Chapter 2

The EMC Directive

2.1 History

The relaxed EMC regime that existed throughout most of Europe up until the early 90s was overturned with the adoption by the European Commission on 1st January 1992 of the EMC Directive, 89/336/EEC [177]. This was at the time widely regarded to be "the most comprehensive, complex and possibly contentious Directive ever to emanate from Brussels" [34]. It has eventually been superseded by its second edition, published at the very end of 2004. This chapter examines the provisions of the new Directive and how manufacturers will need to go about complying with it. But first, we have to understand the background to European Directives and the history of the first EMC Directive.

2.1.1 The New Approach Directives

Of the various aims of the creation of the Single European Market, the free movement of goods between European states† is fundamental. All Member States impose standards and obligations on the manufacture of goods in the interests of quality, safety, consumer protection and so forth. If there are detailed differences in procedures and requirements, these act as technical barriers to trade, fragmenting the European market and increasing costs because manufacturers have to modify their products for different national markets.

For many years the Commission tried to remove these barriers by proposing Directives which gave the detailed requirements that products had to satisfy before they could be freely marketed throughout the Community, but this proved difficult because of the detailed nature of each Directive and the need for unanimity before it could be adopted. In 1985 the Council of Ministers adopted a resolution setting out a "New Approach to Technical Harmonisation and Standards".

Under the "new approach", directives are limited to setting out the essential requirements which must be satisfied before products may be marketed anywhere within the EU. The technical detail is provided by standards drawn up by the European standards bodies CEN, CENELEC and ETSI. Compliance with these standards is expected to demonstrate compliance with the essential requirements of each Directive. All products covered by each Directive must meet its essential requirements, but all products which do comply, and are labelled as such, may be circulated freely within the Community; no Member State can refuse them entry on technical grounds. Decisions on new approach Directives are taken by qualified majority voting, eliminating the need for unanimity and speeding up the process of adoption.

A document (the "Blue Guide") was published in early 2000 by the European Commission setting out the way in which new approach Directives should be

† Appendix E lists the EU and EEA Member States.

implemented in a relatively harmonised fashion. This says that a new approach Directive contains the following elements [179]:

- the *scope* of the Directive;
- a statement of the *essential requirements*;
- the *methods of satisfying* the essential requirements;
- how *evidence of conformity* will be provided;
- what *transitional arrangements* may be allowed;
- a statement confirming entitlement to *free circulation*;
- a *safeguard procedure*, to allow Member States to require a product to be withdrawn from the market if it does not satisfy the essential requirements.

It is the responsibility of the European Commission to put forward to the Council of Ministers proposals for new Directives. Directorate-General III of the Commission has the overall responsibility for Directives in the electrical sector. The actual decision on whether or not to adopt a proposed Directive is taken by the Council of Ministers, by a qualified majority vote. Texts of Directives proposed or adopted are published in the *Official Journal of the European Union*. Consultation on draft Directives is typically carried out through European representative bodies and in working parties of governmental experts.

2.1.2 Background to the legislation

In the UK, previous legislation on EMC was limited in scope to radio communications. Section 10 of the Wireless Telegraphy Act 1949 enables regulations to be made for the purpose of controlling both radio and non-radio equipment which might interfere with radio communications. These regulations have taken the form of various Statutory Instruments (SIs), which cover interference emissions from spark ignition systems, electromedical apparatus, RF heating, household appliances, fluorescent lights and CB radio. The SIs invoked British Standards which are closely aligned with international and European standards. The power existed to make regulations regarding the immunity to interference of radio equipment but this was never used.

At the European level various Directives have been adopted over the years, again to control emissions from specific types of equipment. Directive 72/245 EEC, adopted in June 1972, regulates interference produced by spark ignition engines in motor vehicles. Directives 76/889 EEC and 76/890 EEC, amended by various other subsequent Directives, apply to interference from household appliances and portable tools, and fluorescent lamps and luminaires. These latter two were superseded and repealed by the first EMC Directive. Each Member State is required to implement the provisions of these Directives in its national legislation, as described above for the UK.

This previous legislation is not comparable in scope to the EMC Directive, which covers far more than just interference to radio equipment, and extends to include immunity as well as emissions.

2.1.3 The first EMC Directive

89/336/EEC became fully operational in 1996 after an extended transition period lasting four years. During the initial period, manufacturers had to follow a fairly steep learning curve to get to grips both with the legal requirements and the technical subject of EMC: many had never had to deal with the issue before. The European Commission

clearly assumed that manufacturers would be able to assume responsibility for the compliance of their products from the start, but in fact for many this was a new subject and a substantial extra burden, and the implementation of the Directive was at best patchy for several years. A detailed guidance document [180] was published by the Commission in 1997 which cleared up many of the misunderstandings that had been created, and by the turn of the century the understanding of the Directive within electrical and electronics companies had largely settled down.

Development of enforcement followed a similar uneven course. The Directive itself did not mandate any particular approach to enforcement and so different Member States took different approaches, depending on their particular culture and attitude towards European-initiated laws. This led to a noticeable variation in the gradient of the playing field across Europe, somewhat along the lines of the "traffic lights" principle†. In the UK, the job of enforcement was given to the Trading Standards authorities, more at home with dealing with rogue traders and the safety of consumer products like toys; only a few Trading Standards Officers would consider themselves even slightly familiar with the issues of EMC, and this combined with under-resourcing has meant that enforcement of the Directive in the UK has been somewhat limited in scope.

In fact, a large part of the pressure forcing companies to comply has come not from the enforcement authorities, but from other customers. For instance, in the consumer sector most of the market for electrical goods is dominated by a few large national or international retailers, and these demand correct declarations of conformity as part of their conditions of trade. Many non-consumer products such as industrial instrumentation are sold not to the end user but to a systems integrator, and again these have found that they need to ask for EMC compliance from their suppliers as part of their own compliance stance.

The first EMC Directive had two alternative routes to compliance: application of and self certification to harmonised standards, which was used in the vast majority of cases; and generation and assessment of a Technical Construction File, which was meant to be used if the manufacturer didn't or couldn't use standards, and which involved a review by a Competent Body.

2.1.3.1 SLIM

In 1998 the EMC Directive was subject to a review under the SLIM (Simpler Legislation for the Internal Market) process. Ten governmental experts were charged with making recommendations for improvements and simplifications to the Directive. Their report looked at the following areas amongst others:

- functional safety – explicitly, not to be part of the EMC Directive;
- immunity requirements – to be retained, but clarified;
- standards – a strategic review panel to be set up;
- large machines and installations – not subject to conformity assessment;
- definitions of certain types of environment.

The SLIM recommendations have formed the foundation for a complete rewrite of the EMC Directive, but it would be wrong to suggest that everything the SLIM group recommended has been taken on board unaltered in the new edition. Indeed, the second edition has introduced some new aspects which need a whole new raft of interpretation.

† In Northern European countries, compliance with traffic lights is mandatory. In Central Europe, they are advisory. In Southern Europe, traffic lights are for decoration only.

