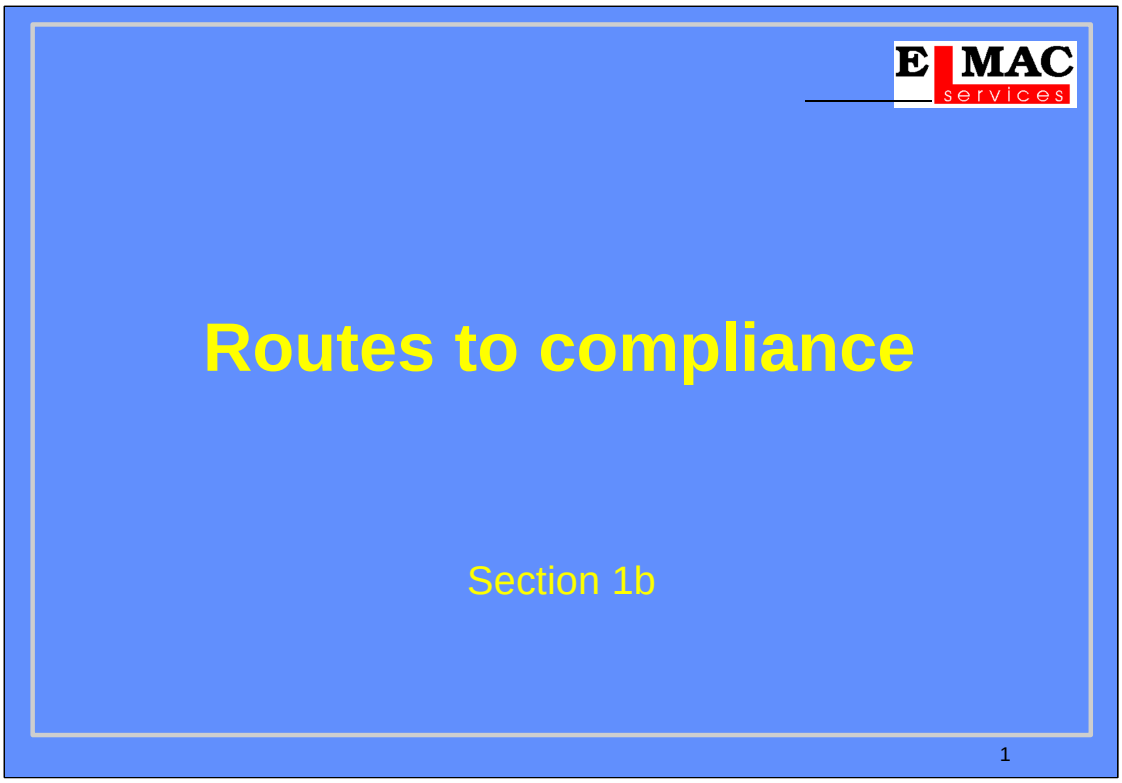
E MAC
services
Routes to compliance
Section 1b
1

Outline

- The standards route
- Availability and generation of standards
- The three types of standard
- Product standards and the effect of revisions
- The Technical Construction File route

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The standards route

- manufacturer judges compliance of product against selected harmonized standards, may use
  - external test house
  - in-house tests
  - engineering judgement
- makes declaration of conformity on the basis of these standards
- applies CE mark and markets product

