TECH TALK 59

EUROPEAN COMMITTEE FOR STANDARDISATION

BACKGROUND

The CEN was founded in 1961 by the national standards bodies in the European Economic Community and EFTA (European Fair Trade Association) countries.

These countries currently include: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

WHAT DOES THE CEN DO ?

The CEN, in conjunction with worldwide bodies contribute to the objectives of the European Union (EU) through voluntary harmonisation of technical standards and regulations.

The CEN also works closely with the European Committee for Electrotechnical Standardisation (CENELEC), the European Telecommunications Standards Institute (ETSI) and the International Organisation for Standardisation (ISO).

WHAT ARE HARMONISED STANDARDS ?

Harmonised standards are essentially limited to safety of workers and consumers, interoperability of products, environmental protection and the sharing of research and development programmes. These standards also assist in the removing of technical barriers to trade.

HOW THESE STANDARDS EFFECT AUSTRALIAN EXPORTERS

In order for an Australian exporter to sell the majority of its products within the European Union their product must bear the CE mark. As the EU is gradually increasing in size this market segment is becoming larger and larger and therefore more lucrative.

Products that are covered by the "New approach directives" must bear the CE marking. This CE mark on a product is a manufacturer's declaration that the product complies with the essential standards of the relevant CEN health, safety and environmental legislation's. The symbol CE – an abbreviation of the French phrase "Conformite Europeene" indicates to government officials that the product may be legally sold on the market in their country and ensures the free movement of the product within the EU.

One of the most important aspects of the CE marking regulation is that producers and exporters from non-European countries need an authorised European agent or distributor when they want to sell their products within the EU. Only when a product conforms to the relevant standards and there is an authorised distributor, then the product may be sold within the EU.

Products that do not carry the CE marking and are not in compliance with the directives may be restricted, prohibited from sale or forced to withdraw from the European market. Manufacturers, authorised agents or anyone responsible for placing such products on the European market can be held personally liable for damages or injury.

The CE Mark

WHICH PRODUCT GROUPS MUST BE MARKED

There are 23 product groups or "New approach directives" for which CE marking is mandatory, they are as follows

- Low Voltage
- Simple Pressure Vessels
- Safety of toys
- Construction products
- Electromagnetic compatibility (EMC)
- Safety of machines
- Personal protection equipment (PPE)
- Measuring Equipment
- Active implantable medical devices
- Appliance burning gaseous fuels
- Telecommunications terminal equipment
- New hot water boilers fired with liquid or gaseous fuels
- Explosives for civil uses
- Medical devices
- Equipment and protective systems for explosive atmospheres (ATEX)
- Recreational crafts
- Lifts for persons
- Energy efficient requirements for household appliances
- Pressure equipment
- Air traffic management equipment
- Marine equipment
- Non automatic weighing equipment
- Trans European conventional rail

EVALUATING CE MARKING CONFORMANCE

Does the product fulfill specific CE marking requirements?

Assessment to the requirements, identified by the related Directive, must be conducted before the product is available for use within the EU. This assessment must be documented in a Technical file.

Each product or family of products requires a technical file. This is a compulsory step of the conformity assessment process. This file must contain all relevant technical and user information, risk assessments and manufacturing details. Each technical file supports the declaration of conformity.

A user manual may also be required to obtain conformity assessment. The directives usually have a direct relation to user safety, therefore information provided to a user plays an essential role in the reduction of risks. The user manual must contain all the information required for the correct and safe use of a product and must be printed in the language of the country or countries in which the product is to be sold.

The 3 methods of certification are as follows;

1. Self Certification
   The Manufacturer performs assessment to Harmonized Standards (where they exist) or to other appropriate standards, either where Harmonized standards do not exist or where the Manufacturer selects to use alternative standards for example a British standard.
   The Manufacturer Issues a Declaration of Conformity and places CE Marking on the product.

2. Voluntary Certification
   An EU notified body (e.g. Sira or TRL compliance services) performs assessment to Harmonized Standards (where they exist) or to other appropriate standards, where Harmonized standards do not exist to determine the appropriateness of CE marking. The Manufacturer's Technical file combines with the notified body report and the notified body issue a Certificate and Approval Mark
   The Manufacturer Issues a Declaration of Conformity and places CE Marking on the product.

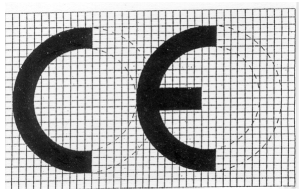
3. Mandatory Certification
   The notified body conducts examinations (to product and/or Quality System) and also performs the assessment to Harmonized standards (where they exist) and Directives applicable to the product. The Technical file, including safety and/or EMC are combined with the notified body report and the notified body Issue the Certificate. The manufacturer issues a Declaration of Conformity to the approval type and places the CE marking on the product.

Note:

Some directives explicitly make use of a quality management system (ISO 9000) as part of the conformity assessment. Only in specific cases this is a requirement to comply with CE marking directives

SPECIFICATIONS FOR THE CE MARKING

Graphically, CE marking takes the following form:



Although CE marking is based on two circles, the “C” and “E” are not formed by perfect semi circles with the top and bottom arms extending one square beyond the semi circles and the middle arm of the E stopping one square short.

The CE marking may be enlarged or reduced as appropriate for reproduction on individual products provided that:

The height of the letters is at least 5 mm (or as specified in the relevant directive), and the proportions of the drawing above are maintained.

The CE marking must be attached to the product or to its data plate. In cases where this is not possible or reasonable due to the nature of the product, it must be printed on the packaging, if any, and on any accompanying documents.

The CE marking must be affixed visibly, legibly and indelibly.

If a notified body in Europe or a designated body in Australia / New Zealand has been involved in conformity assessment procedures during the production stage of manufacture, the CE marking must be followed by the identification number of the body. The European Commission assigns these identification numbers.

DECLARATION OF CONFORMITY

In addition to the Technical file the declaration of conformity must contain the following information

- Name and address of the manufacturer or his authorised distributor established within the EU
- Description of the product
- Reference to the standards or other specifications under which conformity is declared
- Identification of the person empowered to sign on behalf of the manufacturer or his authorised distributor within the EU
- Where required reference to the EC type examination certificate issued by a notified body

A manufacturer or his authorised distributor must keep a copy of the declaration of conformity along with the technical file for at least 10 years from the last date of manufacture.

Liquip’s current certificates can be found on the server at,
\\Server1\liquser\COMMON\Approvals

USEFUL RESOURCES

Standards and Conformance Policy Section
Department of Industry, Science and Tourism
http://www.dist.gov.au

The Delegation of the European Commission to
Australia and New Zealand
http://www.delaus.cec.eu.int

WRITTEN BY TOM 7 Feb 2005. Export Sales Dept, Liquip International Pty Ltd, Sydney.