



Understanding the Machinery Directive (2006/42/EC)



Intertek
70 Codman Hill Road
Boxborough, MA 01719

icenter@intertek.com 1-800-WORLDFLAB

www.intertek.com

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Introduction

In this paper we will look at the Machinery Directive (2006/42/EC), and discuss the differences between 2006/42/EC and its predecessor 98/37/EC. We’ll also look at routes to ensure ongoing conformity.

Brief History

In 1985, a series of ‘New Approach Principles’ were introduced into the European Community (EC) that would enable the free movement of goods across the region.

They laid out a set of market parameters for the EC, including Essential Health and Safety Requirements for workers in the Community and minimum product requirements for goods going on sale in the region.

From these principles, a number of specific Directives were developed to govern particular types of products and operating characteristics, including:

- Low Voltage Directive
- EMC Directive
- Machinery Directive
- ATEX (Explosive Atmospheres)
- Pressure Equipment Directive
- Gas Appliances Directive

The Directives establish specific minimum performance requirements, and products that meet these are said to have a ‘presumption of conformity’. This can be validated through product assessment against harmonized Standards, either by the party that plans to sell its product in the EU or on their behalf by a third-party assessment organization – such as an accredited certification body.

Products that meet the essential requirements of the Directives that govern them can be placed on the market, but a Declaration of Conformity must be made. A technical file for the product must be available in the EU and the product must carry the mandated CE Marking, as required by the Directives. Some of the Directives, e.g. ATEX and Gas, also require that CE Marking for certain product types is supported by mandatory certification from a qualified body. On these products, the CE mark is accompanied by the Notified Body number below the CE symbol. Compliance with these regulations is then enforced by surveillance activities carried out by member states.

Now, the New Approach Directives are under review, particularly relating to the essential requirements of the harmonized Standards, the role of third party certification marks, and the role they play in the compliance process. The goal is to strengthen market surveillance activities and enforcement.

More information on the New Approach Directives can be found at:
<http://www.newapproach.org/Directives/Default.asp>

Overview: The Machinery Directive (2006/42/EC)

- The Directive has been put in place because:
“The machinery sector is an important part of the engineering industry and is one of the industrial mainstays of the Community economy. The social cost of the large number of accidents caused by the use of machinery can be reduced by inherently safe design and construction of machinery and by proper installation and maintenance” (Paragraph 2)
- Article 2 of the Directive specifies the products that the Directive applies to:
 - 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
 - an assembly referred to in the first indent, missing only the components to connect it on site or to sources of energy and motion,
 - an assembly referred to in the first and second indents, ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or a structure,
 - assemblies of machinery referred to in the first, second and third indents or partly completed machinery
 - an assembly of linked parts or components, at least one of which moves and which are joined together, intended for lifting loads and whose only power source is directly applied human effort;

In all cases relevant provisions of other EC Directives where these are appropriate (EMC, ATEX etc) must be taken into account to achieve full compliance with the Directive – including Health and Safety requirements (as indicated in paragraph 14)

- Directive 2006/42/EC replaces 98/37/EC – adoption 29th June 2006
- 2006/42/EC comes into force on 29th December 2009, with very limited exceptions*
- Old directive repealed - **NO TRANSITION PERIOD***
- In the UK it is adopted under the new “Machinery Regulations 2008” (replacing “Supply of Machinery (Safety) Regulations 1992 (SI 1992/3073 and amendments)”)”

* Cartridge-operated fixing and other impact machinery, which were previously excluded – Transition to 29th June 2011

Key Changes to the Directive

Recent changes to the Directive can be considered comprehensive as they encompass a modified range of ‘machinery’. The changes consider product design as well as

construction, and they specify particular aspects of the required associated documentation needed for conformity. Even on-going surveillance and the role of Notified Bodies is explored further. The key changes are as follows:

1) Scope

Previously the scope of Directive covered:

- Machinery
- Interchangeable equipment
- Safety components
- Lifting accessories
- Removable mechanical transmission devices