2.1.3.2 Other Directives

Apart from the EMC Directive, other new approach Directives adopted which may affect some sectors of the electrical and electronic engineering industry include:

- Toy safety (88/378/EEC)
- Non-automatic weighing machines (90/384/EEC)
- Medical devices (93/42/EEC)
- Active implantable electromedical devices (90/385/EEC)
- Machinery safety (89/392/EEC)
- Gas appliances (90/396/EEC)
- Lifts (95/16/EC)
- Refrigeration appliances (96/57/EC)
- In vitro diagnostic medical devices (98/79/EC)
- Radio and telecommunications terminal equipment (99/5/EC) (covered in Chapter 3)

Some of these contain their own EMC requirements which either partially or completely supplant the EMCD, as mentioned in section 2.2.2.3. In addition to this list, there are two other Directives which are relevant although they are not strictly "new approach" Directives. These are the Low Voltage Directive (73/23/EEC)(LVD) and the Automotive EMC Directive (95/54/EC, now superseded by 2004/104/EC). The LVD is concerned with safety, not EMC, but as a result of the CE Marking Directive the CE Mark attests to conformity with this Directive as well as any other applicable new approach Directives.

The Automotive EMC Directive is not a CE Marking Directive. It applies to vehicles and their electrical/electronic sub-assemblies and requires a form of type approval, signified by the 'e' marking. It is discussed in section 5.1.1.

2.2 The second EMC Directive

The second edition of EMC Directive 2004/108/EC [183] was published on 31st December 2004†. The timescale for its adoption is as follows:

- Entry into force: 20th January 2005
- Transposition: Member States shall adopt and publish the provisions necessary to comply with this Directive by 20th January 2007. They shall apply those provisions as from 20th July 2007, and from that date equipment claiming compliance with 2004/108/EC can be put on the market.
- Directive 89/336/EEC is repealed as from 20th July 2007.
- Transitional provisions: Member States shall respect compliance with 89/336/EEC for equipment which was placed on the market before 20th July 2009.

† At the time of writing, the UK legislation and the EU Guidance for the second edition Directive had not been completed. The discussion in the rest of this chapter draws on draft legislation and guidance [192][193], and on consultation workshops that the UK DTI and EMCTLA sponsored in 2005 and 2006.

2.2.1 What changes?

The essential requirements have not changed except for detailed wording, particularly that immunity now requires operation “without unacceptable degradation of its intended use”. The routes to compliance however have been changed. Whereas before, if you didn't “apply” harmonised standards you had to use the Technical Construction File route and pass your TCF by a Competent Body, now, the TCF route has been swept away. The overarching requirement is for the manufacturer to perform and document an “EMC assessment” of his product. This may still involve compliance with harmonised standards: “The correct application of all the relevant harmonised standards whose references have been published in the OJEU shall be equivalent to the carrying out of the electromagnetic compatibility assessment.” But it is also made clear that “Compliance with a harmonised standard is not compulsory”, and the “presumption of conformity” which compliance offers is limited to the scope of the harmonised standard(s) applied and the relevant essential requirements covered by such harmonised standard(s).

The real change here is that, if you don't apply correctly all the relevant harmonised standards, you can, indeed must, still carry out an EMC assessment; but there is no requirement to have this assessment reviewed by a third party such as a Competent Body. On the other hand, you may do so voluntarily, and the Directive allows for “Notified Bodies” to be appointed on pretty much identical terms to the old Directive's Competent Bodies, so that these organizations will most probably continue to offer their services under the new Directive. Their use, though, is entirely at the manufacturer's discretion.

The other major change is to the regime for fixed installations. Equipment that is regulated by the Directive now has two subsets: apparatus, and fixed installations. The change allows different regulatory provisions for each. "Apparatus" now covers virtually everything that was covered by the old Directive, including mobile installations and systems; such apparatus is subject to the full provisions of the Directive, but there is an explicit exemption now for benign apparatus. Fixed installations on the other hand are not subject to much of the conformity assessment procedures, but do have to follow other new requirements.

2.2.2 Scope, requirements and exceptions

2004/108/EC applies to apparatus which is liable to cause electromagnetic disturbance or which is itself liable to be affected by such disturbance. “Apparatus” is defined as any finished appliance or combination of appliances made commercially available as a single functional unit, and intended for the end user. Essentially, anything which is powered by electricity is covered, regardless of whether the power source is the public supply mains, a battery source or a specialized supply. Specific exceptions are discussed in section 2.2.2.3.

An electromagnetic disturbance is any electromagnetic phenomenon which may degrade performance, without regard to frequency or method of coupling. Thus radiated emissions as well as those conducted along cables, and immunity from EM fields, mains disturbances, conducted transients and RF, electrostatic discharge and lightning surges are all covered. *No* specific phenomena are *excluded* from the Directive’s scope.

2.2.2.1 Essential requirements

The essential requirements of the Directive (Article 5 and Annex I) are that the apparatus shall be so designed and manufactured, having regard to the state of the art, that:

- the electromagnetic disturbance it generates does not exceed a level above which radio and telecommunications equipment and other equipment cannot operate as intended;
- it has a level of immunity to the electromagnetic disturbance to be expected in its intended use, which allows it to operate without unacceptable degradation of its intended use.

The intention is to protect the operation not only of other users' radio and telecommunications equipment but any equipment which might be susceptible to EM disturbances, such as information technology or control equipment. At the same time, all equipment must be able to function correctly in whatever electromagnetic environment – that is, all electromagnetic phenomena observable in a given location – it might reasonably be expected to occupy. Notwithstanding these requirements, any Member State has the right to apply special measures with regard to the taking into service of apparatus, to overcome existing or predicted EMC problems at a specific site or to protect the public telecommunications and safety services. Compliance with the essential requirements will be demonstrated via the performance and documentation of an "EMC assessment". This is discussed in section 2.3.

2.2.2.2 Sale and use of products

The Directive applies to all apparatus that is placed on the market or taken into service. The definitions of these two conditions do not appear within the text of the Directive but are the subject of several paragraphs in the 1997 Guidelines [180] and in the Blue Guide [179].

Placed on the market

The "market" means the market in any or all of the European Economic Area (EEA); products which are found to comply within one state are automatically deemed to comply within all others. "Placing on the market" means the *first* making available of the product within the EEA, so that the Directive covers only new products manufactured within the EEA, but both new and used products imported from a third country. Products sold second hand within the EEA are outside its scope. Where a product passes through a chain of distribution before reaching the final user, it is the passing of the product from the manufacturer into the distribution chain which constitutes placing on the market. If the product is manufactured in or imported into the EEA for subsequent export to a third country, it has not been placed on the market.

The Directive applies to each individual item of a product type regardless of when it was designed, and whether it is a one-off or high volume product. Thus items from a product line that was launched at any time before 1996 had to comply with the provisions of the first Directive after 1st January 1996. Put another way, there is no "grandfather clause" which exempts designs that were current before the Directive took effect. However, products already *in use* before 1st January 1996 do not have to comply retrospectively. The transitional provisions for the second EMCD are that you can use the methods of compliance of either, from 20th July 2007 up to 20th July 2009.

