion of "modification" as applied to machinery in service and the rules that employers shall take into consideration when performing such an operation. It also indicates the prevention principles and procedures recommended in this context in order to preserve or

improve the safety of machinery, and to do this in accordance with the regulatory requirements and state-of-the-art practices. It also gives guidance relative to risk assessment and reduction.

The content of this guide only applies to operations whereby the employer modifies, or has a third party modify, machinery in service for his own use.

Consequently, all other operations are excluded from the scope of application of this guide, and in particular those performed on:

- new machinery before it is placed on the market or put into service;
- used machinery intended to be placed on the market in the European Union for the first time and is therefore considered as new;
- used machinery intended for resale (second-hand legal regime);
- a modification in the conditions of use of the machinery (example: reduction in the number of operators on the machine or set of machines without making a technical modification).

This guide comprises the introduction and five chapters.

Chapter 1: "Definitions", contains the definitions established to facilitate the reading of this guide. The majority of the definitions come from texts concerning the design or utilisation of work machines and equipment.

Chapter 2: "Modification typology and examples of modifications", defines for the different machines - with or without the CE marking - what constitutes a modification, the operations that are not modifications and gives examples to illustrate the different cases.

Chapter 3: "Statutory obligations of the employer" reiterates the obligations in the area of health and safety of an employer who modifies or has a person external to the company (a subcontractor for example) modify machinery.

Chapter 4: "Prevention approach and procedure" describes how a risk assessment procedure shall be implemented. One sub-section of this chapter is devoted to the technical reference framework that is useable, while another covers the prevention approach to follow. This section is supplemented by examples.

The Annexes provide details on:

I - Risk assessment;

II - Specifications;

III - Standardisation.

Chapter 1 - Definitions

The following definitions are intended to clarify the terms used in this guide. When the definitions take up the terms of the "Machinery" Directive 2006/42/EC, they do not take away the legal consequences associated with the application of this Directive which sets the rules for the design and placing on the market of new machinery.

Specific application: the specific application characterises the type of use of machinery as provided for by the manufacturer during its design and placing on the market. Such applications include, for example, the transformation, processing or packaging of materials; the lifting and movement of materials, objects or persons; working the soil and sowing seeds, tending to crops and harvesting agricultural or forest products.

Function: the term function is used here to designate the elementary movements of the machine (displacement, rotation, clamping, etc.) or the parts contributing to safety (safety function), etc. The term function is associated with the nature of the function, such as:

- energy transmission function (mechanical, hydraulic, pneumatic, etc.),
- function of coupling or connection between machines (link between self-propelled machine or tractor and machine);
- lifting function;
- control function;
- safety function;
- monitoring function;
- protective function;
- etc.

A machine generally includes several functions to fulfil the specific application.

Element: object, part which is an independent unit in itself and can be added to an assembly to supplement it and make a larger whole.

Employer: within the meaning of this guide, a person who employs workers and provides machines in the workplace in order to perform the work.

Operator: worker tasked with installing, operating, adjusting, maintaining, cleaning, repairing or moving a machine in the workplace.

Machinery: an assembly fitted with a drive system other than direct human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application (see Machinery Directive 2006/42/EC article 2 (a)).

Note: a manually operated lifting device is regarded as machinery.

New machinery: machinery which has never been used and is exhibited, put on sale, imported, rented, provided for any purpose whatsoever in the European Union for the first time (see also the Guide to application of the Machinery Directive 2006/42/EC -§ 72 *New and used machinery*).

Machinery considered as new: machinery which has been used outside the European Union and is exhibited, put on sale, imported, rented, provided for any purpose whatsoever in the European Union for the first.

Machinery in service: machinery used by operators in the workplace.

Note: machinery acquired by an employer and which in practice is not used is regarded as machinery in the scope of this document.

Second-hand machinery: machinery which has already been used in another (preceding) company in a member state of the European Union and is exhibited, put on sale, imported, rented, provided for any purpose whatsoever

Partly-completed machinery: within the meaning of this guide, an assembly which is almost machinery but cannot in itself perform a specific application. Partly-completed machinery is intended to be combined with a machine or other partly completed machines or equipment in order to constitute machinery (see Machinery Directive 2006/42/EC –article 1 (g) and 2 (g)).

Complex installation: within the meaning of this guide, assembly of new machinery and/or machinery in use or partly-completed machinery ordered and assembled for a specific application or organised so as to function as a whole in a production process.

Safety component: component which fulfils a safety function and whose failure and/or malfunction endangers the safety of persons. It is not necessary in order for the machinery to function (See Machinery Directive 2006/42/EC – article 2 (C)).

Note 1: Annex V of the "Machinery" Directive 2006/42/EC (transposed by an Order of 27 October 2009) contains an indicative list of safety components.