The Directive was extended to include:

- Chains, ropes and webbings
- Partly completed machinery

2) Exclusions

In the previous version of the Machinery Directive 98/37/EC, an extensive list of equipment was excluded from its scope. In 2006/42/EC several of these have been removed and others clarified. Several new items have been added as well. The exclusion list now contains:

- Fairground/amusement park equipment
- Machinery for nuclear purposes
- Agricultural and forestry tractors*
- Motor vehicles and their trailers covered by Directive 70/156/EEC of 6 February 1970*
- 2 or 3 wheeled motor vehicles covered by Directive 2002/24/EC of 18 March 2002*
- Motor vehicles intended for competition
- Means of transport by air, water or rail*
- Seagoing vessels and mobile offshore units
- Machinery designed for military or police purposes
- Mine Winding Gear
- Machinery intended to move performers during artistic performances

*Equipment mounted on the excluded types of transportation however is NOT excluded from the scope of the Directive.

Exclusions include:

- Safety components intended to be used as spare parts to replace identical components and supplied by the manufacturer of the original machinery
- Weapons, including firearms
- Machinery specifically designed and constructed for research purposes for temporary use in laboratories
- Electrical and electronic products falling under Directive 73/23/EEC of 19 February 1973 (including household appliances, ordinary office machinery, low voltage switchgear and control gear)**
- High Voltage Switchgear and control gear
- High Voltage Transformers

** This equipment is specifically covered by the Low Voltage Directive 2006/95/EC

Machines powered by human effort are not specifically excluded, nor are medical devices – but the latter are already covered by the Medical Devices Directive 93/42/EEC.

3) Partly Completed Machinery

Directive 2006/42 EC makes provisions for partially completed machinery in a procedure that is outlined in Article 13

“Procedure for partly completed machinery

1. The manufacturer of partly completed machinery or his authorized representative shall, before placing it on the market, ensure that:
 - (a) the relevant technical documentation described in Annex VII, part B is prepared;
 - (b) assembly instructions described in Annex VI are prepared;
 - (c) a declaration of incorporation described in Annex II, part 1, Section B has been drawn up.
2. The assembly instructions and the declaration of incorporation shall accompany the partly completed machinery until it is incorporated into the final machinery and shall then form part of the technical file for that machinery.”

ANNEX VI also makes a requirement for assembly instructions for partly completed machinery.

“The assembly instructions for partly completed machinery must contain a description of the conditions which must be met with a view to correct incorporation in the final machinery, so as not to compromise safety and health.

The assembly instructions must be written in an official Community language acceptable to the manufacturer of the machinery in which the partly completed machinery will be assembled, or to his authorized representative.

Risk assessment documentation should be included in the technical file.

Declaration of incorporation and assembly instructions for partly completed machinery incorporated into machinery are now required.”

4) Radiation & Hazardous Substances

In the Directive, the sections governing the risk to operators from both ionizing and non-ionizing radiation, as well as hazardous substances are significantly clearer and more extensive than those of its predecessor. They read:

“1.5.10 Radiation

Undesirable radiation emissions from the machinery must be eliminated or be reduced to levels that do not have adverse effects on persons.

Any functional ionizing radiation emissions must be limited to the lowest level which is sufficient for the proper functioning of the machinery during setting, operation and cleaning. Where a risk exists, the necessary protective measures must be taken.

Any functional non-ionizing radiation emissions during setting, operation and cleaning must be limited to levels that do not have adverse effects on persons.

1.5.13 Emissions of Hazardous materials and substances

Machinery must be designed and constructed in such a way that risks of inhalation, ingestion, contact with the skin, eyes and mucous membranes and penetration through the skin of hazardous materials and substances which it produces can be avoided.

Where a hazard cannot be eliminated, the machinery must be so equipped that hazardous materials and substances can be contained, evacuated, precipitated by water spraying, filtered or treated by another equally effective method.

Where the process is not totally enclosed during normal operation of the machinery, the devices for containment and/or evacuation must be situated in such a way as to have the maximum effect.”

