

# Cracks Emerge

**Pete Hall** and **Keith Plumb** discuss the confusion over CE marking, and the implications for those designing and building plants

**A**S many readers will know, European single market legislation requires some process equipment to be CE marked to demonstrate compliance with relevant EU directives. However, achieving compliance is not always straightforward. Recent personal correspondence with the UK and Irish market surveillance authorities (responsible for policing CE marking) suggests that their approach is at odds with custom and practice undertaken in the process industries. This difference of approach has recently caused conflict between manufacturers and users – resulting in project delays.

Managing the documentation required to demonstrate compliance is not simple. A few years ago this caused a problem on a major pharmaceutical project where the collection, review and filing of the documentation was poorly managed and unacceptable to the market surveillance authorities. The facility could not be brought on line until this had been resolved – causing a delay of several months, loss of revenue and an erosion of manufacturing time within the precious patent protection period, which can be very costly for pharmaceutical companies.

The EU's previous Machinery Directive was difficult to understand, so manufacturers interpreted it as best they could. Ironically the updated version of the directive is easier to interpret, making it more obvious if previous interpretation was wrong. Also the relevant EU directorate is under pressure from some parts of the European machinery manufacturing industry to tighten up market surveillance (see box). This means that there is now an increased probability that equipment and/or documentation will be identified as non-compliant.

## why CE marking?

The driving force behind the directives is the single European market. The purpose of CE marking is for the manufacturer to indicate that essential health and safety requirements (EHSRs) accepted across the EU and EFTA (European Free Trade Area) have been met. Once legitimately CE marked, it is illegal for a member state to refuse entry to the relevant item on safety grounds.

Prior to the introduction of CE marking, many member states insisted that equipment used in their country was designed to their national standards and approved by national approvals bodies.

## relevant directives

For chemical engineers the most pertinent CE marking directives are the ATEX (Explosive Atmospheres), Machinery, and Pressure Equipment directives since these are relevant to the specifications and data sheets at the design stage and will inevitably cause the most trouble at the equipment acceptance stage due to the complex nature of the directives.

**European standards organisations develop harmonised standards to provide recommended methods to make equipment meet the EHSRs. This process is not complete and there are many standards that have not been harmonised.**

## us or them?

The requirement for review by a notified body frequently causes confusion because the requirements differ depending on the risks associated with the equipment. Furthermore, the lowest category in the Pressure Equipment Directive (PED) is Category I, whereas this is the highest category in the ATEX Directive.

For most directives, the lowest risk equipment is covered by self-assessment. Self-assessment basically means that the manufacturer carries out their own risk and conformity assessment against the EHSRs and declares that their equipment complies with these requirements.

When the risks are higher, notified bodies are required. These are corporate entities established and registered within the EU that offer accredited opinions on the compliance of equipment with the EHSRs.

Recently the EU has become concerned about the quality of notified bodies. A recent incident in Ireland concerning the CE marking of some construction machinery indicated how a notified body in another country could provide fraudulent documents to an Irish company without the market surveillance authority in Ireland being able to take effective action to prosecute the notified body. Urgent action is required by the EU to ensure that equipment users can be confident of the integrity of notified bodies.

## 'placed on the market' and 'put into service'

There are two key milestones in the equipment delivery process. An item is 'placed on the market' when it is sold or made available for sale to an entity established in

the EU whether or not that entity is the end user.

An item is 'put into service' when it starts being used for its intended purpose. This means that the testing must be carried out before equipment is put into service and may be carried out at a factory or on site.

Equipment subject to CE marking must be CE marked before it is put into service even if it was not placed on the market. For example, if a user designs their own piece of equipment, they must still have it CE-marked before putting it into use.

## harmonised standards

European standards organisations develop harmonised standards that recommend methods for making equipment meet the EHSRs. This process is not complete and there are many standards that have not been harmonised.

The harmonised standards make it simpler to carry out self-assessment. However, the use of harmonised standards are not required as long as EHSRs are met.

## market surveillance

Policing the directives is the responsibility of the market surveillance authorities in each member state. These have a designated authority responsible for surveillance of each directive. Since the CE marking directives relate to the operation of the single market, the market surveillance authority in the UK (for directives relevant to the process industry) is the Department of Business, Innovation and Skills. See box for more details on market surveillance.

## ATEX directive

The ATEX Directive has a number of issues for process engineers, particularly since the directive includes sources of ignition from non-electrical equipment that are far more prevalent than those for electrical equipment. Secondly, the definition of an explosive atmosphere is very restricted: *"Mixture with air, under atmospheric conditions, of flammable substances in the form of gases, vapours, mists or dusts in which, after ignition has occurred, combustion spreads to the entire unburned mixture."*

ATEX guidance defines atmospheric conditions as 21% oxygen, -20 to +60°C and 0.8–1.1 bar. However, many processes operate outside this range and are therefore excluded from the ATEX Directive. This includes those operating at higher pressures and temperatures where the explosion hazards are greater. On the other hand, these processes are covered by the ESHRs of the PED and Machinery Directive that do not contain the pressure and temperature restrictions.