Note 2: from a strictly legal aspect, a component that fulfils a safety function and is incorporated in machinery from the design stage or provided by the machinery manufacturer as a spare part is not regarded as a safety component within the meaning of the "Machinery" Directive 2006/42/EC. Conversely, if this component is placed on the market independently, it shall comply with the relevant technical rules and prerequisite formalities, including the CE marking.

Interchangeable equipment: a device which, after putting into service machinery or a tractor, is assembled with that machinery or tractor by the operator himself in order to change its function or attribute a new function, insofar as this equipment is not a tool (see machinery directive 2006/42/EC article 1 (b) and 2 (b)).

Tool: a working element of the machinery installed directly or using handling equipment by one or more operators on one or more supports provided for that purpose.

Note 1: a tool is not regarded as an integral part of the machinery.

Note 2: a tool shall be distinguished from interchangeable equipment because it does not modify the function or introduce a new function.

Modifications: (see chapters 2 below).

Chapter 2 - Modifications and examples of modifications

2.1 – What a modification is – What it is not

Within the meaning of this guide, the following are regarded as modifications: the replacement, the addition or the removal of an element or function, the addition of interchangeable equipment or the modification of the specific application when these operations are performed on machinery:

- that is subject to the CE marking and when this operation is not intended by the original manufacturer in the instruction manual;
- that is not subject to the CE marking and when the end-purpose of this operation is to renovate the machinery in whole or in part, to modify its performance or to modify the working conditions.

An assembly of machinery involving at least one machine in service with which can be associated new machinery, partly completed machinery or another machine in service, insofar as that assembly is not provided for in the instruction manual(s) or if there is no instruction manual, is also regarded as a modification.

The following are not regarded as modifications:

- the implementation of a function foreseen by the manufacturer and specified in the instruction manual;
- an operation to ensure conformity with the requirements or technical rules applicable to the machinery;
- the integration or removal of a tool;
- any adjustment, maintenance or servicing operation, and the replacement of a part that figures in the manufacturer's catalogue;
- the installation of interchangeable equipment foreseen by the machinery manufacturer and specified in the instruction manual;
- the installation of interchangeable equipment for which the manufacturer has defined the specific modules or the technical characteristics of the machinery unit(s) intended to accommodate it (**see note 3 below**);
- the construction of machinery using used and/or new parts (**see section 4.5 of this guide**).

Modification examples:

- construction of a straw spreader using parts of a manure spreader,
- construction of a winding machine by reusing the chassis of a parallel lathe.

Note 1: It is strongly advised not to introduce modifications that cause certain categories of machinery in service to change, particularly towards the machinery listed in Annex IV of the "Machinery" Directive.

Examples:

- automatic press modified to permit manual loading and/or unloading;
- machinery for lifting loads transformed into machinery for lifting persons.

Note 2: Whatever the case, the removal of a safety function and its replacement by an organisational measure is prohibited by the regulations because this reduces the intrinsic safety of the machinery and

induces a nonconformity in the machinery (see chapter 3 on the statutory obligations, and more specifically the obligation to maintain conformity).

Note 3: The manufacturer of interchangeable equipment shall provide the instructions to permit assembly and utilisation in complete safety. The employer using the machinery shall verify by examining the documentation the compatibility of the characteristics of the machinery unit(s) with the interchangeable equipment and verify that it can be safely used in the workplace.

2.2 - Modification examples

2.2.1 - Replacement or change of location of a safety component

The replacement of a safety component is regarded as a modification when:

- it is replaced by a component whose performance differs from that of the initial component (product technical characteristics and safety function);
- its location changes, even if the new component has the same performance; for example the positioning of a two-hand control device nearer to or further from the original position (the repositioning can result from the replacement of the control or a change in the industrial process);
- the safety component is replaced by a component of another type, for example replacing a two-hand control device by a sensitive protective device as a light barrier.

2.2.2 - Replacement of a part

Two cases are to be considered depending on whether a CE marking is present on the machinery or not.

1st case - For machinery subject to CE marking, the replacement of a part by a spare part whose characteristics or part number are not given in the instruction manual or in the manufacturer's documentation constitutes a modification.

Examples:

- replacement of a braking unit by a unit with different characteristics which reduces the braking time;
copy of a transmission shaft having a 'keying' system in the absence of characteristics or part number in the instruction manual or in the manufacturer's documentation.

2nd case - For a machine not subject to CE marking, when the replacement is not identical, that is to say when the replacement part does not have the same performance or technical characteristics, it is a modification.

Examples:

- the replacement of a position sensor by a sensor that uses a different technology or has a different lifetime (number of actuations);
- the replacement of a CE winch by a non-CE winch.

2.2.3 - Addition of an element or a function

The addition of a new element or of a function not intended by the manufacturer and not specified in the instruction manual is a modification.

Examples:

- addition of an automated cleaning system in a milk conditioning process in order to improve the efficiency of cleaning;
- installation of an adaptation on the fork of an industrial lifting truck which adds the "suspended load lifting" function;
- addition of a screw grain conveyor on a tipper;
- addition of a mechanised unloading system on a sawing line.