The picture becomes less clear for products which are modified before being re-sold. If used apparatus, which has been modified during its operational life, is placed

on the EU market then the procedure will depend on the extent to which those modifications affect the EMC performance of the apparatus. If the apparatus has been maintained and also modified, but not to any significant degree in terms of EMC, then it is termed "reconditioned" and is not subject to the provisions of the Directive. If the apparatus has been modified more substantially then it is referred to as "upgraded" and the Directive does apply. The choice remains in the hands of whoever carries out the modifications and places the product on the market, who is expected to carry out a new EMC assessment – or at least to validate the conclusions of the original assessment.

If the manufacturer resides outside the EEA, then the responsibility for maintaining the certificate of conformity with the Directive rests with the person placing the product on the market for the first time within the EEA, i.e. the manufacturer's authorized representative or the importer. Any person who produces a new finished product from already existing finished products, such as a system builder, is considered to be the manufacturer of the new finished product.

Taken into service

"Taking into service" means the first *use* of a product in the EEA by its final user. If the product is used without being placed on the market, if for example the manufacturer is also the end user, then the protection requirements of the Directive still apply. This means that sanctions are still available in each Member State to prevent the product from being used if it does not comply with the essential requirements or if it causes an actual or potential interference problem.

2.2.2.3 Exceptions

There are a few specific exceptions from the scope of the Directive. Self-built amateur radio apparatus is specifically excluded. Military equipment is excluded, at least in the UK, as a result of an exclusion clause in the Treaty of Amsterdam which established the European Union, but equipment which has a dual military/civil use will be covered when it is placed on the civilian market. Equipment which falls within the scope of the R&TTE Directive is specifically excluded, since this Directive refers back to the EMCD's essential requirements for its EMC provisions. Another exclusion is aeronautical products, parts and appliances that are referred to in Regulation (EC) No. 1592/2002 on common rules in the field of civil aviation, i.e. equipment that will be used on aircraft. Equipment for display at trade fairs need not comply provided that it carries a warning notice, and provided that "adequate measures are taken to avoid electromagnetic disturbances".

Benign equipment

The most widely drawn exclusion is for electromagnetically benign equipment. This is defined as equipment, the *inherent qualities* of which are such that:

(a) it is incapable of generating or contributing to electromagnetic emissions which exceed a level allowing radio and telecommunication equipment and other equipment to operate as intended; and

(b) it will operate without unacceptable degradation in the presence of electromagnetic disturbance normally consequent upon its intended use.

Both conditions must be met, but if they are, such equipment is completely excluded from the application of the Directive. As a general rule, the requirements are contingent on the nature of the apparatus: such that it cannot create power supply or RF disturbances, and does not include active electronic components which could be affected by such disturbances. Most electronic equipment could not be regarded as

benign, since it wouldn't meet one or both of these criteria, but some simple electrical apparatus such as switches, fuses, induction motors and filament lamps may be.

The picture is slightly clouded by the EC's draft guidance, which allows as examples "Protection equipment which only produce transitory disturbances of short duration" and "High voltage types of equipment in which possible sources of disturbances are due only to localised insulation stresses which may be the result of the ageing process and are anyway under the control of other technical measures", even though such devices do create disturbances, which can affect radio reception.

Other Directives

The only other exclusions are for those types of apparatus which are subject to EMC requirements in other Directives or regulations, to the extent that those Directives specifically lay down, in whole or part, the essential EMC requirements. These are:

- 90/385/EEC active implantable medical devices;
- 98/79/EC in vitro medical devices;
- 93/42/EEC medical devices;
- 72/245/EEC EMC of vehicles as amended by 95/54/EC and 2004/104/EC, but see section 5.1.1.2 regarding non-safety-critical aftermarket equipment;
- 75/322/EEC EMC of agricultural or forestry tractors as amended by 2000/2/EC;
- 97/24/EC two- and three-wheel motor vehicles;
- 96/98/EC on marine equipment;
- 90/384/EEC non-automatic weighing instruments.

In addition, equipment covered by the Measuring Instruments Directive 2004/22/EC which is CE marked and "M" marked according to that Directive, is excluded in respect of the immunity of such equipment. This exclusion is somewhat more complex, since the MI Directive is voluntary for some instruments. For the MI and non-automatic weighing instruments Directives, the EMCD still applies as far as emissions requirements are concerned.

2.2.2.4 Components

The question of when does a "component" (which is not within the scope of the Directive) become "apparatus" (which is) has been problematical. The Commission's 1997 guidelines introduced the concept of the "direct function", that is, any function which fulfils the intended use specified by the manufacturer in the instructions to the end user. It is available without further adjustment or connections other than those which can be performed by a technically naive user. Any component without a direct function is clearly not apparatus and is therefore outside the scope of the Directive. Thus individual small parts such as ICs and resistors are definitely outside the Directive.

Unfortunately, the second edition of the Directive, in defining what is meant by a component, has completely ditched this distinction. The question has now become, is the device intended to be placed on the market for incorporation into an apparatus by an end user, or likely to follow this path even if not intended directly for the end user? If so, then it is apparatus and must follow the full procedure required by the Directive. If not, then such components must be intended for incorporation into apparatus by other manufacturers, who take on the responsibility for compliance of their final product.

A component may be complex provided that its only purpose is to be incorporated inside an apparatus, but the manufacturer of such a component must indicate to the equipment manufacturer how to use and incorporate it. The distinction is important for manufacturers of board-level products and other sub-assemblies that may appear to have their own function and are marketed separately, yet cannot be used separately from the apparatus in which they will be installed.

However, in the particular case of plug-in cards for personal computers, which are supplied by a third party for the user to insert, the situation has been clarified: although such boards clearly need a host computer to have any purpose, they are placed on the market for the final end user and therefore need to carry a CE mark. They will need to be tested in a "representative" host computer, and certified accordingly. This position has been carried through into the harmonised standards, particularly EN 55022, which includes specific advice on how to treat such modules.

For products which may be both supplied to OEMs for incorporation into other apparatus, and supplied to the end user – an example might be some types of industrial sensor – then the item becomes apparatus and needs separate certification. If the manufacturer can insist that the item is only ever sold to OEMs then it is a component. This distinction has been made by many suppliers to shrug off the responsibility of ensuring that their products are properly specified for EMC ("Oh no, the Directive doesn't apply to us, we make components"). But since their customers are demanding EMC performance specifications anyway, to help them meet their own responsibilities, this is not a sustainable position.

2.2.3 The CE mark and the paperwork

The manufacturer or his authorized representative is required to attest that the protection requirements of the Directive have been met. This requires two things:

- he issues a declaration of conformity, which must be kept available to the enforcement authority for ten years following the last date of manufacture (a subtle change from the first Directive, which referred to the last date of placing on the market);
- he affixes the CE mark to the apparatus, or if this is not possible, to its packaging, instructions or guarantee certificate, in that order of priority.