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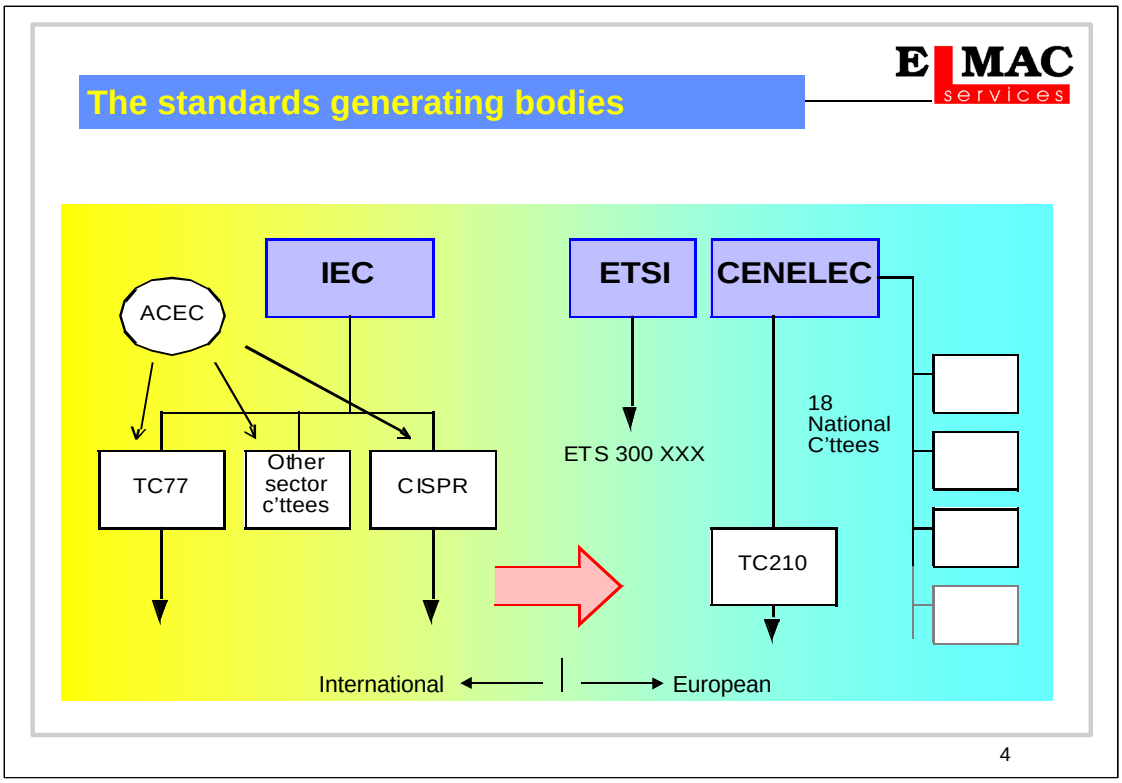
The preferred method of demonstrating compliance with the EMC Directive is by self certification to harmonized European standards. Under this route the manufacturer/importer declares that the product conforms to a given set of standards, applies the CE mark and markets the product. He may test the product in-house or at an external test house to determine compliance, or may decide that testing is unnecessary.

Difficulties with this route mainly lie with the availability and applicability of standards. Historically, published and harmonized standards were only available for some types of product and for some EM phenomena, and the proper application of even these few was subject to considerable variations in interpretation. This situation has improved to the extent that most types of product are now covered by product-specific or generic EMC standards. “Grey areas” that remain include the types of apparatus that fall under the scope of a given standard, the configuration and operating modes of equipment under test that would satisfy the standard, and even sometimes the way in which the tests are applied.



Two IEC technical committees are devoted full time to EMC work, although nearly forty others have some involvement with EMC as part of their scope. The two full time committees are TC77, Electromagnetic compatibility between equipment including networks, and the International Special Committee on Radio Interference or CISPR, which is the acronym for its French title. Co-ordination of the IEC's work on EMC between the many committees involved is the responsibility of ACEC, the Advisory Committee on EMC, which is expected to ensure against the development of conflicting standards.

CENELEC and ETSI use IEC/CISPR results wherever possible as a basis for preparation of drafts for such standards, and the committee charged with the duty of preparing the EMC standards is TC210. Representatives of National Committees meet in TC210 about once a year to discuss the technical implementation of the drafts. CENELEC is made up of the National Committees of each of the EC and EFTA countries; adoption of standards is based on a qualified weighted voting by the 18 National Committees.

Availability of standards

- harmonized standards produced by CENELEC on the basis of work done in IEC/CISPR technical committees
- product specific harmonized standards have now been produced: some refer to RF emissions and some to immunity, a few to both
- “generic” standards for emissions and immunity are intended to apply where possible in the absence of product specific standards

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The reference numbers of harmonized standards are published in the Official Journal of the European Communities. Some product sector standards have already been available for some time based on work done by CISPR.