2.2.4 - Removal of an element or a function

The removal of a safety function and its replacement by an organisational measure are prohibited by the regulations because this reduces the intrinsic safety of the machinery and induces a nonconformity in the machinery.

The removal of an element or a function is always a modification.

Examples:

- removal of an operating mode, of a means of access, of an at-source fume extraction system, or a machinery element in a complex assembly,
- removal of the motorisation of the advance mechanism of the table of a circular saw for wood working to permit use with a manual advance mechanism.

2.2.5 - Addition of interchangeable equipment

The installation of interchangeable equipment which was not originally intended by the machinery manufacturer, or where the characteristics of the machine(s) intended to receive the equipment were not specified by the interchangeable equipment manufacturer, is a modification.

Example: installation of a concrete mixer on an industrial lifting truck not initially designed for this purpose.

If the addition of this interchangeable equipment leads to a modification in the specific application, see section 2.2.7 of this guide.

2.2.6 - Assembly of machinery or partly-completed machinery

If there is no instruction or assembly manual or if the assembly is not foreseen in the instruction manual(s), an assembly of at least one machine in service with one or more new machines or machines in service or one or more partly-completed machines is a modification.

Examples:

- addition of a part-unloading manipulator - placed on the market as partly-completed machinery - to a plastic materials injection moulding machine in service which no longer has an instruction manual;
- addition of a lifting winch to a travelling crane;
- grouping together of numerical control machines in service and integration of a transfer manipulator in order to constitute a production island;
- addition of a crusher in a quarry plant set-up.

2.2.7 - Modification of the specific application

When the specific application of the machinery is modified, this is a modification.

This type of modification shall be avoided if it compromises the principle of safety integration which provides that the machinery shall be designed and constructed so that it is capable of safely fulfilling a specific application.

The reason behind this is that if the modification creates new risks, it may not be possible to eliminate, mitigate or prevent them to a satisfactory extent because they will not have been taken into consideration in the initial design of the machinery.

Chapter 3 - Statutory obligations of the employer with regard to modifications

3.1 - General

An employer who modifies or has a person external to the company (a subcontractor for example) modify machinery made available to his employees is responsible for compliance with the regulations in the field of health and safety. Whatever the case, the employer shall ensure that the modified machinery remains in conformity with the applicable safety rules, that it is suitable for the work conditions and characteristics as provided for in Article 3 of the Directive 2009/104/EC relative to the use of work equipment and that its functions and uses do not contradict the manufacturer's initial recommendations, where they exist.

The writing of specifications is recommended. Refer to annex 5.2

3.2 - Prevention principles and the rules for the use of machinery

The employer has obligations to meet, particularly those relative to the installation, use and maintenance of machinery that he puts into use in his company. These same obligations also apply if the machinery undergoes modifications.

This machinery shall be maintained in conformity with the rules applicable when it was put into service in the company, including with regard to the instruction manual (Article 4 (2) of the Directive 2009/104/EC concerning the minimum safety and health requirements for the use of work equipment by workers at work). Consequently, the employer who uses machinery and introduces a modification to it shall ensure that the modified machinery complies with the following applicable provisions at least:

- for machinery subject to the CE marking within the meaning of the "Machinery" Directive, the technical design rules contained in Annex I introduced by the "Machinery" Directive in the version in effect at the first placing on the market within the European Union;
- for machinery not subject to the CE marking, the technical utilisation instructions provided for in annex I of the Directive 2009/104/EC concerning the minimum safety and health requirements for the use of work equipment by workers at work.

3.3 – Risk assessment obligation

The employer shall analyse the risks for worker health and safety, including when choosing working equipment and defining the operating positions (see chapter 4 of this guide for the risk prevention approach). The same applies for the risks present at the operating position or new risks that could arise on account of the machinery modification. Taking into account the results of the risk analysis, the employer implements the prevention measures and production methods that guarantee the best level of health protection and safety of the workers (see the directive 89/391/EEC - section II article 2).

The employer who modifies machinery ascertains that it remains suitable for the tasks to perform and that the modification has been incorporated taking into account the current state of the art. To achieve this objective, the employer chooses the technical solutions according to their effectiveness and their impact on the work of the operators.

3.4 - Modification file

To fulfil these obligations and provide proof of maintaining conformity, it is necessary to constitute a technical file containing a description of the modification and the result of the risk assessment.

This file takes into account the modified elements and their possible impact on the operation, maintenance, service, installation or use of the machinery.

This file is different from the instruction manual, which is updated at this time to integrate the modifications. It serves to transmit the information to the operators responsible for use or maintenance. It also serves as a reference for the updating of the operating position description sheets.

It ensures the traceability of the modification. When a modified machine in service is transferred, this modification file should be handed over in addition to the certificate of conformity.