2.2.3.1 The CE Mark

A further Directive concerning the affixing and use of the CE mark was adopted in 1993 [182]. This Directive harmonised the provisions regarding CE marking among the various previous new approach Directives. The mark consists of the letters CE as shown in Figure 2.1. The mark should be at least 5mm in height and be affixed "visibly, legibly and indelibly" but its method of fixture is not otherwise specified. Affixing this mark indicates conformity not only with the EMC Directive but also with the requirements of any other Directives relevant to the product which provide for CE marking – for instance, an electrical toy with the CE mark indicates compliance both with the Toy Safety Directive and the EMC Directive. Many electrical products fall under the scope of the Low Voltage Directive and the CE mark also indicates compliance with this. But during the transition period of any such applicable Directive, the CE mark need not indicate compliance; those Directives which *are* complied with should be listed in the appropriate documentation, such as the declaration of conformity.

It's worth pointing out that the CE Mark is not in any sense a quality mark, since all

Figure 2.1 The CE mark

products that desire European market access must have it. Nor is it an approval mark, since in most cases there has been no third party oversight to check that it is valid. Its presence is largely meaningless in any technical sense; if you want to know anything about the performance of a product, you need to demand much more than simply that it carries the CE Mark.

2.2.3.2 The D of C

The EC Declaration of Conformity is required in every case. It must include the following components:

- a reference to the EMC Directive;
- a description of the apparatus to which it refers;
- the name and address of the manufacturer and, where applicable, the name and address of his authorized representative;
- a dated reference to the specifications under which conformity is declared;
- the date of the declaration;
- an identification of the signatory empowered to bind the manufacturer or his authorized representative.

It should also, perhaps self-evidently, certify that the apparatus to which it relates conforms with the protection requirements. You can write a single D of C in such a way that it covers all Directives that apply; you don't need a separate declaration for each.

Under the EMC Directive, an actual copy of the D of C is not required to accompany each item of equipment, although under the R&TTE Directive (see section 3.2.4) it is. Perhaps to forestall anticipated problems with some countries' enforcement officers who may be less than fully familiar with the distinction, many manufacturers take the safe route of including it in the documentation anyway. There is no requirement to have the CE mark on the D of C, but neither is it forbidden.

2.2.3.3 Description

The description of the apparatus should be straightforward; assuming the equipment has a type number, then reference to this type number (provided that supporting documentation is available) should be the starting point. The new EMCD is more stringent with regard to identification than the old one, requiring that equipment is identified by "type, batch, serial number or any other information" which would identify it. The description on the D of C should then encompass the range of such identifications so that there is an unambiguous correlation between the two.

Difficulties can arise when the type is subjected to revision or modification. At what stage do modifications or updates result in a new piece of equipment that would require

re-certification? If the declaration of conformity refers to the Widget 3000 with software version 1.0 launched in 1996, does it continue to refer to the Widget 3000S of 2003 with version 3.2? The sensible approach would be to determine whether the modifications had affected the EMC performance and if so, re-issue the declaration for the new product; but this will require that you re-test the modifications, with the attendant cost penalties, or you exercise some engineering judgement as to whether a minor change will affect performance. No general guidance can be given on this point, but it should be clear that the breadth of the EMC requirements means that very few modifications will have absolutely no effect on a product's EMC performance.

2.2.3.4 Signatory

The empowered signatory will not necessarily be competent to judge the technicalities of what is being declared. Normally this will be one of the directors of the manufacturing or importing company, since the phrase used in the Directive is "empowered to bind" the manufacturer or his authorized representative. In small companies the technical director will probably be close enough to the product in question to understand the detail of its EMC performance, but in medium or large-scale enterprises the directors will expect to rely on the technical advice of their product development and manufacturing engineers and/or the EMC test and management personnel. Such companies will have to define clearly the levels of responsibility that exist for each person involved in making the declaration.

2.2.3.5 Specifications

In most cases the references to the specifications under which conformity is declared, will be a list of the harmonised standards – with dates, to distinguish which version has been used – that have been applied to the apparatus. If harmonised standards have been used only partially or not at all, a reference to the technical documentation (see section 2.3.1.3) where the detailed technical EMC assessment is given should be included as well as a reference to any identifiable non-harmonised standards or specifications that have been applied.

The reference to specifications raises the question of whether you have to *test* to these specifications. Three possibilities are apparent. Firstly, you may deem that the product intrinsically meets the requirements of the Directive and does not need testing. An example might be a simple linear unregulated stand-alone power supply which is below the power level at which harmonic currents are controlled. You may sometimes be able to convince your signatory that this is a competent engineering judgement, but many electronic products will not be able to follow this option.

Secondly, you may be able to make a declaration based on pre-existing test results. If for example you have already been conforming to existing non-harmonised standards, then you may be confident enough to state that the product will meet the appropriate harmonised standards without further testing, or with only partial testing.

The final option is to test fully to harmonised standards. For a sophisticated product this will be lengthy and expensive, and may involve some complex judgements as to what tests to apply. For new products though, testing will be essential. In fact, the new EMCD has subtly introduced a significant extra hurdle: it says (in the preamble)

> Compliance with a harmonised standard means conformity with its provisions and demonstration thereof by the methods the harmonised standard describes or refers to.

This appears to mean, in effect, that you must follow in every case the full compliance test method, in all its complexity and expense, whenever you are going to make a

compliance declaration with a reference to a harmonised standard. The concept of pre-compliance testing, discussed in later chapters in this book and used successfully for many years in pursuance of the old Directive, has been closed off. However, what is almost certain to be the outcome of this is that pre-compliance testing will continue, supported by a brief statement in the technical documentation that harmonised standards have been applied "in part", and justifying the effectiveness of such partial application. In essence, the manufacturer will make an assessment of the risk of not following harmonised standards in full versus the risk (in terms of cost to the company) of doing so.

A fourth option, of course, is not to test at all; just make the declaration, stick on the CE mark and hope that nobody ever notices. A reputable company, of course, won't take this route, but the possibility of competitors doing so may be a factor in assessing your market position.

2.2.3.6 Other information

In keeping with the EC's general desire to keep the user informed, the second edition EMCD makes new requirements for information to be supplied with each apparatus. As well as identification of the apparatus and the name and address of the manufacturer, there should be:

- information on any specific precautions that must be taken when the apparatus is assembled, installed, maintained or used in order to ensure that when put into service the apparatus complies with the protection requirements;
- a clear indication (easily understood by the intended user) of restriction of use for apparatus for which compliance with the protection requirements is not ensured in residential areas;
- information required to enable the apparatus to be used in accordance with its intended purpose.

It is assumed that if no information is given with the apparatus, then users can install, use and maintain it without any special considerations regarding its EMC aspects, and it will still comply with the protection requirements. This is naturally the preferred default position, but the possibility exists that you could, for instance, require the use of, say, particular cables or earthing regimes if these were necessary for compliance, provided that this was made clear to the user.

The residential area limitation has been a knotty problem for the Commission for some time. It has its origins in the text of a warning notice which appears in CISPR 22/EN 55022, the IT equipment emissions standard, referring to Class A equipment:

> Such equipment should not be restricted in its sale but the following warning shall be included in the instructions for use:
>
> **Warning**
>
> This is a class A product. In a domestic environment this product may cause radio interference in which case the user may be required to take adequate measures.