CENELEC has given priority to producing generic standards which represent the minimum parameters necessary to meet the Directive’s essential requirements. These only lay down the tests to be performed and the limit levels, and refer to “basic” EMC standards for the detailed test methods. Both pairs of generics for the residential, commercial and light industrial environments, and for the heavy industrial environment, have been published for some years.

Various product sector trade associations, having decided that the generic standards are unsuited to their particular needs, developed drafts for their own product specific EMC standards. These have mostly been published and harmonized now.

Reasons for using standards

- phenomena, tests and levels clearly defined
- quickest method – no external review of documentation
- need not involve third party if manufacturer has own test facilities

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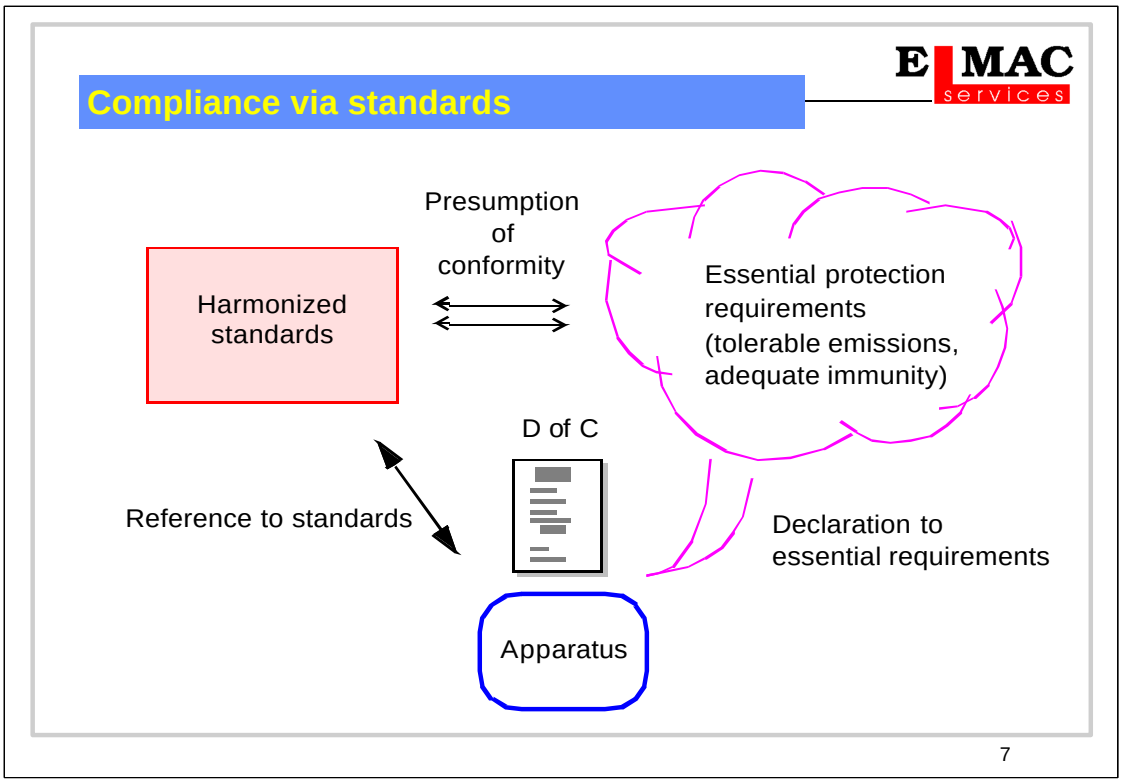
It is the manufacturer's choice as to whether to use a harmonized standard, given that appropriate ones are available. The Commission certainly envisaged that for most products, self certification to harmonized standards would be the preferred route, and it is particularly easy to apply standard tests to individual, stand-alone equipment. The publication of the generic standards mean that for most apparatus, the choice is there to use them. The standards are deemed to represent the Directive's essential requirements and compliance with them allows the manufacturer to presume conformity with these requirements. Given that the phenomena to be tested, the test methods and the limit levels are all defined in the standards, all that is needed is for a manufacturer to apply the relevant tests and provided they are successful, the apparatus can be CE marked.

