Know Your Standards

Diversion

I planned to follow the treatment of CISPR 16/EN 55016 with a similar piece on the IEC/EN 61000-4- series of Basic EMC standards, but the Kindly Editor has agreed that it would be timely to deal with the planned changes to the CE Marking, EMC and Low Voltage Directives prompted by the implementation of the New Legislative Framework, even though EU Directives are not standards and that distinction is important.

Note - Some 'Old style' Directives include technical requirements just like those in a standard, but they are still produced by the Commission and not by CEN, CENELEC or ETSI.

There is opportunity here to introduce pages of legalistic prose, but I hope the diversion will be more diverting than that.

New Legislative Framework

We have to start right here, otherwise none of it will make sense. The NLF is said to be about 'improving the free market', and one of its specific objectives is to remove different interpretations of Directives in the Member States. But a second specific objective is to remove different **implementations** of Directives in the Member States, and effectively that addresses the subject of **market surveillance**. It is well-known that some Member States have invested very heavily in this activity, while others, including UK, have not. There is still a difference among the 'have nots'; some, including UK, have procedures that are likely to catch high-volume non-conforming products, while not bothering too much about low-volume stuff, while others simply don't bother at all. Once products come within the EU borders via a 'not bothered' country, they can legally be marketed anywhere until they are proven non-conforming, which can be a very costly and slow process. This has prompted some countries to devise ingenious methods of preventing their marketing. Other Member States don't like this, because such measures could be applied selectively to products originating outside a *state* border, not the EU border; in other words, scuppering the Free Market. Small and medium sized enterprises (SMEs) should no longer be discouraged from export business. A Member State that refuses a product access to its market has to give detailed reasons, making life easier for companies. Market surveillance systems for industrial products will be strengthened, thus improving the credibility of CE marking.

The NLF is implemented with three documents:

Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC

Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93

Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC

Regulations are immediately binding on all Member States: they are not debated in Parliaments. Brussels hath spoken! The Decision does not have quite the same legal force, but it includes mandatory provisions related to CE marking and has a great deal to say about conformity assessment. It also includes an explicit format for a Declaration of Conformity:

EC DECLARATION OF CONFORMITY

1. No … (unique identification of the product):
2. Name and address of the manufacturer or his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer (or installer):
4. Object of the declaration (identification of product allowing traceability. It may include a photograph, where appropriate):
5. The object of the declaration described above is in conformity with the relevant Community harmonisation legislation: . . . . . .
6. References to the relevant harmonised standards used or references to the specifications in relation to which conformity is declared:
7. Where applicable, the notified body ... (name, number) … performed … (description of intervention) … and issued the certificate: …
8. Additional information:

Signed for and on behalf of: ……
(place and date of issue):
(name, function) (signature):

One wonders what the interpretation of 'installer' is in item 3. Is it the fellow who installed my bathroom heater? (;-)

The aim is to strengthen the application and enforcement of internal market legislation and Improve market surveillance rules. There is also seen to be a need to eliminate non-performing conformity-assessment bodies (test houses). T**he meaning of CE marking** needs to be more clearly established and its legal position strengthened, as a trade mark. A common legal framework is said to be needed in the form of **measures for use in future legislation**. One welcome measure is to

establish uniform definitions of some terms which are used with different meanings in current EU documents.

Regulation 765 and Decision 768 are separated for legal reasons, and form a basis for future legislation. There is far more in these documents than I can even summarize in one article. You really DO need to download them and read them. Like the ISO/IEC Directives, they are the rules of the game, and if you want to win often, you need to know the rules. It is important to read not only the body text but also the preamble, introduced by the keyword 'Whereas'. This text often clarifies the purpose and real meaning of the provisions, in particular what they DO NOT mean. For example, 'Whereas 28' of Regulation 764 says:

> It is important for the internal market in goods that the accessibility of national technical rules be ensured, so that enterprises, and in particular SMEs, can gather reliable and precise information concerning the law in force.

There is one country in particular that has traditionally established product acceptability rules that no-one in that country is allowed to mention to outsiders. One wonders if the practice will now cease; that is certainly the intention of the Regulation.

Regulation 765 deals with the accreditation of conformity assessment bodies, the market surveillance of products to ensure that those products fulfil requirements providing a high level of protection of public interests, such as safety, consumer interest and environmental protection. It also sets out the principles of CE marking.

Decision 768 deals with the conformity assessment procedures themselves and has a 40-page series of annexes specifying different procedures that can be selected for application when Directives are prepared.

Effects on Directives

The above document were issued in 2008, and have applied form the beginning of 2010, so of course you have had plenty of time to learn them by heart, but the implications for the Low Voltage and EMC (and eight other) Directives are still not finalized. The introductions to the draft Directive revision documents are virtually identical and cite the problems that need to be addressed:

- the presence of non-conforming products on the market, leading to a certain lack of trust in CE marking;
- competitive disadvantages for economic operators complying with the legislation as opposed to those circumventing the rules;
- unequal treatment in the case of non-compliant products and distortion of competition amongst economic operators due to different enforcement practices;
- differing practices in the designation of conformity assessment bodies by national authorities;
- problems with the quality of certain notified bodies;
- Inconsistencies in legislation applying simultaneously to one product, making it difficult to correctly interpret and apply that legislation.

I think few of us would argue with that.

Changes to Directives

The revision documents include very many purely editorial revisions of references and dates, which somewhat obscure the more important proposed changes. A new Regulation on European Standardisation sets out a horizontal legal framework for European standardisation, so some words are no longer needed in each Directive on this subject.

A new provision specifies the steps to be taken when a non-compliant apparatus is found. The full 'safeguard' procedure – leading to a Decision at Commission level on whether a sanction is justified - is launched only when another Member State objects to a sanction. If there is no disagreement, all Member States must take the same action.

A provision that may prove controversial is that a manufacturer and an importer must put their name **and address** on the product (or on the packaging if that is not possible). Addresses are liable to change very often, so they do not seem to have much value for market surveillance purposes. Importers and distributors are to have virtually the same obligations as manufacturers, including, for importers, providing a name and address. Indeed they may, under some circumstances, be deemed to be manufacturers (e.g. if they apply their own brand name), with respect to ensuring conformity, preservation of documentation, including the Declaration of Conformity, and informing the surveillance authority if they become aware of any violation of the provisions.

Manufacturers, importers and distributors ('economic operators') must on demand disclose the sources of their merchandise and the purchasers of it.

DoCs must be provided in a language acceptable to the Member State in which the product is marketed, and a single DoC is required even if several Directives apply to the product. A colour picture of the product is required if the LVD applies.

Will it work?

There is a 2 year transitional period after adoption of the new Directives (whenever that will be), and by that time at least some Member States may be able to afford the costs associated with these new provisions. Otherwise, nothing much can change.

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