This text has caused headaches for the lawyers because, properly speaking, Class A equipment should never be marketed for or used in the domestic environment. The text is in the international (CISPR) version of the standard and other non-European countries, which have varying legal requirements, do not want to see it removed. The adopted compromise has been to delete the phrase "Such equipment should not be

restricted in its sale" from the EN modified version of CISPR 22, and make it also a requirement in the new EMCD that "apparatus for which compliance with the protection requirements in residential areas is not ensured by the manufacturer has to be accompanied by a clear indication of this restriction of use".

2.2.4 Manufacturing quality assessment

The Directive covers every individual, physically existing finished product, but it would be impractical to test every item in series production fully for all the EMC characteristics that it must exhibit. The conformity assessment procedures for all the technical harmonization Directives are contained in Council Decision 90/683/EEC [181]. This document contains a range of modules which may be applied in the case of each specific Directive. However, the EMC Directive does not specifically refer to this Decision, and therefore conformity assessment requirements have been left somewhat open.

2.2.4.1 Production control

The second edition Directive requires in Annex II that "the manufacturer must take all measures necessary to ensure that the products are manufactured in accordance with the technical documentation ... and with the provisions of this Directive that apply to them". No specific means of determining what these measures might be are mentioned in either the Directive or the Council Decision.

CISPR sampling schemes

For many years before the adoption of the EMC Directive, the standards committee CISPR (see section 4.1.1.2) had recognized the need for some form of production quality testing, and had incorporated sampling schemes into the RF emission standards which form the basis of EN 55011, EN 55014 and EN 55022. The purpose of these schemes is to ensure that at least 80% of series production complies with the limits with an 80% confidence level, the so-called 80/80 rule. Practically, to comply fully with the 80/80 rule the manufacturer has to aim at about 95% of the products being in compliance with the specified limit.

The first scheme requires measurements of the actual emission levels from between 3 and 12 identical items, from which the mean and standard deviation are derived. The limit levels are then expressed in the form:

$$L \geq \overline{X} + k \cdot S_n \qquad (2.1)$$

where $\overline{X}$ is the arithmetic mean and S_n the standard deviation of the measured emission levels, and k is a constant derived from the non-central t-distribution between 2.04 and 1.2 depending on sample size

If the emission levels are similar between items (a low value of S_n) then a small margin below the limit is needed; if they are highly variable, then a large margin is needed. This sampling method can only be applied to emissions measurements and cannot be used for immunity.

A second scheme which is applicable to both emissions and immunity is based on recording test failures over a sample of units. Compliance is judged from the condition that the number of units with an immunity level below the specified limit, or that exceed the emissions limits, may not exceed c in a sample of size n, as per Table 2.1: this test is based on the binomial distribution and produces the same result as the first, in accordance with the 80/80 rule.

Table 2.1 Acceptable number of failures versus sample size n

n (sample size)	7	14	20	26	32
c (no. of failures)	0	1	2	3	4

As well as the above sampling schemes, published EN standards also allow a single test to be made on one item only, but then advise that subsequent tests are necessary from time to time on samples taken at random from production. The "one item only" dispensation is, of course, used in the vast majority of cases, although manufacturers with a high production volume and, especially, their own in-house test facilities, may well carry out some sample testing to reinforce and protect their compliance position.

Significantly, according to the CISPR standards the banning of sales is to occur only after tests have been carried out in accordance with one or other sampling scheme. This appears to put an onus on the enforcement authorities always to carry out testing of multiple samples in their market surveillance campaigns.

2.2.5 Fixed installations

The question of how the EMCD applies to installations has been an issue ever since the original Directive was under discussion:

> ... Finally, there is something of a problem concerning systems comprising assemblies of apparatus. In some cases, the EMC of a system can differ from the EMC of its constituent parts, and a system which is marketed as such requires separate certification under the Directive. To a large extent, the problems can be resolved by ensuring that the standards contain adequate practical test methods for systems, but some systems can only be tested "in situ" – ie long after the marketing stage. A similar problem applies to "one off" items of large capital equipment. We are trying to obtain clarification of the legal implications and will report back.
>
> *John Ketchell, DTI, 28th February 1989, in a circular to interested parties regarding progress on the negotiations prior to introducing the EMC Directive*

> The application of the EMC Directive to installations is, from the experience obtained over the last four years, a very controversial issue.
>
> *EC Guidelines on the application of the EMC Directive, July 1997, section 6.5.2.1*

Throughout the life of the first EMCD, systems and installations have been a bone of contention. So it is hardly a surprise that the biggest effect of the second edition is to substantially change the compliance regime for installations.

2.2.5.1 Changes in the second EMCD

The second EMC Directive has a separate section on fixed installations, defined as follows:

> Fixed installation means a particular combination of several types of apparatus and, where applicable, other devices, which are assembled, installed and intended to be used permanently at a predefined location

This distinguishes a fixed installation from a mobile installation, which has its own definition as "a combination of apparatus and, where applicable, other devices, intended to be moved and operated in a range of locations", and which is subject to the same compliance regime as other apparatus. A fixed installation has to be installed applying "good engineering practices" and respecting the information on the intended

use of its components, with a view to meeting the protection requirements. Those good engineering practices are to be documented, and the documentation held by the person(s) responsible for as long as the fixed installation is in operation. However, fixed installations do not need to be CE marked or subject to a declaration of conformity. Also, apparatus that is intended for incorporation into a specified fixed installation does not have to comply with certain aspects of the Directive.

This represents a significant change in the way that fixed installations and the apparatus that goes into them are regulated. Not all of the implications are yet clear, but one is that operators of installations will have to designate a "responsible person" who has responsibility for the establishment of compliance of a fixed installation with the relevant essential requirements. This will be new to most if not all such operators. Another is that the vague term "good engineering practices" will have to be fleshed out; at present there are no harmonised standards for installations, but the Commission clearly envisages that some will have to be created.

The principal dilemma of applying the Directive to complete installations is that to make legally relevant tests is difficult, but the nature of EMC phenomena is such that to test only the constituent parts without reference to their interconnection is meaningless. Two main possibilities have been explored in TCFs under the first EMCD. The first is to ensure that the system is built out of individual items which are themselves compliant, and that the method of installation follows suppliers' instructions such that this compliance is not breached. The TCF would reference installation drawings and work instructions that ensure this. This approach is continued and expanded in the new regime.

The alternative has been to perform limited site testing once the installation has been assembled to show that it is compliant. Since this would be less comprehensive, it would need to be balanced by a greater amount of documentation in the form of a matrix defining the EMC threats and a rationale for the claim to compliance, including a justification for the tests that were done. The new regime does not mention testing in any specific way.