The attraction of the standards route to manufacturers is that under this route the manufacturer or importer declares that the product conforms to a given set of standards, applies the CE mark and markets the product. He may test the product in-house or at an external test house to determine compliance, or may decide that testing is unnecessary. If the tests are done in-house, then no further involvement by a third party is needed: hence this is known as the "self-certification" route.



Compliance with standards is stated to give a *presumption of conformity* with the essential protection requirements. This is not the same as *guaranteeing* that the product does conform. The declaration of conformity states that the product complies with the protection requirements and it is presumed that the application of standards is enough to achieve this, unless the situation is proved otherwise. But, given the technical inadequacy of many standards, it is quite likely that breaches of the protection requirements will occur.

If, though, an actual breach of the protection requirements does arise – the product actually causes or suffers interference – then although an offence has been committed, proper compliance with the standards would almost certainly constitute part of the manufacturer's defence of due diligence.

The three types of EMC standard

- Basic standards: define measurement methods for specific phenomena
- Generic standards: for emissions and immunity, define the minimum requirements for the EMC Directive, based on environment classification
- Product or product-family standards: define the emissions and/or immunity requirements for specific product sectors

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Self-certification may only be made against standards whose reference numbers have been published in the OJEC. These will almost invariably be CENELEC standards, prefixed by “EN”, although these may themselves merely be transpositions of IEC documents. If a standard has not been published in the OJ it cannot be used for self-declaration, however relevant it might be. Basic standards, because they do not give explicit requirements for products, are not published in the OJ, but generic and product-specific standards are.

Basic standards

- Basic standards:
  - specify the general conditions or rules necessary for achieving electromagnetic compatibility applicable to all products
  - product committees may refer to them
  - are, by definition, independent of any specific product
- Examples:
  - IEC/EN 61000-4 series

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A decision was taken some while ago in IEC that since the scope of EMC standards that would be required was so vast, no extra measurement methods would be defined on a product-by-product basis. Instead, existing and proposed measuring methods would be applied to all products, modified by the provisions of each product standard where appropriate or necessary. Such measurement methods would be defined in the so-called Basic standards. The subjects dealt with by Basic EMC publications are reflected in the structure of the IEC 61000 series (formerly IEC 1000) developed by TC 77. Essentially, they concern:

– general subjects like terminology and safety;

– descriptions of the electromagnetic environment: phenomena and levels;

– recommendations for the limitation of emission of electromagnetic disturbances;

– guidance values for immunity tests;