This file, which records the history of the modifications, is very important, because the reasons justifying a modification along with the accompanying risk prevention choices are often forgotten. This traceability record provides the "memory" of the equipment.

3.4 - Training and information

The employer informs the workers appropriately of the risks that concern them and which are due to the modifications affecting the modified machinery. He also informs them of the new conditions of use and maintenance and the instructions or directives concerning them (Article 8 of the Directive 2009/104/EC relative to the use of work equipment).

The safety training which is dispensed more generally to the workers tasked with the operation or maintenance of work equipment is renewed and supplemented whenever necessary to take into account the changes to this equipment (Article 9 of the Directive 2009/104/CE).

The conditions of this training are determined by the employer taking account of the knowledge and experience of the workers and the complexity of the equipment. To provide the training, the employer can call upon competent personnel from within the company or use an outside service provider (for example: a specialised training organisation, the service provider who conducted the modification design study or the company that implemented the modification).

The employer organises refresher and additional training courses as and when necessary.

All the workers working on the modified machinery benefit from these training measures, including occasional personnel (apprentices, trainees, temporary workers, etc.) and the maintenance personnel (including outside service providers).

Furthermore, the workers assigned to the modification of machinery receive specific training relative to the specific instructions and rules to follow, the conditions of work execution and the equipment and tools to use.

Chapter 4 - Risk prevention approach and methodology

The obligation to maintain the machinery in conformity with the design and construction technical requirements and rules applicable when they are put into service constitutes an essential requirement of the regulations concerning the prevention of risks associated with the use of machinery (see Chapter 3). This obligation remains with the employer throughout the machine's lifetime and any subsequent modifications. Prior to the modification, it is necessary for the employer to conduct a risk analysis using a method comparable to the one that shall be used by the manufacturer in the design of new machinery.

The employer shall also undertake a more general assessment of the operating position and the work environment with regard to the use of the modified machinery.

The employer who uses machinery and decides to modify it, or have a third party modify it, can apply the following risk prevention approach:

- risk identification and assessment;
- assessment of the conformity of the planned modification with regard to the applicable rules and technical specifications;
- implementation of any risk elimination or reduction measures resulting from this assessment;
- production of a modification file ensuring, for the modifications made, the traceability of the assessment results, the diagrams and drawings, the design calculation notes, the technical characteristics and the part numbers of the parts replaced and/or used;
- the updating of the machinery instruction manual and the information notices for the operators (example: operating position description sheet).

The risk prevention approach is carried out taking into account the relevant technical criteria which are specific to each type of modification. The following paragraphs illustrate this approach for the most common modifications.

4.1 - Presentation of the notion of risk analysis

Risk assessment is a notion present in two legal orders:

- that resulting from the economic Directive known as the "Machinery" Directive (2006/42/EC) which covers those requirements for machinery design and placing on the market which are incumbent on the manufacturer,
- that resulting from the Directive relative to the health and safety of workers which sets the rules for the use of work equipment (Directive 2009/104/EC) which come under the responsibility of the employer who uses machinery.

The risk assessment differs depending on whether it takes place at the design stage when the machinery does not yet exist, or in the phase of use in the workplace, during the lifetime of the machinery 2006/42/EC. From a strictly legal standpoint, the *risk assessment* provided for by the "Machinery" Directive is not applicable to machinery in service, but its method can be useful in cases of machinery modifications.

4.1.1 - Analysis of risks specific to the design of the machinery

This analysis must be undertaken by the person who places the machinery on the market (manufacturer, distributor, company manufacturing machinery for its own use).

The "Machinery" Directive (2006/42/EC) devotes several articles to the risk assessment obligation. The general principle is set out in its preamble 23, then detailed in the general principles of Annex I.

The European text establishes a direct link between the risk analysis and the essential health and safety requirements (EHSR) of Annex I, stipulating that the purpose of the analysis is to determine those requirements which are applicable to the machinery in question. This is because the essential health and safety requirements (EHSR) are only applicable if the corresponding hazards exist for the machinery. Following this reasoning, the risk assessment is inseparable from the conformity assessment which shall be carried out by the manufacturer.

The analysis procedure is then presented in the "Machinery" Directive as an iterative process comprising several steps:

Directive 2006/42/EC: Annex I, section 1 of the general principles

- *determine the limits of the machinery, which include the intended use and any reasonably foreseeable misuse thereof,*
- *identify the hazards that can be generated by the machinery and the associated hazardous situations,*
- *estimate the risks, taking into account the severity of the possible injury or damage to health and the probability of occurrence,*
- *evaluate the risks with a view to determining whether risk reduction is required, in accordance with the objective of this Directive,*
- *eliminate the hazards or reduce the risks associated with these hazards by application of protective measures in the order of priority established in section 1.1.2 b).*

4.1.2 - Analysis of risks specific to the use of the machinery

This duty falls on the employer who makes the machinery available to his employees.