2.2.5.2 Scope

The definition shown above for a fixed installation distinguishes it from a large system (discussed below in section 2.2.6) in that it is not a single functional unit, that is, it is "a particular combination of several types of apparatus", and it is not placed on the market and cannot enjoy "free movement" around the EU: it is "assembled, installed and intended to be used permanently at a predefined location". The phrase "intended to be used permanently" has caused problems in interpretation; some people have thought that it meant being used 24 hours a day. Actually, the likely interpretation (still to be fully accepted at the time of writing) is related to duration. The requirement would be fulfilled if it were intended at the time of putting into service that the constituent parts were to be used in the defined location for their expected lifetime. If they were expected to be moved for use at another location, it would not.

It is recognized that modifications will be made to fixed installations throughout their operational life, and such modifications would not invalidate the original intent. Indeed, many such installations (such as telecommunications centres) are in a continuous state of modification, and the legislation cannot be drafted in such a way as to prevent this. But the implication of the requirements are that the EMC dimension of such modifications must always be taken into account and properly documented.

One problem that arises when considering fixed installations is what the boundaries of the installation are, and therefore what parts have to be considered – and indeed, what

entity should take responsibility for it. For instance, in a campus with a network of power supplies and telecommunication lines, where is the physical "edge" of the installation? Sometimes the service entrance of the conductors can be easily located, but not always, and this certainly doesn't define the boundary for radiated phenomena. Knowing the boundary should enable the electromagnetic environment to be defined, but there will be many examples where the boundary is fuzzy at best. The question also introduces the idea of "nested" installations, that is, smaller installations within a larger one, with different boundaries and responsibilities. The DTI's draft guidance wryly points out that in the case of interference between installations in such a situation, "it is likely that only by further co-operation between the responsible persons will a solution be able to be found".

There is another consequence of the generalized definition given above, which if pursued to its logical end could have dramatic consequences. This is that there is no effective lower limit on the size or extent of the installation. It is clear, historically, that the definition was meant to encompass large premises such as telecommunication centres, factories, power stations or substations, and so forth. But actually, any location which has "a particular combination of several types of apparatus" that are intended only for that location would fall within the scope, and therefore need a responsible person and a documentation of good practice. It is possible that this definition could extend down to the level of individual shops, offices and even homes, if electrical or electronic equipment is installed in them which is specific to that one location. Such a possibility is not excluded by the EC's draft guidance, which suggests "The definition covers all installations from the smallest residential electrical installation through to national electrical and telephone networks, including all commercial and industrial installations."

2.2.5.3 The responsible person

Annex I of the EMCD requires that

> good engineering practices shall be documented and the documentation shall be held by the person(s) responsible at the disposal of the relevant national authorities

and Article 13.3 says

> Member States shall set out the necessary provisions for the identifying the person or persons responsible for the establishment of compliance of a fixed installation

In the UK, the DTI has drafted a definition of the responsible person as the person who, "by virtue of their ownership or control of the relevant fixed installation is able to determine that the configuration of the installation is such that when used it complies with the protection requirements". It is accepted that this may be a different entity according to circumstances. For example in some cases it could the site owner, in others the operator of the installation, in others the maintainer of the installation, and so on. Operators will need to identify the responsible person before the installation is taken into service, and often this will have to be determined contractually.

The implication of the DTI's definition above is that whoever the entity turns out to be for a given case, they will need to have a sufficient understanding of the EMC issues raised by the installation to be able to make the required judgement, as well as having sufficient seniority to be able to take on the required responsibility. As a matter of simple observation, such individuals, groups or departments rarely exist in typical organizations that administer installations, although there are exceptions: for instance large telecom organizations will usually have the technical capability in-house, as will

groups in some sectors that already deal with installation EMC, such as the railway industry as discussed in section 5.4.

Consequently, we can envisage either of two outcomes:

- either organizations will take their responsibilities seriously, and appoint or employ an individual, a consultant or an in-house group to deal with the likely proliferation of documentation that the new regulations imply; or
- comprehension of the scope and implications of the new regulations will be so minimal, and their enforcement so weak, that little if anything will be done to bring installations into compliance with the new regulations.

2.2.5.4 Good engineering practices

There is no definition in the EMCD of what is meant by the phrase "good engineering practices", except that by implication they are capable of being documented. There are various good practices that have been established for electrical installations, for instance in the UK the IEE's Wiring Regulations, now enshrined in BS 7671; but these have nothing significant to say about EMC and certainly wouldn't be useful in complying with the essential requirements. It is an emerging consensus that what is meant is "good *EMC* engineering practices", but this leaves the field wide open for interpretation. To date, such interpretation has been highly generalized, pointing at best to a few IEC documents such as those in the IEC 61000-5 series and to the existence of some books on the subject, a canon to which this author amongst others has already contributed [22]. Much of the more detailed material in fact applies to military systems and would be irrelevant or hard to apply in the context of the EMC Directive.

Certainly, it seems very unlikely that any responsible person would be prosecuted for non-compliance on the basis that their documented engineering practices were actively bad for EMC; even if this were to be the case, actually proving it in a court of law would be expensive and uncertain in outcome at best. For instance, many system designers and installers use traditional engineering practices that they assume are good, such as single-point earthing and terminating cable screens at one end only using long lengths of wire, when in fact these are inimical to good EMC at the frequencies of interest for the EMCD's protection requirements. To prove the case, though, would require long, involved and probably inconclusive technical arguments that would not be compatible with an effective enforcement action. What is left is the requirement to "respect the information on the intended use of components", and this boils down to ensuring that if any such components include strictures on their installation and operation that have relevance for EMC, these should be observed and the fact that they have been observed should be documented.

The level of detail that is needed in the documentation will vary according to the complexity of the fixed installation. It should be sufficient to enable an enforcement authority to determine whether good practices have been followed. When interpreting this requirement, you should bear in mind that enforcement authorities (certainly in the UK) are not experts in EMC.

One point to note about the good practices that might be adopted is the distinction between intra-system and inter-system EMC, as already discussed in section 1.2. The EMCD is only concerned with interference between the fixed installation and the outside world, that is, *inter*-system EMC. So, although of great interest to the owner and operator of the installation, good practices for *intra*-system EMC, which are intended only to ensure mutual compatibility of the various parts of the installation, are of themselves not relevant for the EMCD.

2.2.5.5 Specific apparatus

Apparatus that is intended for incorporation into a specified (named) fixed installation – and not otherwise commercially available to an end user as a single functional unit – does not have to comply with:

- the essential requirements;
- the conformity assessment procedure;
- the technical documentation and EC declaration of conformity – but some technical documentation is required;
- CE marking.

The basis for this difference is that it is not necessary, and sometimes not possible, to carry out a conformity assessment for apparatus that is intended solely for a specific fixed installation, in isolation from that installation. This exemption cannot be used for apparatus which may become available in a general sense. Apparatus can only benefit from it if there is a direct link between the manufacturer of that specific apparatus and those responsible for the fixed installation for which that apparatus is intended. A relationship, probably contractual, between the provider and the customer is required. The information requirements remain, that is, the apparatus must be fully identified and include the name and address of its manufacturer; and it needs to document exactly which fixed installation it is intended for "and its EMC characteristics" and must indicate "the precautions to be taken for the incorporation of the apparatus into the fixed installation in order not to compromise the conformity of that installation".

