

2.3.4 MACHINERY DIRECTIVE REQUIREMENTS

Introduction

In common with the other CE marking directives, the Machinery Directive 2006/42/EC is primarily a free market measure. However, it also provides for a widely applicable framework for safety assessment and even when it is not strictly applicable, it can provide a good basis for risk assessment and documentation in order to demonstrate due diligence on the part of a manufacturer or supplier.

Directive 2006/42/EC is fully implemented into UK law by The Supply of Machinery (Safety) Regulations 2008 (SI 2008 No.1957) All new machinery introduced into the EEA must now comply with this Directive.

Scope

The definition of machine is very broad and will include an assembly fitted with, or intended to be fitted with, a drive system other than directly applied 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.

There are some specific exclusions from the Directive - for example military equipment and machines which are already covered by other, more specific, directives (e.g. lifts and medical devices). However, there is also a general exclusion from the Machinery Directive for equipment which falls within the scope of the Low Voltage Directive and which presents hazards which are primarily of an electrical nature. This is an important exclusion and will be relevant to many weighing applications where, although there are moving parts, they do not present any significant hazards.

Second-hand machinery which was first used within the EEA prior to the date of the implementation of the directive (i.e. before 1 January 1995) is excluded from having to comply with the Directive itself. However, any machinery which was manufactured before 1 January 1995 must be made to comply with the Directive if it is subsequently brought into Europe from outside, just as any newer machinery would that is manufactured outside the EU.

Equipment manufactured for the manufacturer's own use is not excluded from the requirements, but may be subject to slightly lesser obligations with respect to marking and documentation.

In the context of weighing and lifting equipment, it's important to understand that lifting accessories such as chains, strops, shackles and load-cells are all also within the scope of the Directive, whether or not they meet the strict definition of being 'an assembly of linked parts'.

History

The original Machinery Directive was numbered 89/392/EEC. This was modified by a number of amendments which extended the scope to equipment which was originally excluded, and clarified the requirements. Then, in 1998, Directive 98/37/EC provided a consolidation of the previous directives into one document, although it made no changes in the actual requirements. Finally, in 2006, the Commission completed work on a replacement Directive, 2006/42/EC, which is the one in force at the moment.

Requirements

The requirements of the directive can essentially be split into two sections – the ‘essential protection requirements’ and administrative provisions.

The essential protection requirements demand that machine manufacturers identify the hazards which their products contain and then assess the risks which these hazards present to users. Any risks thus identified must be reduced to as low a level as is reasonably practicable.

Annex I of the Directive gives a comprehensive list of the potential hazards which may arise from the design and operation of machinery, and gives general instructions on how the risks from these hazards must be avoided. Detailed requirements are laid out in a series of safety standards. The standards are drafted by multi-national committees of industry experts and reflect design requirements for particular pieces of machinery much more closely than could ever be achieved by specific legislation. Once a standard has been accepted by the European Commission (the process of ‘harmonisation’), it is given the ‘EN’ prefix. This means conformity with the requirements of the standard gives a ‘presumption of conformity’ with the requirements of the Directive.

Because so many standards are required to cover the full range of machines covered by the Directive, the European Standards bodies have devised a hierarchy which can be applied in every situation. The most basic standards, known as ‘Type A standards’, set out requirements for the safety of machines only in the most general terms: indeed, part 2 of EN ISO 12100 is essentially a reproduction of annex 1 of the Machinery Directive. ‘Type B’ standards deal with more specific issues: design of emergency stops (EN ISO 13850); prevention of unexpected start-up (EN 1037); pneumatic systems (EN 983); temperature of touchable surfaces (EN ISO 13732-1) and many others. Finally, ‘Type C’ standards deal with specific classes of machinery: for example, EN 619 and EN 620 deal with safety of conveyors; EN 415 deals with packaging machinery and EN 201 deals with injection moulding machines.