It is the Framework Directive 89/391/EEC concerning the implementation of measures to encourage the promotion of the safety and health of workers at work which provides for the risk assessment obligation of employers. Among the stated measures figures the principle of a prior and overall assessment of the risks in the workplace, including in the choice of work equipment and the defining of operating positions. The employer is also required to take into account the technological state of the art in the choice of processes and of the prevention measures.

4.2 - Risk analysis procedure when machinery is modified

Within the framework of a machinery modification, the risk analysis can be based on the method used at the design stage for new machines, on condition that this remains appropriate (machinery in service is not new machinery). On the other hand, the analysis shall also take into account the *in situ* risk assessment. The method for assessing risks in the case of a modification is thus conducted from both the design and use aspects.

The primary responsibility for assessment lies with the employer who carries out, or has a third party carry out, the machinery modification.

4.2.1 - Risk identification and estimation¹

Three types of risk shall be identified:

- risks associated with the functioning of the machine: in the first instance employers must **identify the hazardous features** associated with the planned technical modifications to the machinery (mechanical resistance, stability, speed of hazardous moving parts, etc.);

- the risks associated with the work situation: in the second instance the risks associated with the utilisation of the machine should be identified in order to **take into account all the hazardous situations and events** that could occur during the work process. This involves taking into account the impact of the modification on the machinery operating modes in all the production and servicing phases (adjustment, supply, production, maintenance, etc.) for all the tasks and manufacturing processes associated with the machinery;
- the risks in the operating position: in the third instance, **all the risks in the operating position** shall be identified in order to take account of the effects of the modification on the work environment and work organisation (interference, work rate, falling objects, movement of persons, noise or toxic pollution, etc.).

The estimation of the risks consists in determining the severity and frequency factors. It enables the employer to carry out a risk assessment and if necessary to determine the required level of safety performance for the choice of safety devices and control systems.

4.2.2 – Risk assessment and choice of prevention measures

The risk assessment shall enable the essential health and safety requirements (EHSR) of Annex I of Directive 2006/42/EC that are relevant with regard to the planned modification to be determined and the objectives set out in the applicable regulations to be met. Whenever technically possible, the most recent safety objectives set out in the "Machinery" Directive 2006/42/EC (Annex I) should be met.

The risk assessment shall be carried out for each risk identified. The risk assessment must give priority to eliminate of the risk as from the modification design project. This should be carried out by removing in priority the hazardous features, then the hazardous situations and events. When this is impossible, it will be necessary to implement prevention measures.

Whatever the case, the technical means employed shall be adapted according to their effectiveness and their cost in relation to the overall cost of the machinery concerned.

4.3 - Usable technical reference frameworks

As a general rule, the European design standards relative to the safety of machinery constitute useful technical reference frameworks for machine designers. Users can demand that the modification operation specifications make compliance with these standards contractually binding. When making a modification to machinery, the latest version of the standards concerning new machinery can give indications of the state of the art in a given domain and aid with the choice of the most appropriate technical solutions, with respect to the machinery characteristics and the most recent safety objectives set by the regulations (essential health and safety requirements (EHSR) of Annex I of the "Machinery" Directive 2006/42/EC.

In order to take technical progress into account, the specifications provided in the latest version of the published harmonised European standards should be favoured insofar as possible for the aspects that concern the machinery element undergoing the modification.

The use of the standards applicable to new machinery is recommended for the completely new sections or components. This being said, their compatibility with the other sections and functions of the machinery shall be assessed.

For example, the addition of a new function requiring the installation of a safety light curtain can have an impact on the machinery control safety functions. In this case, the standard relative to the design of the safety sections of control systems, such as EN ISO 13849-1 "*Safety related parts of control systems – General principles for design*" can be used. In effect, if the choice of a new safeguard concerns a safety light curtain of type 2 per EN 61496-1 "*Safety of machinery – Electro-sensitive protective equipment*", the performance level of the system for stopping the hazardous moving elements of the new

function shall match the performance level of the safety light curtain. Likewise, standard EN ISO 13857 "*Safety distances to prevent hazard zones being reached by upper and lower limbs*" can be used to dimension the guards put in place to prevent access to the newly installed elements.

4.4 - Illustrations of the different types of modifications

4.4.1 - Replacement or change of location of a safety component

If a safety component is replaced by a component with different performance characteristics or is installed in a different location, the risks should be assessed taking into account the performance of the component and its installation conditions. With a safety light curtain for example, it is necessary to have information such as detection height, sensitivity, response times, etc.

It is possible to use the type C standard (see section 5.3 of this guide for the order of precedence of standards) of the machinery in question if it exists, or otherwise a type A or B standard, such as Standard EN ISO 13855 "*Positioning of safeguards with respect to the approach speeds of parts of the human body*" dealing with the positioning of safeguards with respect to the approach speeds of parts of the human body or standard EN ISO 14119 "*Interlocking devices associated with guards*", or the other technical reference frameworks mentioned in section 4.3.

