

Using standards under the second edition

Tim Williams
Elmac Services

Outline

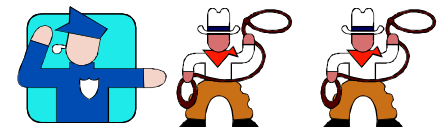
- What happens at present?
 - application and the presumption of conformity
 - what different people understand by “application”
- What might happen in future?
 - The EMC assessment and the risk assessment

The present situation

- 95% use standards route
- present directive says “applying” the right set of standards gives a presumption of conformity
- guidelines say (8.2):
 - The manufacturer is fully responsible; after the EMC analysis referred to in chapter 4 of this guide, he has decided to use the applicable harmonised standards, has **applied** them, prepared an EC declaration of conformity, and affixed the CE marking

The meaning of “applied”

- How people interpret “applying” a standard varies widely:
 - may mean doing all the tests exactly as per the standard in a 3rd party test lab
 - may mean doing all the tests correctly as per the standard but with some deviations or interpretations, in manufacturer’s own test lab
 - may mean doing most but not all of the tests in a “pre-compliance” manner
 - may mean doing few if any tests and just using engineering judgement



DTI: minimising the cost

“Whilst carrying out the tests defined in those standards will give confidence that a product meets the provisions of the Directive, **such tests are not in themselves mandatory**. When self certifying to a standard, a manufacturer is declaring that he believes his product(s) will meet the limits specified in that standard under the prescribed test conditions. Provided he has sufficient confidence that his product will meet those standards, **he need not undertake an extensive or indeed expensive test programme.**”

- DTI document, “*Minimising the cost of meeting the EMC Directive*”, March 1993

The manufacturer's risk assessment

- For every product, the manufacturer must already make a **risk assessment**, with at least the following dimensions:



- what is the likelihood that this product will breach the protection requirements because I haven't tested it comprehensively enough?
- if the protection requirements are breached, what is the risk to my company and/or product?
- will the project fail economically because of over-testing or testing too comprehensively?

What does the 2nd edition say?

- The manufacturer shall perform an EMC assessment of the apparatus, based on the relevant phenomena, with a view to meeting the protection requirements. *The correct application of all the relevant harmonised standards shall be equivalent to the carrying out of the EMC assessment*
 - Annex II (1)
- BUT *Compliance with a "harmonised standard" is not compulsory*
 - Article 6 (1)

The presumption of conformity

- The *compliance* of equipment with the relevant harmonised standards shall raise a presumption of conformity with the essential requirements to which such standards relate. This presumption of conformity is limited to the scope of the harmonised standard(s) applied and the relevant essential requirements covered by such harmonised standard(s).

– Article 6 (2)

- “Compliance with” has replaced “application of”; clarification of presumption of conformity, but many companies still find it difficult to understand the scope and coverage of their chosen standards

What did the European Parliament do?

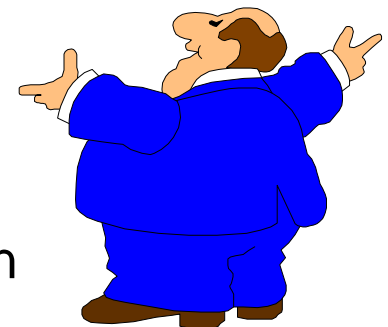
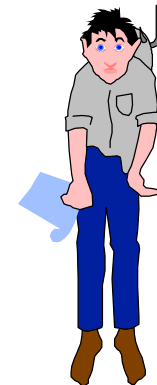
- At first sight, just re-shuffled the words, but in fact it has relaxed the application of standards:
 - the draconian statement in the Commission’s draft Annex V “Compliance with a harmonised standard means conformity with its provisions *and demonstration thereof by the methods the harmonised standard describes or refers to*” **has been diverted to the preamble**
 - the technical documentation requirement of Annex IV, “evidence of compliance with the harmonised standards, if any, applied in full or in part”: **the word “evidence” has replaced the word “report”**



What will change?

The risk assessment must still be made!

- *Nervous* manufacturers:
 - will not do much different from now:
 - will still want maximum assurance, so will continue to do thorough testing, probably at a 3rd party lab
- *Confident* manufacturers:
 - will not do much different from now:
 - will tailor the degree of assurance through testing to their perception of risk
 - may well pay less regard to standards as they gain confidence with their own assessments



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Thanks for listening!