The administrative provisions of the Directive (at least so far as manufacturers are concerned) are primarily aimed at forcing manufacturers to provide documentary evidence that the machinery complies with the Directive. This is done via the creation of a “Technical File”. The general form and content of the Technical File is dictated in the Directive and manufacturers must be able to make this information available for inspection by the authorities (the HSE in the UK) for up to 10 years after date on which the machine was sold. However, except for Annex IV machines (see below), there is no obligation to produce a copy of the file unless demanded to do so by the enforcement authority, and only the enforcement authority has a right to see it. The manufacturer does not have to provide a copy to the customer unless they choose to.

Machinery meeting the requirements of the Directive is required to have the CE symbol clearly affixed to indicate compliance. It must also show the year of manufacture, some form of serial number, and other ratings as required by the relevant standards. An item of equipment may only display the CE mark when the equipment satisfies all relevant directives; for instance, machines with electrical controls must also comply with the requirements of the Low Voltage and EMC Directives.

Where volume production is envisaged, the Directive requires that control measures must be identified to ensure that all of the machines manufactured will conform to the provisions of the Directive.

Finally, the manufacturer must prepare and sign an ‘EC Declaration of Conformity’. This is basically a statement which confirms the identity of the manufacturer and the machinery for which they are claiming compliance, and is signed to confirm that the correct procedures have been followed.

Annex IV machines

The vast majority of machinery may be self-certified by the manufacturer. What this means is that so long as the administrative and protection requirements of the Directive are properly completed, the manufacturer can perform all of the assessment and documentation procedures in-house and does not need to submit to any form of external test or approval.

However, annex IV of the Directive contains a list of about 15 types of machine which are subject to special procedures. Machines in this list must either be made fully in accordance with the provision of the relevant type C standard, or they must be subject to a type examination by a Notified Body. In either case, a copy of the technical file for the machinery must be lodged with a Notified Body before the CE mark is applied.

Declaration of Incorporation

The application of the CE mark under the Machinery Directive is in effect a statement which confirms that the machinery fully complies with the requirements of the Directive and is safe to use. Clearly, this is not appropriate for partly completed machines which are intended to be incorporated into another machine or which cannot function unless they are built into a complete production line. For these circumstances, instead of signing a Declaration of Conformity, the manufacturer does what they can to assess the machine they have built and to mitigate any risks to the user, and then signs a document called a 'Declaration of Incorporation'. This basically states that the machinery is incomplete and must be made to fully conform with the requirements of the Directive before it is brought into service. The manufacturer must provide information on the residual risks which the machine contains and on the assessment work which they have completed.

The Declaration of Incorporation is a concept which exists only in the Machinery Directive and so, if other CE marking directives apply (e.g. a check-weigher which is intended for incorporation into a packaging line, and which is covered by the EMC and Low Voltage directives as well as being a machine) then the machinery must carry the CE mark for these directives even though it is not CE marked as a machine.

Future Developments

In December 2006, after a long gestation, the European Commission finally published a new Machinery Directive, 2006/42/EC. So far as the vast majority of manufacturers and users are concerned, the basic requirements of the Directive remain unaltered, and in particular the assessment and documentation requirements are basically the same. Annex IV is also untouched. In general terms, the key differences between the new and old directive are:

- Greater clarity and more explanations of the scope and certain definitions;
- A narrowing of the scope of the exclusion which permits certain equipment also covered by the LVD to be excluded from the scope of the Machinery Directive;
- Greater clarity in the requirements for partly completed machinery

The Directive 2006/42/EC is implemented via the Supply of Machinery (Safety) Regulations 2008.

References

The European Commission have a special section on machinery with a great deal of useful information on their EUROPA server. This includes the full text of the directive and lists of the current harmonised standards.

Main Europa page on the Machinery Directive:

(http://europa.eu.int/comm/enterprise/mechan_equipment/machinery/index.htm).

UK Weighing Federation Technical Articles

List of current harmonised standards:

(<http://europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/reflist/machines.html>)

For details of draft standards, the New Approach web site is a good EU-funded resource.

(<http://www.newapproach.org/Directives/ProductFamilies.asp?98/37/EC>)

The UK government's Department for Business, Enterprise and Regulatory Reform (BERR) publishes a number of useful guides on the Directive and these are available for download from the following address:

(<http://www.berr.gov.uk/dius/innovation/regulations/ecdirect/page12543.html>)