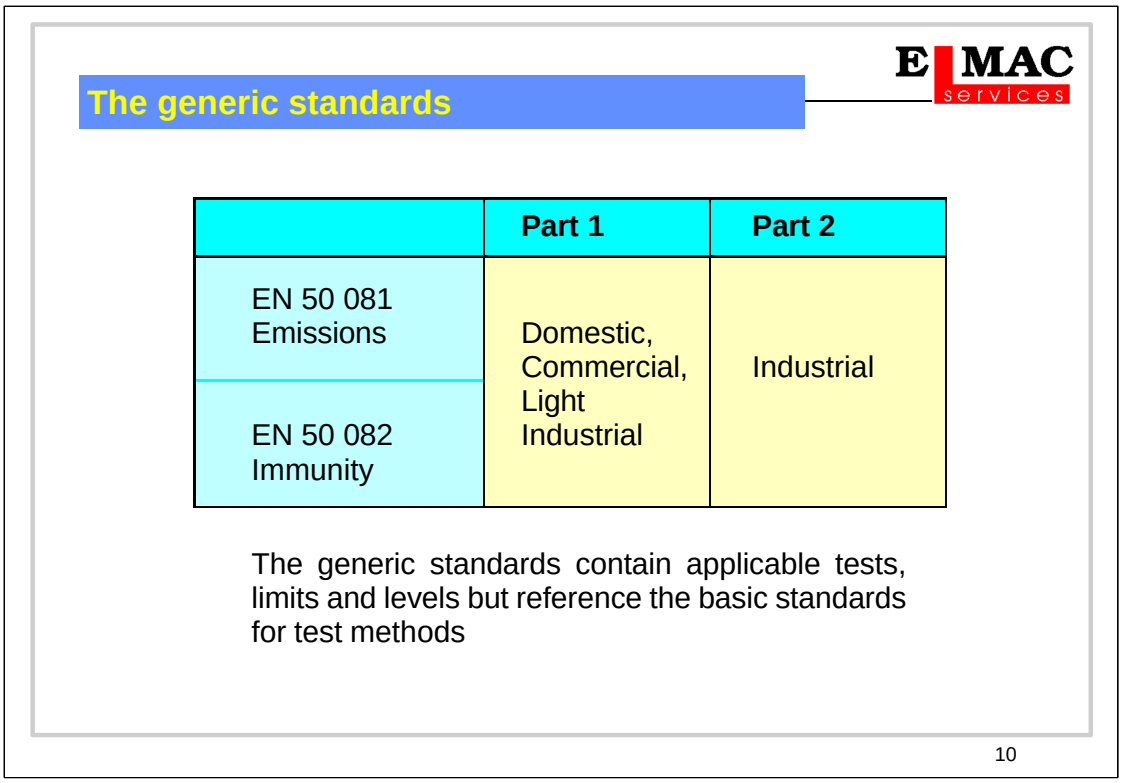
– measurement techniques;

– testing techniques;

– installation guidelines;

– mitigation methods.

Basic EMC publications are mostly produced by two committees with horizontal functions, TC 77 and CISPR.



There are many industry sectors, especially for immunity, for which no product-specific standards have been developed. In order to fill this gap wherever possible, CENELEC gave a high priority to developing the Generic Standards - the first two, EN 50081-1 and EN 50082-1, were published in 1992. These are standards with a wide application, not related to any particular product or product family, and are intended to represent the essential requirements of the Directive. In fact, the generics have been very influential in setting the pattern for the subsequent development of product standards.

Generic standards are “simplified” product standards relating to a given environment and are applicable to all equipment installed in this environment when there is no EMC standard specific to the equipment.

Two sets of standards, each comprising two publications, have been developed. The first set is for residential, commercial and light industry environments, the second set for industrial environments. Each includes an emission and an immunity standard.

They specify a relatively limited number of requirements and tests so as to attempt to hold a balance between technological and economic considerations. The distinction between environmental classes is based on the electromagnetic conditions that obtain in general throughout the specified environments. The inclusion of the “light industrial” environment (workshops, laboratories and service centres) in class 1 has been the subject of some controversy. Equipment for the class 2 “industrial” environment is considered to be connected to a dedicated transformer or special power source, in contrast to the class 1 environment which is considered to be supplied from the public mains network.

Product standards

- apply in preference to the generic standards for particular product types
- reference basic standards for test methods
- apply limits and levels as determined by product committee
- include test setup, operating mode and detailed failure criteria as appropriate
- now been developed for many product sectors

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EMC Product standards specify the requirements and tests specific to the products considered. A Product Family standard relates to a group of similar products to which the same rules may be applied.

These standards should:

– apply only the Basic standards (apart from fully justified exceptions);

– be coordinated as far as possible with the Generic standards relating to the environment in which the products are installed;

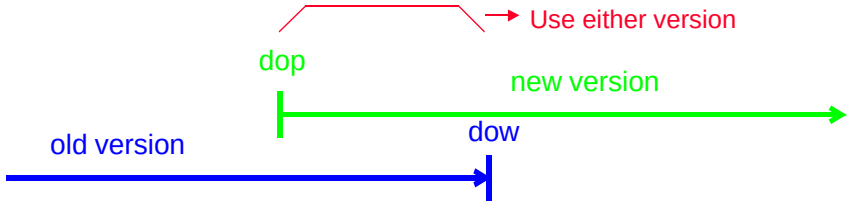
– keep to the emission limits specified by TC 77 or CISPR in the “horizontal“ emission standards. The share of individual sources of disturbance must be coordinated such that none assumes too great an importance with respect to the others. A product committee has no freedom in this regard; in the case of special conditions, it must consult the relevant horizontal committee.