5) Notified Bodies

Article 14 on the role of Notified Bodies defines the roles and responsibilities that a Notified Body plays in the conformity and surveillance process. One particular section of importance reads:

2. The Member States shall ensure that the notified bodies are monitored regularly to check that they comply at all times with the criteria set out in Annex XI. The notified body shall provide all relevant information on request, including budgetary documents, to enable the Member States to ensure that the requirements of Annex XI are met.*

Notified Bodies for the Machinery Directive will now explicitly be monitored by the member states for impartiality, competence, processes and anti-bribery under the Directive.

Also new, is the provision for the appointing authorities of Notified Bodies, to exchange information. This will enable them to bring greater continuity to the process of selection and appointment, and contribute to the uniform application of this Directive across the community.

6) Surveillance & Enforcement

The combined clauses of Articles 4, 14, and 19 strengthen the surveillance and enforcement of the Directive for machines and incomplete machines. They also facilitate the sharing of information between member states, to make the process more rigorous across the EU.

Article 4 leads with:

1. Member States shall take all appropriate measures to ensure that machinery may be placed on the market and/or put into service only if it satisfies the relevant provisions of this Directive and does not endanger the health and safety of persons and, where appropriate, domestic animals or property, when properly installed and maintained and used for its intended purpose or under conditions which can reasonably be foreseen.
2. Member States shall take all appropriate measures to ensure that partly completed machinery can be placed on the market only if it satisfies the relevant provisions of this Directive.
3. Member States shall institute or appoint the competent authorities to monitor the conformity of machinery and partly completed machinery with the provisions set out in paragraphs 1 and 2.
4. Member States shall define the tasks, organization and powers of the competent authorities referred to in paragraph 3 and shall notify the Commission and other Member States thereof and also of any subsequent amendment”

Paragraph 6 of Article 14 states:

“6. If a notified body finds that relevant requirements of this Directive have not been met or are no longer met by the manufacturer or that an EC type-examination certificate or the approval of a quality assurance system should not have been issued, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate or the approval issued or place restrictions on it, giving detailed reasons, unless compliance with such requirements is ensured by the implementation of appropriate corrective measures by the manufacturer.

In the event of suspension or withdrawal of the certificate or the approval or of any restriction placed on it, or in cases where intervention by the competent authority may prove necessary, the notified body shall inform the competent authority pursuant to Article 4. The Member State shall inform the other Member States and the Commission without delay. An appeal procedure shall be available.*

Article 19 adds:

“Cooperation between Member States

1. Member States shall take the appropriate measures to ensure that the competent authorities referred to in Article 4(3) cooperate with each other and with the Commission and transmit to each other the information necessary to enable this Directive to be applied uniformly.

2. The Commission shall provide for the organization of an exchange of experience between the competent authorities responsible for market surveillance in order to coordinate the uniform application of this Directive.”

7) ‘Under conditions that can reasonably be foreseen’

Previously, the Directive’s emphasis of the safety of machinery was within the context of its intended use or purpose. However, in the newer version of the Directive it is interesting to note that ‘foreseeable’ other use (or misuse) must also be taken into consideration. Paragraph 12 of Directive 2006/42 EC states:

“The putting into service of machinery within the meaning of the Directive can relate only to the use of the machinery itself for its intended purpose or for a purpose which be reasonably foreseen.”

This concept appears several times during the text of the Directive – most notably in Annex 1 in clause 1.1.2. c)

c) When designing and constructing machinery and when drafting the instructions, the manufacturer or his authorized representative must envisage not only the intended use of the machinery but also any reasonably foreseeable misuse thereof.

The machinery must be designed and constructed in such a way as to prevent abnormal use, if such use would engender a risk. Where appropriate, the instructions must draw the user's attention to ways — which experience has shown might occur — in which the machinery should not be used.

Perhaps this can best be addressed by manufacturers and facility staff via a risk assessment, where 'foreseen' alternative uses for a machine can be highlighted and mitigated as necessary.