4.4.2 - Replacement of a part

In the case of replacement of a part:

- the effects of this replacement on the machinery and its support should be evaluated, whatever the technologies involved. For example, with a mechanical part it may be necessary to produce a design calculation note taking into account all the stresses (mechanical, thermal, etc.) to which the part is subjected;
- if applicable, the impact on the residual lifetime of the machinery resulting from this replacement should be reassessed.

4.4.3 - Addition of an element or a function

When an element or a function is added, the risk assessment is performed taking into account:

- the characteristics of the new element or the new function;
- the interaction between the new element or the new function and the rest of the machinery and its support;
- the impact of this addition on the work conditions;

The risk reduction measures resulting from the modification should be implemented and the new function connected to the power and control system of the machinery.

The addition of an element or a function can necessitate, among other things, the installation of additional safeguards. In this case it is possible to dimension the guards in accordance with standard EN ISO 13857 "*Safety distances to prevent hazard zones being reached by upper and lower limbs*" and to position the protective devices in accordance with standard EN ISO 13855 "*Positioning of safeguards with respect to the approach speeds of parts of the human body*", unless otherwise specified in the type C standard applicable to the machinery.

4.4.4 - Removal of an element or a function

When an element or a function is removed, the risk assessment takes into account:

- the characteristics and the function of the removed element;
- the impact of the removal of the element or function on the work conditions;

- the elimination of the possible interactions between the removed element and the machinery.

The removal of an element or a function can necessitate the installation of additional safeguards. It is possible to position the guards in accordance with standard EN ISO 13857 "*Safety distances to prevent hazard zones being reached by upper and lower limbs*" and to position the protective devices in accordance with standard EN ISO 13855 "*Positioning of safeguards with respect to the approach speeds of parts of the human body*", unless otherwise specified in the type C standard applicable to the machinery.

4.4.5 - Addition of interchangeable equipment

When machinery is fitted with interchangeable equipment not foreseen by the original manufacturer of the machinery or interchangeable equipment, the risk assessment takes into account:

- the characteristics (mechanical resistance, stability, size, etc.) of the machinery;
- the characteristics of the interchangeable equipment that the employer wishes to install;
- the conditions of attachment and connection of the equipment to the machinery;
- the possible interactions between the interchangeable equipment and the machinery;
- the impact of this operation on the work conditions and the environment of the machinery.

4.4.6 - Assembly of machinery or partly-completed machinery

When machinery in service is assembled to other machinery or partly-completed machinery, the risk assessment takes into account:

- the characteristics of the machinery in service;
- the characteristics of the machine(s) or partly-completed machine(s) that the employer wishes to install;
- the conditions of assembly, attachment and connection of the machine(s) or partly-completed machine(s) to the machinery in service;
- the possible interactions between the machine(s) and the partly-completed machine(s);
- the impact of this assembly on the work conditions and the environment of the machinery.

The assembly of machinery or partly-completed machinery with machinery in service can necessitate the installation of additional safeguards. The guards can be dimensioned in accordance with standard EN ISO 13857 "*Safety distances to prevent hazard zones being reached by upper and lower limbs*" and the protective devices can be positioned in accordance with standard EN ISO 13855 "*Positioning of safeguards with respect to the approach speeds of parts of the human body*", unless otherwise specified in the type C standard applicable to the machinery.

4.4.7 - Modification of the specific application

If the machinery application is changed, the risk assessment focuses on the overall operation of the machinery. It is carried out on the basis of the essential safety requirements applicable to new machines. The risk assessment, elimination or reduction process implemented by the employer shall enable the risks associated with the machine to be analysed in a systematic manner. Standard EN ISO 12100 "*Safety of machinery - General principles of design - Risk assessment and risk reduction*" is a useful methodological support for carrying out the risk analysis task.

During this operation it is recommended to have a competent person or organisation verify the modified machine in order to assess the conformity of the working equipment.

4.5 - Particular case: Construction of machinery using used and/or new parts

This case is not regarded as a modification, the machinery is considered as new and all the provisions of Article 5 of the "Machinery" Directive relative to placing on the market are applicable.

The employer shall meet the same requirements as a manufacturer (compliance with the essential health and safety requirements, compliance with the conformity assessment procedures, constitution of a technical file, application of the CE marking, and writing of the instruction manual). It is in the best interests of an employer who does not have the experience of a manufacturer to seek the assistance of a competent safety specialist from the initial stage of his design work.

Before putting new machinery into service, the employer can call upon a person or organisation competent in the assessment of the conformity of work equipment.

Annexes

I - Risk assessment - analysis example

A - Description of the machine and its modification for the machining cycle

Type of Machine: Drilling machine for rework operations on plastic parts after moulding.

Nature of the operations: The parts are placed on a support by an operator then held in place by clamping devices before starting the machining cycle. At the end of the machining cycle, the parts are unclamped and removed manually by the operator.