The reference to EMC characteristics of the installation implies that the manufacturer of such apparatus must be familiar with the installation's electromagnetic environment. The level of detail needed, and the form that the information should take, is not given: it could mean as little as classifying the fixed installation as having a domestic, commercial, light-industrial, or industrial electromagnetic environment as per the generic standards; but this would hardly be enough to design a product that would not compromise the compliance of the installation. Similarly, indicating the precautions to be taken for EMC may simply mean listing well-known EM mitigation measures and letting the installer decide what to do; or it could mean giving the installer clear and detailed instructions for every aspect of the installation. Both of these issues are so novel, and the available guidance so limited, that for the present it is hard to see how an acceptable general practice could be developed to deal with the requirements.

The Commission's draft guidance envisages a number of instances where the exemption for specific apparatus might be used:

- specific apparatus made according to particular specifications and intended for a fixed installation or installations considered as equivalent by the manufacturer;
- apparatus designed according to a specification given by a customer, intended for a given fixed installation;
- apparatus derived from a generic model adapted to the specific need of the customer or to the specificity of any particular location, in a fixed installation;
- apparatus made in small series and delivered for incorporation into a well-defined type of installation, each item necessitating appropriate EMC adjustments at the final location.

2.2.6 Systems

A fixed installation cannot "enjoy free movement" within the EEA, in contrast to a system (or a moveable installation) which can. A typical system might be a personal computer workstation comprising the PC, monitor, keyboard, printer and any other peripherals. If the units were to be sold separately they would have to be tested and certified separately; if they were to be sold as a single package then they would have to be tested and certified as a package.

The definition unfortunately does not help system builders who will be "placing on the market" – i.e. supplying to their customer on contract – a single system, made up of separate items of apparatus but actually sold as one functional unit, not necessarily intended for a pre-defined location. Many industrial, commercial and public utility contracts fall into this category. According to the published interpretation, the overall assembly should be regarded as a system and therefore should comply as a package. As it stands at present, there are no standards which specifically cover large systems, i.e. ones for which testing on a test site is impractical, although some emissions standards do allow measurements in situ. These measurements are themselves questionable because of the difficulty of distinguishing external interference at the measurement position from that due to the installation, and because the variability of the physical installation conditions introduces reflections and standing waves which distort the measurement. There are no provisions for large systems in the immunity standards. Therefore the EMC assessment has to be performed in the absence of standards, but there is little guidance as to how to interpret the Directive's essential requirements in these cases.

2.2.7 Implementation, enforcement and sanctions

Member States cannot impede for EMC reasons the free circulation of apparatus covered by the Directive which meets its requirements when properly installed and maintained, and used for its intended purpose. They must presume that apparatus which bears the CE mark, and for which the manufacturer has performed and documented an EMC assessment, does in fact comply with the protection requirements unless there is evidence to the contrary.

On the other hand, Member States are required to ensure that equipment which is found not to comply is not placed on the market or taken into service, and to take appropriate measures to withdraw non-compliant apparatus from the market. Legislation which translates the Directive's requirements into national law in each Member State was required to be in place by 20th January 2007.

In the UK the enforcement regime includes the issue of "suspension notices" which prohibit the supply or use of specified equipment that the enforcement authorities believe does not comply with the EMC requirements. The notice may or may not have immediate effect, depending on the urgency of the situation; an appeal procedure allows persons on whom a notice is served to make representations for it to be revoked. Enforcement authorities can also apply to a court for forfeiture of apparatus, with its consequent destruction, modification or disposal, and officers of the enforcement authorities may be empowered to enter premises and inspect or seize apparatus and documents.

2.2.7.1 Offences

The EMC legislation does include criminal sanctions. But because of the difficulty of judging whether or not apparatus actually complies with the requirements, the UK

legislators have not created an absolute criminal offence of supplying or using non-compliant equipment. Users and retailers cannot normally be expected to know whether or not the apparatus in question is non-compliant. Criminal offences on other fronts are necessary, for instance to guard against misuse of the CE mark or the provision of false or misleading information, and to penalize breaches of prohibition notices.

2.2.7.2 Practice

Two important questions are: how is enforcement operated in practice, and is the Directive enforced equally in all Member States (the so-called "level playing field"). These questions are directly related to the resources that national governments are prepared to devote to the task. The UK DTI has previously indicated that its enforcement efforts are complaint-driven. As well as investigating interference complaints arising from actual use of apparatus, it is open to complaints that apparatus does not conform to the Directive's requirements regardless of whether or not there is a problem in its use. A possible source of complaint will therefore be from companies testing samples of their competitors' equipment and, if they find that it does not comply, "shopping" them to the authorities. It is also likely, though, that such complaints will need to be backed by serious evidence of non-compliance before the authority will take them seriously.

On the other hand, the German authorities have stated that it is necessary to gain information from the market in the form of random spot checks in order to react to violations [115]. Germany already had a strong regime for the control of RF emissions before the first EMCD in the form of the mandatory VDE standards, and these were stricter than the EN standards which are now used to demonstrate compliance with the Directive. The Germans have been concerned that the Directive might dilute the effectiveness of their previous regime, and have therefore insisted that it is thoroughly enforced.

It is apparent that differences in enforcement practices within the various Member States work contrary to the stated intent of the Directive, which is to reduce technical barriers to trade. Article 10 of the Directive requires that "where a Member State ascertains that apparatus bearing the CE Marking does not comply with the [protection] requirements, it shall take all appropriate measures to withdraw the apparatus from the market, prohibit its placing on the market or restrict its free movement", and shall immediately inform the Commission of any such measure. If the Commission finds, after consultation, that the action is justified, it will inform all other Member States. The competent Member State shall then take appropriate action against the author of the attestation. Therefore any Member State can take immediate action to prohibit an offending apparatus from its own market, but sanctions against the company that put the apparatus on the market in another Member State are dependent on the deliberations of the Commission and on the enforcement practices of the latter Member State.

2.2.7.3 Interpretation

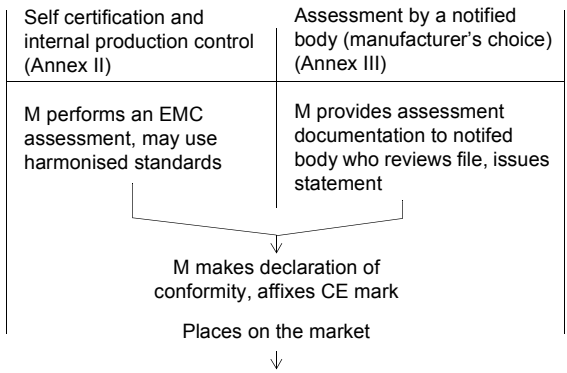
As has already been indicated, the Directive is so widely drawn that many of its provisions have to be the subject of interpretation. You might expect that this interpretation would be the function of the EC or of the national implementing authorities, but it has been remarkably difficult to obtain answers to detailed questions of interpretation from such authorities, especially so when there is a technical dimension to the question. The 1997 Guidelines gave considerable interpretive help, but do not cover many more abstruse technical issues.