Similarly, manufacturers must also take into account that some types of equipment will be utilized by non-professional operators, and so designers and builders will need to be aware of that when they create the equipment. This should encourage inherently safer and more intuitive design.

8) Annex IV

Annex IV of the Machinery Directive defines categories of machinery to which the Conformity Assessment routes outlined in Article 12 refer, creating 3 categories of equipment, Non-Annex IV Machinery, Annex IV Machinery and Safety Components and Incomplete Machinery – the latter we have already discussed.

The requirements for Non Annex IV Machinery are:

- Self declaration
- Technical File
- That manufacturer takes all necessary measures to ensure that the manufacturing process ensures compliance with the Technical File and the Directive

The requirements for Annex IV Machinery using Harmonized Standards are:

- Machine manufactured in accordance with Harmonized Standards AND, these standards meet the EHSR's
- While the onus is on the manufacturers to ensure 'state of the art' they must choose one of the following approaches:
 - Internal checks as Annex VIII
 - EC Type Examination by Notified Body and Internal checks as Annex VIII
 - Full Quality Assurance by Notified Body to Annex X
 - Onus on manufacturer to ensure 'State of the Art'

The requirements for Annex IV Machinery using Non-Harmonized Standards are:

- Machine manufactured in accordance with Non-Harmonized Standards or Harmonized standards only partially applied, or if Harmonized standards do not exist or these standards meet do not address all the EHSR's
- While the onus is on the manufacturers to ensure 'state of the art' they must choose one of the following approaches:
 - EC Type Examination by Notified Body and Internal checks as Annex VIII
 - Full Quality Assurance by Notified Body to Annex X

Full Quality Assurance to Annex X by Notified Body is a robust solution

9) Lifting Equipment

The Directive's requirements for lifting equipment and lifting accessories are also clearer and more extensive than those of the prior Directive. Within Article 24, Lifts Directive 95/16/EC was modified to align with the scope of 2006/42/EC as the Machinery Directive covers this type of equipment. Some types of lifting equipment are still excluded - this is detailed in Article 24, paragraph 3:

- lifting appliances whose speed is not greater than 0,15 m/s,
- construction site hoists,
- cableways, including funicular railways,
- lifts specially designed and constructed for military or police purposes,
- lifting appliances from which work can be carried out,
- mine winding gear,
- lifting appliances intended for lifting performers during artistic performances,
- lifting appliances fitted in means of transport,
- lifting appliances connected to machinery and intended exclusively for access to workstations including maintenance and inspection points on the machinery,
- rack and pinion trains,
- escalators and mechanical walkways

Later in Annex 4.3.3 the particular requirements for lifting equipment that are included in the scope of the Directive are detailed. The old version of the Directive required that nominal loads be marked on machinery. Now this must be the maximum load.

For lifting machinery in particular, a new clause d) has also been added to the instruction content requirements –

“4.4.2. Lifting machinery

Lifting machinery must be accompanied by instructions containing information on:

d) where appropriate, a test report detailing the static and dynamic tests carried out by or for the manufacturer or his authorized representative”

10) Safe ‘Transportation’ not just ‘handling’.

Annex 1.1.5 makes reference to how ‘transportation’ of the machinery, not just ‘handling’ should be taken into consideration. This explicitly extends the protection of the Directive to those involved in the freight and logistical transfer of equipment, as well as those who might handle it on site. Specifically:

“During the transportation of the machinery and/or its component parts, there must be no possibility of sudden movements or of hazards due to instability as long as the machinery and/or its component parts are handled in accordance with the instructions.

Where the weight, size or shape of machinery or its various component parts prevents them from being moved by hand, the machinery or each component part must:

- either be fitted with attachments for lifting gear, or
- be designed so that it can be fitted with such attachments, or
- be shaped in such a way that standard lifting gear can easily be attached.”