Nature of the modification: Replacement of the manual clamping devices that hold the parts on the work table by pneumatic clamping devices.

This modification has three objectives:

- improve work conditions by reducing the number of manual operations;
- increase the machine production rate by reducing the clamping and unclamping times;
- ensure reproducible clamping conditions to limit the risk of deforming the parts.

This operation is regarded as a modification of the machine corresponding to the replacement of a part as specified in section 2.2.2 of this document.

B - Modification risk analysis table

The sole aim of the following example is to present the approach; it is limited to one identified risk.

This analysis is performed for each of the potential risks (see chapter 3 of this guide)

OPERATION		COMPONENTS of the RISK					PREVENTION MEASURES				
No.	Identification	Hazardous feature or hazard	Hazardous situation or exposure	Hazardous event	Possible damage or risk	Initial risk		On which component do you take action?	Means used	Residual risk	
						P	S			P	S
1	Clamping the part	Travel of moving section of clamps	Positioning of part on its support by the operator	Activation of clamp tightening while the operator's hands are in the zone	Crushing of fingers	D	3	Elimination of hazard	Clamp with limited opening gap (impossible to insert a finger between the part and the moving section)	A	1
								Reduction of hazard	Limitation of clamping force in approach phase	D	2
								Access limitation by control	Installation of a synchronised two-hand control device actuated during the clamping phase	A	3

P: Probability of damage occurrence: A Improbable, B Rare, C Occasional, D High

S: Severity of the possible damage: 1 Negligible, 2 Low, 3 Serious, 4 Deadly

II - Specifications and safe modification of machinery

References

EN 16271:2013, Value management — Functional expression of the need and functional performance specification — Requirements for expressing and validating the need to be satisfied within the process of purchasing or obtaining a product, AFNOR

ZANIN J-P - Cahier des charges fonctionnel, Technique de l'ingénieur, A 5 090

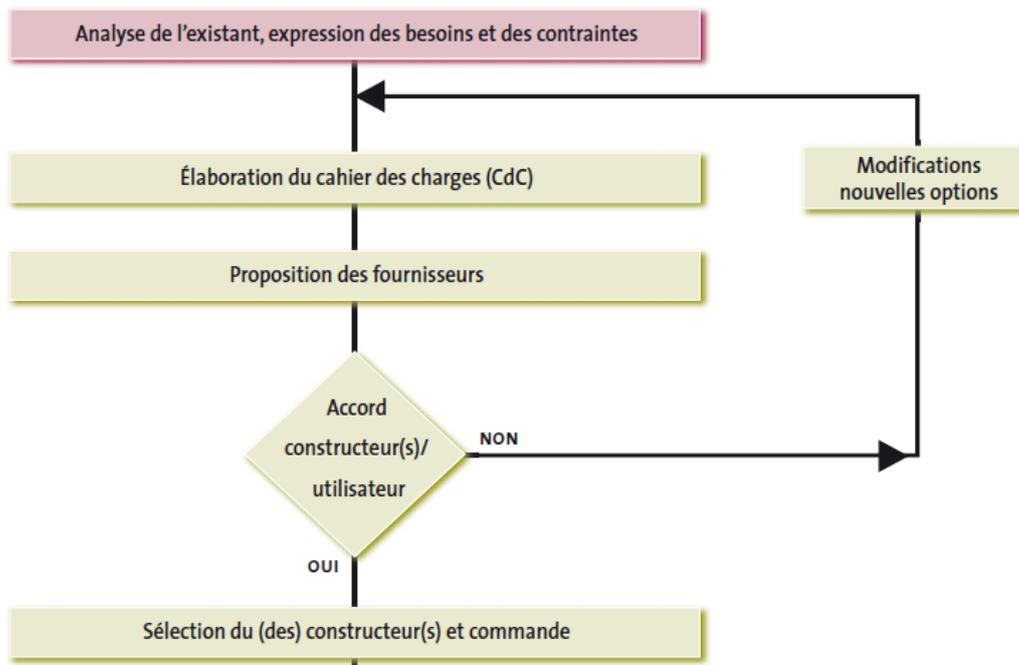
LEMARCHAND C. Technique de l'ingénieur, Cahier des charges du point de vue de l'activité de travail, A 5 093

ED 103 - Réussir l'acquisition d'une machine ou d'un équipement de production, INRS

The specifications constitute an essential document in the contractual relationship between employer and service providers. Well-written specifications minimise the risk of subsequent disputes.

The specifications document enables the employer to express his need and requirements precisely and to consult service providers. The service providers then use this document as a basis for proposing solutions, giving price estimates and work performance time frames.

Once the service provider(s) has/have been chosen, the specifications can be appended to the order and thus become contractually binding.