The requirements and tests relating to immunity should in principle be specified by the product committees, in the light of their knowledge of the products and the environment in which they are used.

The theory of the development of product standards has worked reasonably well in the case of newer documents started from scratch within the last few years. It becomes complicated, and does not hold up to close inspection, for standards which either pre-date the concept of the product standards and have defiantly gone their own way since, or which were developed in the early days of the concept and managed to apply their own rules.

Revisions to standards

- Product already certified to harmonized product or generic standard: revision to standard occurs, or new product standard appears
  - OJEC reference gives date of cessation of presumption of conformity (date of withdrawal, DOW) of previous version; either previous or new standard can be used up until DOW; after this date re-certification to new standard is necessary



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Standards are in a state of constant change and revision. To help manufacturers cope with this situation, there is normally an overlap between the date of publication of a new version and the date of withdrawal of an old version of a standard, during which either may be used for a declaration of conformity. These dates are published in the foreword of the European version of the standard.

The EC then publish the date of “cessation of presumption of conformity of earlier standards” in the OJEC when a new standard is harmonized. This date is normally but not invariably identical to the DOW in the foreword of the standard itself. After this date, the superseded standard is no longer regarded as giving presumption of conformity. The correct course for the manufacturer is to re-certify to the new version at some time before this date. This may well involve re-testing, if the newer version is different or more stringent - it is rare for standards requirements to become more relaxed.

The Technical Construction File

- for use when the manufacturer does not certify conformity to harmonized standards
- manufacturer draws up a “technical construction file”
- competent body reviews t.c.f., may carry out tests if necessary, and issues report/certificate which forms part of the t.c.f.
- manufacturer makes declaration of conformity, affixes CE mark and maintains t.c.f. for ten years

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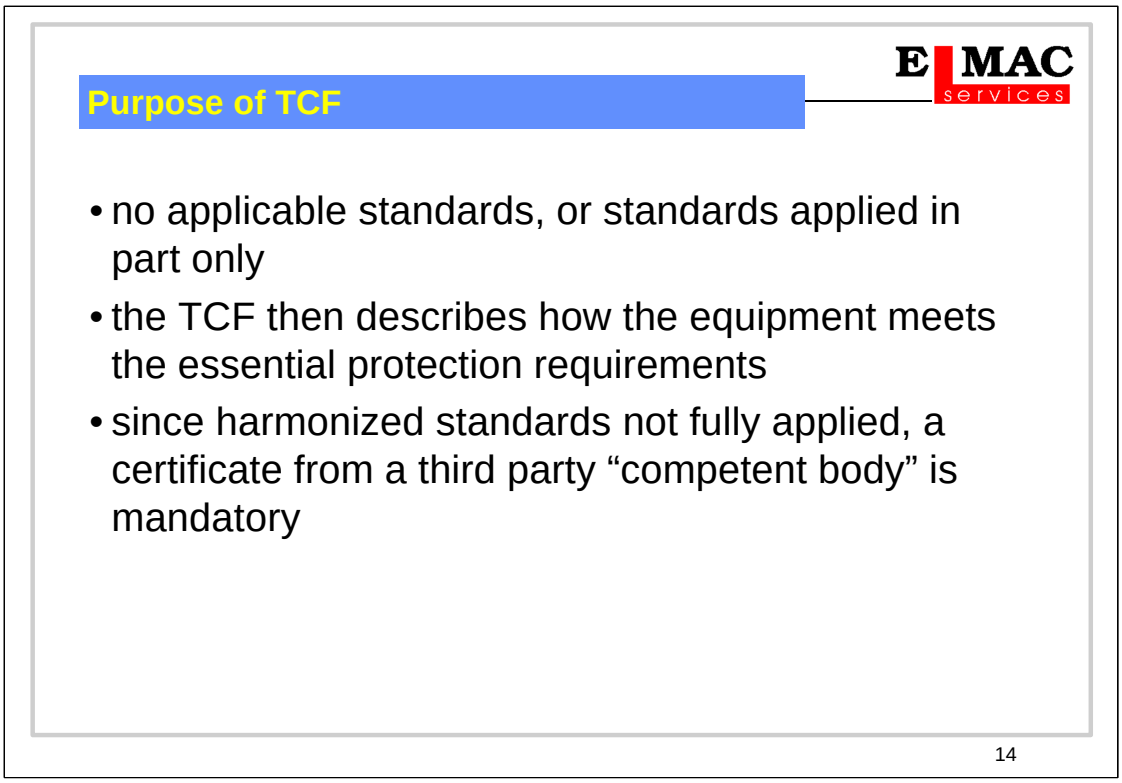
A second route is available if the manufacturer/importer cannot or will not apply harmonized standards. Possible reasons for choosing this route would be if existing standards could not be applied or if testing to standards would be impractical because of the nature of the apparatus, if the apparatus was so simple that testing was clearly unnecessary, or when the apparatus had already been tested to non-harmonized standards that were believed to meet the essential requirements.