11) Requirements on Ergonomics, Operating Positions and Seating

These were less explicit in the previous version of the Directive, but they now have a greater alignment with health and safety best practices:

“1.1.6. Ergonomics

Under the intended conditions of use, the discomfort, fatigue and physical and psychological stress faced by the operator must be reduced to the minimum possible, taking into account ergonomic principles such as:

- allowing for the variability of the operator's physical dimensions, strength and stamina,
- providing enough space for movements of the parts of the operator's body,
- avoiding a machine-determined work rate,
- avoiding monitoring that requires lengthy concentration,
- adapting the man/machinery interface to the foreseeable characteristics of the operators.

1.1.7. Operating positions

The operating position must be designed and constructed in such a way as to avoid any risk due to exhaust gases and/or lack of oxygen.

If the machinery is intended to be used in a hazardous environment presenting risks to the health and safety of the operator, or if the machinery itself gives rise

to a hazardous environment, adequate means must be provided to ensure that the operator has good working conditions and is protected against any foreseeable hazards.

Where appropriate, the operating position must be fitted with an adequate cabin that is designed, constructed and/or equipped to fulfil the above requirements. The exit must allow rapid evacuation. Moreover, when applicable, an emergency exit must be provided in a direction which is different from the usual exit.

1.1.8. Seating

Where appropriate and where the working conditions so permit, work stations constituting an integral part of the machinery must be designed for the installation of seats.

If the operator is intended to sit during operation and the operating position is an integral part of the machinery, the seat must be provided with the machinery. The operator's seat must enable him to maintain a stable position. Furthermore, the seat and its distance from the control devices must be capable of being adapted to the operator.

If the machinery is subject to vibrations, the seat must be designed and constructed in such a way as to reduce the vibrations transmitted to the operator at the lowest level that is reasonably possible. The seat mountings must withstand all stresses to which they can be subjected. Where there is no floor beneath the feet of the operator, footrests covered with a slip-resistant material must be provided.”

12) Instruction Documentation

The requirements for instructions for assembly demand much more detail than previously.

“1.7.4 All machinery must be accompanied by instructions in the official Community language or languages of the Member State in which it is placed on the market and/or put into service. The instructions accompanying the machinery must be either ‘Original instructions’ or a ‘Translation of the original instructions’, in which case the translation must be accompanied by the original instructions.

By way of exception, the maintenance instructions intended for use by specialized personnel mandated by the manufacturer or his authorized representative may be supplied in only one Community language which the specialized personnel understand.”

Interestingly, the concept of ‘under conditions that can be reasonably foreseen’ appears again in the instructions annex, requiring the manufacturer should take any foreseeable

misuse into consideration when drafting their instructions, despite the fact that it is still misuse and could be hazardous.

“1.74.1 General principles for the drafting of instructions

(c) The contents of the instructions must cover not only the intended use of the machinery but also take into account any reasonably foreseeable misuse thereof.”

The description of what must be included in the instructions reads:

“1.7.4.2. Contents of the instructions

Each instruction manual must contain, where applicable, at least the following information:

- (a) the business name and full address of the manufacturer and of his authorized representative;
- (b) the designation of the machinery as marked on the machinery itself, except for the serial number (see section 1.7.3);
- (c) the EC declaration of conformity, or a document setting out the contents of the EC declaration of conformity, showing the particulars of the machinery, not necessarily including the serial number and the signature;
- (d) a general description of the machinery;
- (e) the drawings, diagrams, descriptions and explanations necessary for the use, maintenance and repair of the machinery and for checking its correct functioning;
- (f) a description of the workstation(s) likely to be occupied by operators;
- (g) a description of the intended use of the machinery;
- (h) warnings concerning ways in which the machinery must not be used that experience has shown might occur;
- (i) assembly, installation and connection instructions, including drawings, diagrams and the means of attachment and the designation of the chassis or installation on which the machinery is to be mounted;
- (j) instructions relating to installation and assembly for reducing noise or vibration;