Français	English
Analyse de l'existant, expression des besoins et des contraintes	Analysis of current state, statement of needs and constraints
Elaboration du cahier des charges (CdC)	Drafting of specifications
Modifications nouvelles options	Modifications new options
Proposition des fournisseurs	Supplier proposals
Accord constructeur(s) / utilisateurs	Manufacturer(s) / users agreement
oui	yes
non	no
Sélection du (des) constructeur(s) et commande	Selection of manufacturer(s) and order

Writing the specifications

When writing the specifications, it is recommended to involve the various persons concerned with the project, notably:

- representatives from process engineering, production and maintenance;
- representatives from human resources (for the impacts of the project on the personnel, on training, etc.);
- representatives from the occupational health and safety committee (OHSC).

The preparation of this document is also based on discussion with the service provider(s) as proposed in the above schematic diagram.

Content of the specifications

The specifications document is not only a technical document covering the functions and performance of the modified machinery.

It also contains all the elements necessary for risk prevention:

- a reminder of the applicable safety rules (regulations in force, rules specific to the company).

Knowledge of and compliance with the standards form part of the know-how of the designers (service providers). Nevertheless, this does not preclude referral to certain standards that address the main known risks (handling operations, explosive atmospheres, etc.). It is however unrealistic to mention an excessively large number, with which compliance would become difficult to verify.

- a **detailed description of the expected uses** for each technical function of the modified machinery. This description shall be based on analyses of activities and experience feedback (see box at end of document).

The designer will then have all the necessary information to define principles and technical solutions that are safe and which satisfy the required modifications. The modified machinery will then be suited to the uses throughout its foreseen lifetime. This will greatly reduce any subsequent modifications, adaptations or "reasonably foreseeable misuse" of the equipment.

- the **conditions of machinery acceptance**. The writing of specifications is only worthwhile if achieving the set objectives is verified without waiting for production release. It is therefore necessary to define milestones (project reviews), verification procedures (drawings, numerical simulation, mock-ups, prototypes, etc.), and assessment scenarios and criteria.

Method for describing the uses

The description of the expected uses shall not simply be juxtaposed on to the technical functions (in separate paragraphs). It shall be interlinked with the technical functions. To achieve this, an approach based on designers' practices is proposed^(*), namely the functional analysis. It adds simple questions (why, what, who, how, where, when) to be asked for each function:

- **Why** have this function (this intervention, etc.)? The fact of explicitly writing down the reason will enable this need to be called into question if necessary during the negotiation between the employer and the service provider.
- On **What** does this function (this intervention, etc.) act? This question serves to clarify the product, the process, the section of the machine concerned, by indicating its state, its quantity, its weight, etc.
- **Who or what** intervenes to fulfil this function (this intervention, etc.)? Which operator(s) is (are) going to intervene (number, qualifications, etc.)? What part of the machine in the case of "automatic mode" operation?
- **How** does this function (this intervention, etc.) proceed? Here it will be a question of operating procedure, process, as well as of means and necessary or prohibited tools.
- **Where?** In which environment, in which zone does the function (or intervention) take place?
- **When?** At what stage, at what frequency does the function (or intervention) take place?

The functional analysis supplemented by this questionnaire provides an expression of the technical needs enhanced with the expected uses of the future work equipment.

^(*) *Daille-Lefevre B., Marsot J., Roignot R., Fadier E., Falconnet E.: Sécurité des machines : proposition d'une démarche de spécifications basée sur l'analyse fonctionnelle du besoin et la notion de situations de travail, actes du Congrès LM 18, Tours France, octobre 2012.*

Content of the specifications: points to define clearly (non-exhaustive list)

- ❖ **Nature of the need**
- ❖ **Performance criteria**
- ❖ **Limits of the supply**
- ❖ **User population**
- ❖ **Conditions of personnel training** (production, adjustment, maintenance, etc.)
- ❖ **Maintenance requirements** (access, conditions of intervention, assigned work times, etc.)
- ❖ **Conditions and constraints associated with the installation site**
- ❖ **Conditions of delivery and assembly** on the installation site
Who does what? (project manager, person in charge of the certification procedure, etc.)
- ❖ **Acceptance requirements**
- etc.**

III - Standardisation - reminders

The standards concerning machinery safety have the following structure:

- a) - Type A standards (basic safety standards), containing basic concepts, design principles and general aspects that can be applied to all machines;
- b) - Type B standards (group safety standards), addressing one or more aspects of safety or a protective device valid for a wide range of machines:
 - Type B1 standards, addressing particular safety aspects (such as safety distances, surface temperature, noise);
 - Type B2 standards, addressing protective devices (such as two-hand control devices, interlocking devices, pressure-sensitive devices, guards);
- c) - Type C standards (safety standards by machine category), addressing detailed safety requirements applicable to a particular machine or a particular group of machines.

Note: When the requirements of a type C standard differ from those set out in the type A or type B standards, the type C standard requirements take precedence over those of the other standards for machines which have been designed and constructed in accordance with the requirements of the said type C standard.