In this case the manufacturer must involve a competent body, normally (in the UK) an accredited EMC test house appointed by the DTI, who will vet the technical construction file drawn up by the manufacturer, perform whatever tests it thinks are necessary, and if satisfied will issue a report or certificate. The manufacturer is then free to make a declaration of conformity and affix the CE mark as before. The TCF – which in many respects is the EMC aspect of the product design file – must be held at the disposal of the competent authorities for ten years after the apparatus is placed on the market.

It is important to distinguish the EMC TCF from the Technical File which is mandatory for use with other CE Marking Directives. This is legally a quite different type of document.



The purpose of the technical construction file route is to allow compliance with the essential requirements of the Directive to be demonstrated when harmonized or agreed national standards do not exist, or exist only in part, or if the manufacturer chooses not to apply existing standards for his own reasons. Since the generic and product standards are intended to cover the first two of these cases, the main useage of this route is under the following circumstances:

- the nature of the apparatus precludes application of standards
- testing would be impractical because of size or extent of apparatus
- apparatus already tested to non-harmonized standards

Equipment which is built according to the drawings and procedures documented within the TCF is presumed to be compliant with the essential requirements of the EMC Directive and can then be CE Marked.

Content of TCF

- an identification of the apparatus (which may be a series of variants)
- a technical description
- a technical rationale for the procedures used to ensure conformity
- details of design elements that are significant for EMC
- test evidence where appropriate
- a report or certificate from a competent body

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The UK DTI has produced a guidance document to clarify the expected level of detail in the TCF, and this document is forming the basis for pan-European guidance. It suggests circumstances in which the TCF might be used, and also suggests the basic requirements for contents. These are as shown above. There is considerable disagreement within Europe as to how to assess some of these aspects, notably test data and control of variants.

The technical file may or may not contain test data. The critical item is the technical report or certificate issued by a competent body, and this is what distinguishes this route from the previous one. Essentially, the manufacturer is required to get an independent qualified opinion on the validity of his belief that the product meets the essential requirements. The competent body should review the technical file to check the rationale for the product's EMC, and the testing that has been done (if any). Either a report or certificate may be issued, both having equivalent weight. If the manufacturer has been able to partially apply harmonized standards then this document need only certify conformity with those aspects not covered by these standards.

Competent body requirements

- availability of personnel and of the necessary means and equipment;
- technical competence and professional integrity;
- independence of staff and technical personnel in relation to the product in question;
- maintenance of professional secrecy;
- possession of civil liability insurance.

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The EMC Directive Annex II lays down the requirements placed on a competent body and these are shown above. Many of these requirements are met by accreditation, which in Europe is at present based on the EN45000 series of standards (soon to be converted to ISO17025). This covers organisation and management, calibration and maintenance of test equipment, measurement traceability and procedures, records and reports, the quality system, and staff competence. In the UK the body which handles accreditation is UKAS, formerly the National Measurement Accreditation Service.