- (k) instructions for the putting into service and use of the machinery and, if necessary, instructions for the training of operators;
- (l) information about the residual risks that remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted;
- (m) instructions on the protective measures to be taken by the user, including, where appropriate, the personal protective equipment to be provided;
- (n) the essential characteristics of tools which may be fitted to the machinery;
- (o) the conditions in which the machinery meets the requirement of stability during use, transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns;
- (p) instructions with a view to ensuring that transport, handling and storage operations can be made safely, giving the mass of the machinery and of its various parts where these are regularly to be transported separately;
- (q) the operating method to be followed in the event of accident or breakdown; if a blockage is likely to occur, the operating method to be followed so as to enable the equipment to be safely unblocked;
- (r) the description of the adjustment and maintenance operations that should be carried out by the user and the preventive maintenance measures that should be observed;
- (s) instructions designed to enable adjustment and maintenance to be carried out safely, including the protective measures that should be taken during these operations;
- (t) the specifications of the spare parts to be used, when these affect the health and safety of operators;
- (u) the following information on airborne noise emissions:
 - the A-weighted emission sound pressure level at workstations, where this exceeds 70 dB(A); where this level does not exceed 70 dB(A), this fact must be indicated,
 - the peak C-weighted instantaneous sound pressure value at workstations, where this exceeds 63 Pa (130 dB in relation to 20 μ Pa),
 - the A-weighted sound power level emitted by the machinery, where the A-weighted emission sound pressure level at workstations exceeds 80 dB(A). These values must be either those actually measured for the

In the case of very large machinery, instead of the A-weighted sound power level, the A-weighted emission sound pressure levels at specified positions around the machinery may be indicated.

Where the harmonized standards are not applied, sound levels must be measured using the most appropriate method for the machinery. Whenever sound emission values are indicated, the uncertainties surrounding these values must be specified. The operating conditions of the machinery during measurement and the measuring methods used must be described.

Where the workstation(s) are undefined or cannot be defined, A-weighted sound pressure levels must be measured at a distance of 1 meter from the surface of the machinery, and at a height of 1.6 meters from the floor or access platform. The position and value of the maximum sound pressure must be indicated.

Where specific Community Directives lay down other requirements for the measurement of sound pressure levels or sound power levels, those Directives must be applied and the corresponding provisions of this section shall not apply;

- (v) where machinery is likely to emit non-ionizing radiation which may cause harm to persons, in particular persons with active or non-active implantable medical devices, information concerning the radiation emitted for the operator and exposed persons”

13) Symbols & Pictograms

Related to the specific requirements for detailed machine instructions is the new section in Annex 1 on the use of symbols and pictograms in information and warnings. With the increasing migration of workers between member states, local languages may not necessarily be understood by machine operators, so the Directive makes provision for non-textual communication on the machinery so risks and warnings can be easily understood by all.

1.7.1 Information and warnings on the machinery

Information and warnings on the machinery should preferably be provided in the form of readily understandable symbols or pictograms. Any written or verbal information and warnings must be expressed in an official Community language or languages, which may be determined in accordance with the Treaty by the Member State in which the machinery is placed on the market and/or put into service and may be accompanied, on request, by versions in any other official Community language or languages understood by the operators.

Who is affected by this Directive?

- Manufacturers
- Machine Builders
- Manufacturers performing final assembly and CE Marking of machinery
- Agents and representatives placing imported machinery within the EU
- Manufacturers of special purpose tools, rigs and skids

Complications

- No list of harmonized standards has yet been published
- EN954 (Safety of Machinery, Safety related parts of control systems) has a date of Withdrawal of November 2009
- Introduction of ISO EN 13489

Conformity Assessment

The first task is to conduct a Gap Analysis between the old and new version of the Directive:

- What standards are you using now?
- Are they still up to date?
- Do transposed harmonized standards exist?
- What is the current ‘State of the Art’
- Does a risk assessment exist for the machine?

If all of these are up to date, then only a Declaration of Conformity change is required

- Self Declaration (for certain categories)
- Third Party Certification and Role of Notified Body

Conformity Assessment – Requirements

Paragraph 20 of the Directive states:

“Manufacturers should retain full responsibility for certifying the conformity of their machinery to the provisions of this Directive. Nevertheless, for certain types of machinery having a higher risk factor, a stricter certification procedure is desirable.”