In general, purchasing ATEX electrical equipment poses few problems if one specifies the equipment correctly. This is because design of this equipment is well established. Non-electrical equipment is more complex because there are many more potential sources of ignition (eg friction and mechanical sparks) and the protection methods for this equipment are less well established. The real problem for process engineers is working out how to handle the major risks that fall outside the ATEX directive.

## pressure equipment directive (PED)

The requirements for categorising equipment for the PED are covered by Annex II of the directive. The process engineer must specify the design pressure, the size and the fluid contained for each piece of equipment so that the equipment designer can select the appropriate category.

The PED's approach to assemblies adds complexity. Assemblies that are supplied by a manufacturer to a user need to be CE marked, whereas installations assembled on-site under the user's responsibility need not be CE marked. Assemblies are subject to a global conformity assessment procedure to check that the EHSRs relating to assemblies have been met. Installations are regulated by national work equipment regulations. It should be noted that the Machinery Directive treats assemblies in a different way.

## machinery directive

This directive is complex and the official EU guidance is 430 pages long. Despite its length, the EU guidance still needs extensive interpretation since none of the examples directly apply to the process industries, although the directive's requirements most certainly do.

A major problem is that the definition of machinery in the directive is not clear. The directive defines it as: *"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."*

Custom and practice within the process industries has been to designate any assembly that includes rotating equipment as machinery. However, it appears that the market surveillance authorities among others (including the HSE in the UK) do not have the same view. The authors are currently trying to understand why this has occurred but the best indication at the time of writing was that they do not consider equipment connected together with pipework as linked. This seems very strange to a chemical engineer.

## CE marking directives relevant to the process industries

**ATEX Directive 94/9/EC**

**Construction Products Regulation 305/2011**

**Electro-magnetic Compatibility (EMC) Directive 2004/108/EC**

**Lifts Safety Directive 95/16/EC**

**Low Voltage Directive 2006/95/EC**

**Machinery Directive 2006/42/EC**

**Pressure Equipment Directive (PED) 97/23/EC**

**Radio and Telecommunications Terminal Equipment (RTTE) Directive 1999/5/EC**

**Simple Pressure Vessels Directive 2009/105/EC**

## Market surveillance authorities

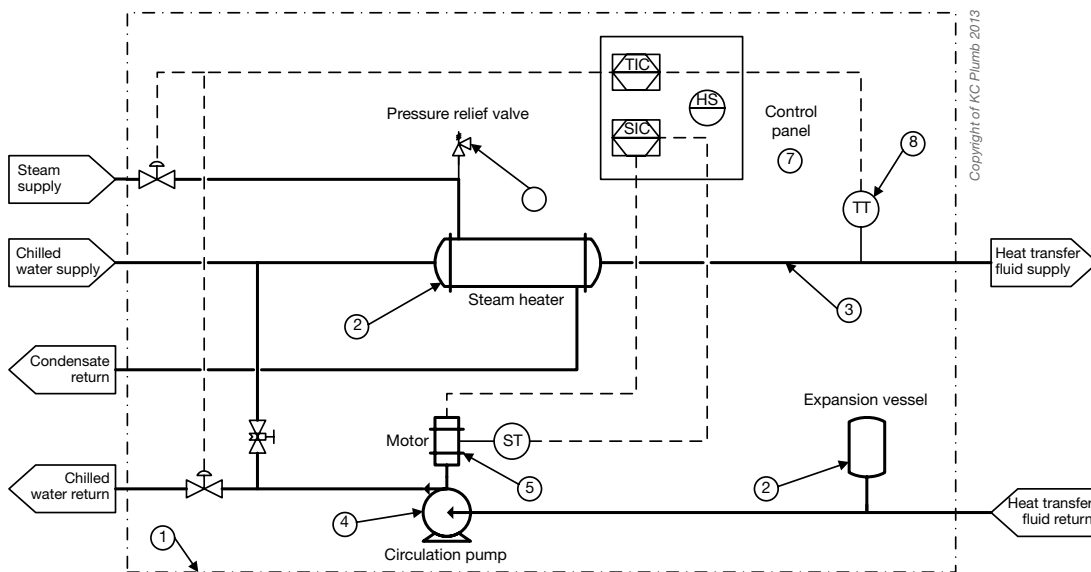
**The EU webpage on market surveillance ([bit.ly/12L94vJ](http://bit.ly/12L94vJ)) says:**

*"The objective of market surveillance is to ensure that products placed on the market do not endanger health, safety or any other aspect of protection of public interests. In practice, market surveillance includes any necessary action (eg bans, withdrawals, recalls) to stop the circulation of products that do not comply with all the requirements set out in the relevant EU harmonisation legislation, to bring the products into compliance and to apply sanctions. Market surveillance is vital to the smooth functioning of the single market. It is essential in protecting European consumers and workers against risks presented by non-compliant products. In addition, market surveillance helps to protect responsible businesses from unfair competition by unscrupulous economic operators who ignore the rules or cut corners."*

This webpage also details a new package of measures to strengthen market surveillance.