Accreditation is not the only requirement. In the UK, the Secretary of State for Trade and Industry has actually appointed competent bodies, and the DTI has indicated that a further requirement is the capability to make engineering judgements on the contents of a technical file, which is not a feature of test accreditation. It may be possible for a manufacturer to gain competent body status for his own test facility, assuming it meets the accreditation criteria. UKAS are presently undergoing an assessment exercise on behalf of the DTI (separate from testing accreditation) to confirm the capabilities of the UK competent bodies.

Europe vs. the US: EMC requirements

- FCC Rules:
  - emissions only, for certain classes of intentional and unintentional transmitters only
- EMC and R&TTE Directives:
  - emissions and immunity, for all types of equipment

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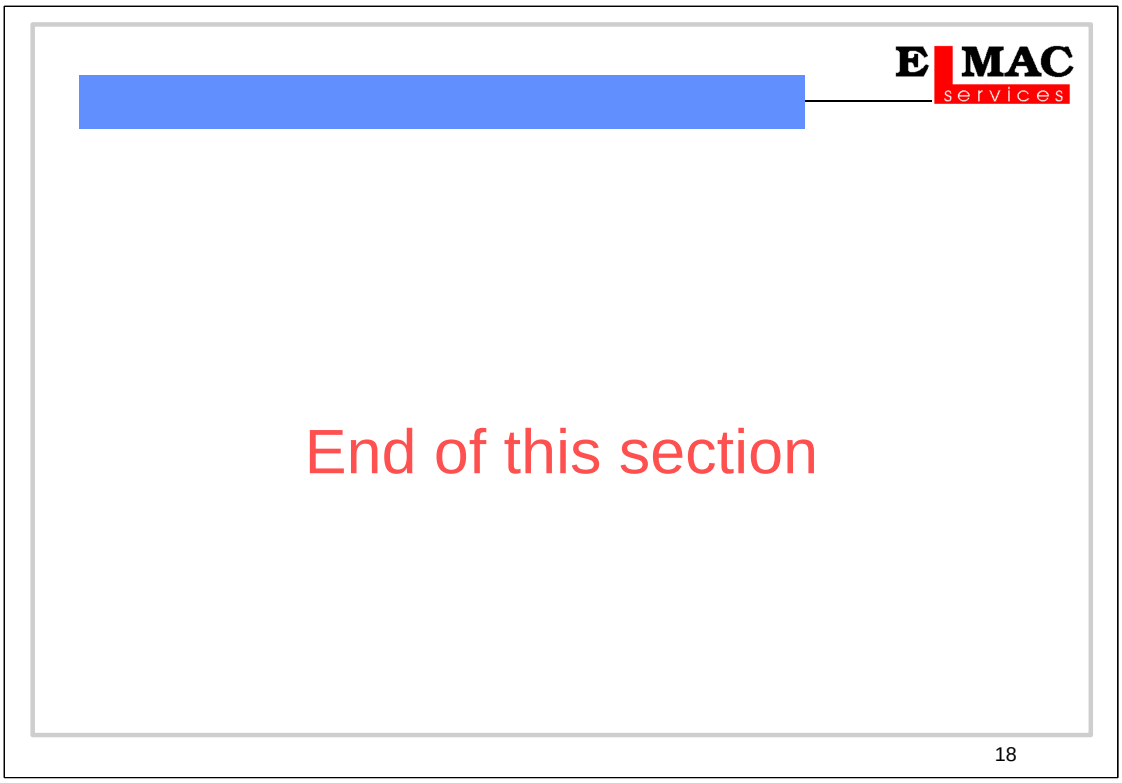
Information technology manufacturers are familiar with US FCC (Federal Communications Commission) requirements for control of RF emissions. These have been in place for well over a decade and the requirements are well established, although the method of declaring compliance changes occasionally.

The European EMC Directive is significantly more stringent than the FCC rules. Although the emissions limits are effectively the same, they are applied to many more classes of product. More importantly, the EMC Directive has a requirement for adequate immunity, which does not appear at all in the US regulations.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