Paragraph 23 additionally states:

“The manufacturers or his authorized representative should also ensure that a risk assessment is carried out for the machinery which he wishes to place on the market. For this purpose, he should determine which are the essential health and safety requirements applicable to his machinery and in respect of which he must take measures”

According to the conformity assessment process, the first thing a manufacturer should do is a risk assessment on the proposed product. Annex 1 helpfully states what this should include:

“1. The manufacturer of machinery or his authorized representative must ensure that a risk assessment is carried out in order to determine the health and safety requirements which apply to the machinery. The machinery must then be designed and constructed taking into account the results of the risk assessment.

By the iterative process of risk assessment and risk reduction referred to above, the manufacturer or his authorized representative shall:

- 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 its 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).”

Then a manufacturer should review all the Directives that are applicable to their products – not just the Machinery Directive. If they need guidance on which Directives these are, their test and certification partner will be happy to identify them. These are likely to include the ATEX Directive, EMC Directive, the Energy Related Products Directive, the Pressure Equipment Directive and the Gas Appliances Directive.

Once the correct Directives have been identified and the design team has used the guidance of the Directive to design the machine for maximum compliance, the

applicable harmonized Standards governing that machine should be applied to the test process. Again, these can be identified by a national Standards making body (from where the Standards can be purchased), or from a test and certification partner.

Once the product has been tested to confirm compliance, then a test report and a Technical File (including the risk assessment, test reports etc) and a manufacturers 'Declaration of Conformity' for the machine needs to be generated.

Then CE Marking can be applied to the machine and it can be shipped with the declaration and the instructions for assembly and use.

Requirements: The Technical File

The technical file is a mandatory requirement and should include:

- Equipment's general description
- Drawings/Service manual
- Information on standards applied
- Test reports / Photos
- Rationale for compliance including reference to Harmonized or other Technical Standards
- Copy of Declaration of Conformity
- Changes control procedure
- ISO 9001 – Approval Related Procedures
- Any other safety related documents/procedures

The file does not have to be held in the EU but must be capable of 'being assembled and made available' by the person designated on the EC D of C

Requirements: The EC Declaration of Conformity

The declaration of conformity must identify:

- Manufacturer
- Responsible person (by name and job title)
- Exact product type/name
- Year of affixation of CE Marking
- List of applicable standards
- Place and Date

It is the written declaration by the manufacturer or his authorized representative that:

The equipment to which the CE Mark has been affixed, complies with the Machinery Directive.

A flow chart illustrating the Conformity Assessment Routes can be found in Appendix 1 of this document.

Conclusion

Machinery Directive 2006/42/EC is as much about improving the design of a Machine, as it is about manufacturing it, building it correctly and using it safely. Annex 1, paragraph 1 sums up the purpose of the entire Directive succinctly.

“1.1.2. Principles of safety integration

(a) Machinery must be designed and constructed so that it is fitted for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen but also taking into account any reasonably foreseeable misuse thereof.

The aim of measures taken must be to eliminate any risk throughout the foreseeable lifetime of the machinery including the phases of transport, assembly, dismantling, disabling and scrapping.”

Help is always available from your partner test and certification body - who will be happy to go through the requirements, processes and options with you. Their experts can also conduct a gap analysis to identify your current areas of conformity risk and give you advice on any additional testing, paperwork updates or quality assurance you might need.

To review a copy of Machinery Directive (2006/42/EC) for yourself, visit the Europa Website at: http://ec.europa.eu/enterprise/mechan_equipment/machinery/revdir.htm

For more information on specific testing and certification information, please contact Intertek at 1-800-WORLDCON, email icenter@intertek.com, or visit our website at www.intertek-etlsemko.com.

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Appendix 1:
Conformity Assessment Routes

Machinery Directive 2006/42 Process Flow Chart