**Carrying out an audit as early as possible in the purchasing process will ensure that you avoid expensive delays caused by CE marking problems.**

## Heat transfer skid – simplified diagram to show CE marking requirements



- Whole skid** – machinery directive and EMC directive. PED is also required for items 2 (steam heater and expansion vessel) and/or 3 (pipe work) if they are higher than Category I. Component parts 'placed on the market' separately can be presumed to be compliant if they are properly marked by their manufacturers to the following directives.
- Pump** – Machinery Directive.
- Motor** – Low Voltage directives and EMC Directive.
- Pressure relief valve** – takes the highest PED category of the equipment it protects or category IV if supplied for general purpose.
- Control system** – Low Voltage Directive of greater than 50 volts AC or 75 volts DC. Also PED if pressurised to more than 0.5 bar g and is higher than Category I.

### Harmonised standards

There is an EU webpage for each directive and a simple internet search will find the relevant pages.

An index to these can be found at: [bit.ly/11QsAX4](http://bit.ly/11QsAX4)

The webpage says the following about harmonised standards:

*"Compliance with harmonised standards provides a presumption of conformity with the corresponding requirements of harmonisation legislation. Manufacturers, other economic operators or conformity assessment bodies can use harmonised standards to demonstrate that products, services or processes comply with relevant EU legislation."*

To create the capacity to confer this presumption of conformity, the references of harmonised standards must be published in the Official Journal of the European Union.

The use of these standards remains voluntary. Manufacturers, other economic operators or conformity assessment bodies are free to choose any other technical solution that provides compliance with the mandatory legal requirements."

The Machinery Directive includes the concept of "partly completed machinery", where the manufacturer supplies an assembly that is only part of the final 'machinery'. If partly-completed machinery is placed on the market it must be accompanied with a declaration of incorporation that states that the partly-completed machinery does not conform with all the applicable EHSRs, and the conformity assessment must be completed when it is incorporated into the finished machinery prior to issuing the EC declaration of conformity and putting into service.

The third problem with the Machinery Directive is that it states that where there is no other manufacturer of the finished machinery, the user shall be considered the manufacturer. This means that the user is required to CE mark machinery made for their own use. This can occur when partly-completed machinery is purchased or because the Machinery Directive requires "assemblies of machinery" to be CE marked (two or more items of machinery or partly-completed machinery that are interlinked such as process plants and production lines). This requires the user to carry out CE marking even when the machinery will never be placed on the market, and is contrary to the approach in the PED.

machine is in PED Category I, it can then be covered by the Machinery Directive. This is because the pressure containment EHSRs of the Machinery Directive are considered adequate for the low hazards of Category I equipment.

Electric motors could be considered to be machinery but have previously been and still are covered by the LVD. However, for other types of electrical machinery, electrical risks are covered by the Machinery Directive and the LVD should not be listed on the EC Declaration of Conformity listing the Machinery Directive.

### are you compliant?

Are you confident that the equipment that you are purchasing is compliant? Carrying out an audit as early as possible in the purchasing process will ensure that you avoid expensive delays caused by CE marking problems. [tce](http://tce)

**Pete Hall** ([pete.hall@conformance.co.uk](mailto:pete.hall@conformance.co.uk)) is a CE marking consultant at Conformance; **Keith Plumb** ([keith.plumb@integpharma.com](mailto:keith.plumb@integpharma.com)) is a process and equipment consultant at Integral Pharma Services

### further reading

- ATEX Guidelines, 4<sup>th</sup> Edition Sep 2012 [bit.ly/1ddQWQo](http://bit.ly/1ddQWQo)
- Guidelines related to the Pressure Equipment Directive 97/23/EC (PED) [bit.ly/1cS2AOh](http://bit.ly/1cS2AOh)
- Guide to the application of the Machinery Directive 2006/42/EC [bit.ly/9GEoo3](http://bit.ly/9GEoo3)
- European Commission – Enterprise and Industry – harmonised standards webpage [bit.ly/11QsAX4](http://bit.ly/11QsAX4)

### Chemical Engineering Matters

The topics discussed in this article refer to the following lines on the vistas of IChemE's technical strategy document *Chemical Engineering Matters*:



Health and wellbeing  
Lines 8–9, 11–14

Visit [www.icheme.org/vistas1](http://www.icheme.org/vistas1) to discover where this article and your own activities fit into the myriad of grand challenges facing chemical engineers

### the crossover

As expected there is some overlap between the directives and equipment can be covered by two or more directives. Two significant overlaps are between the Machinery Directive and the PED and between the Machinery Directive and the Low Voltage Directive (LVD).

Where pressure equipment within a