The new Directive also has a guidance document, a draft of which [192] is referred to at various points throughout this chapter. The intent of this is that it should have been available in advance of Member States' transposition of the Directive into their own laws, so that such transposition took place more uniformly than was the case for the first Directive. Because of the delays and contention in creating the document, this has happened only imperfectly. Furthermore, it is intended as an internet-based document, partly for ease of access and linking to other sources of information, but also so that it can be readily updated if the need arises. This latter aim may not be seen entirely as an advantage by its users, who generally would like such guidance to be consistent rather than fluid, but the Commission is distinctly in favour of it.

In the UK, a group known as the EMC Test Laboratories Association (EMCTLA) was formed primarily to ensure a reasonable uniformity of approach to the assessment of technical construction files under the first EMCD by different competent bodies. Within that association, a working group has been set up which responds to queries regarding the implementation of the Directive and issues technical guidance notes which have a reasonably wide circulation, and which can form the basis for a uniform interpretation. These guidance notes are available via the EMCTLA's website; many are still relevant, despite the removal of the TCF route. The EMCTLA has been instrumental in founding a pan-European Association of Competent Bodies which is intended to spread this uniform approach within the EU.

2.3 Compliance of apparatus with the Directive

Of themselves, the essential protection requirements are too generalized to enable manufacturers to declare that their product has met them directly. So Annexes II and III of the Directive provide a more detailed route (Figure 2.2) for manufacturers to achieve compliance with them.



M: manufacturer, authorized representative within the EU, or person who places apparatus on the EU market

Figure 2.2 Routes to compliance

2.3.1 Self certification and internal production control

The route which is expected to be followed by most manufacturers is that given in Annex II, known as self certification with internal production control. This requires you as the manufacturer firstly to perform

> an electromagnetic compatibility assessment of the apparatus, on the basis of the relevant phenomena, with a view to meeting the protection requirements ... The electromagnetic compatibility assessment shall take into account all normal intended operating conditions. Where the apparatus is capable of taking different configurations, the electromagnetic compatibility assessment shall confirm whether the apparatus meets the protection requirements ... in all the possible configurations identified by the manufacturer as representative of its intended use.

On the assumption that the assessment does indeed confirm that the apparatus meets the protection requirements, you then have to

> draw up technical documentation providing evidence of the conformity of the apparatus with the essential requirements of this Directive, [and] hold the technical documentation at the disposal of the competent authorities for at least ten years after the date on which such apparatus was last manufactured.

This documentation requirement is no more than you would have done under the first edition of the Directive, since you would have kept your own CE Marking documentation on file for your own purposes, whether or not you ever involved a third party such as a Competent Body. In other words, there is little change so far from the first Directive. Having developed the documentation, you then make the Declaration of Conformity and prepare to retain that also for ten years. You are then free to apply the CE Mark and market the apparatus, ensuring that each product is manufactured in accordance with the technical documentation and in compliance with the essential requirements (hence, "internal production control").

2.3.1.1 The EMC assessment

We now have to interpret what is meant by the phrase "EMC assessment". Annex II.1 specifically refers to "on the basis of the relevant phenomena, with a view to meeting the protection requirements". It also makes clear that the assessment must cover all configurations and normal operating conditions. In the first edition of the Directive, either you had to apply harmonised standards or you had to generate a Technical Construction File and run it past a Competent Body. In this new regime, all the responsibility of what to do is in your hands. The Commission's view is, fairly clearly, that having let manufacturers in gently with the first EMCD, the time has come for them to grow up and deal with the EMC of their products on their own.

Use of harmonised standards in the assessment is not mandatory, but if they are not used or are used only in part, you then have to decide how you are going to show that the protection requirements have been met. This means that the assessment will have to look at least at:

- a description of the apparatus' operating conditions and its intended use;
- the environments in which the apparatus will be used;
- the electromagnetic phenomena covered and compatibility levels applied;
- the performance criteria of the apparatus;
- test plan, including techniques, emissions limits and imunity stress levels;
- EMC design and installation techniques used;

- the user's information requirements, including any restriction (or not) on use in residential areas, and any precautions on installation;
- definition of the test selection matrix for variants, using worst case criteria.

Clearly, in the absence of other guidance, this could be a substantial exercise in its own right. So at this point, the Directive refers you to standards.

2.3.1.2 Application of harmonised standards

Annex II.1 says

> The correct application of all the relevant harmonised standards whose references have been published in the Official Journal of the European Union shall be equivalent to the carrying out of the electromagnetic compatibility assessment.

Article 6.2 goes on to say

> The compliance of equipment with the relevant harmonised standards whose references have been published in the Official Journal of the European Union shall raise a presumption, on the part of the Member States, of conformity with the essential requirements referred to in Annex I to which such standards relate.

But

> 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).

Harmonised standards are those CENELEC, CEN or ETSI standards which have been announced in the *Official Journal of the European Union* (OJEU). In the UK these are published as BS EN standards, and each Member State has a similar system, administered by its own national standards body, for publishing them. They are not available from CENELEC itself, although ETSI ones can be obtained (for free) direct from ETSI. The most widely used ones are detailed in Chapter 4, and section 2.3.4 covers the use of standards.

The potential advantage of using standards in the EMC assessment from the manufacturer's point of view is that the assessment process is simplified. There is no mandatory requirement for testing by an independent test house. The only requirement is that the manufacturer makes a declaration of conformity (see section 2.2.3.2) which references the standards against which compliance is claimed. Of course the manufacturer will normally need to test the product to assure himself that it actually does meet the requirements of the standards, but this could be done in-house. Many firms will not have sufficient expertise or facilities in house to do this testing, and will therefore have no choice but to take the product to an independent test house. This is discussed further in sections 2.3.3 and 16.3. But the long-term aim ought to be to integrate the EMC design and test expertise within the rest of the development or quality department, and to decide which standards apply to the product range, so that the prospect of self certification for EMC is no more daunting than the responsibility of functionally testing a product before shipping it.

2.3.1.3 The technical documentation

The documentation needs to support the case that you have made using the EMC assessment for meeting the protection requirements for any particular product. One requirement for placing on the market in the draft UK regulations is that "the technical documentation has been prepared and is available".

Contents

Annex IV of the Directive specifies the general content of the documentation, whose overall purpose is "to enable the conformity of the apparatus with the essential requirements to be assessed". The content includes:

- a general description of the apparatus (one purpose of this is to allow an unambiguous link between the actual apparatus and the documentation);
- evidence of compliance with the harmonised standards, if any, applied in full or in part;
- where the manufacturer has not applied harmonised standards, or has applied them only in part, a description and explanation of the steps taken to meet the essential requirements of the Directive.

The third of these of course is the record of the EMC assessment described in 2.3.1.1. Notice that the second requirement is for "evidence" of compliance with standards; this may well not mean a full test report. What constitutes a minimum of "evidence" has yet to be ascertained.

As we have already mentioned, the products that are placed on the market must be "manufactured in accordance with the documentation". Since products change and develop over their lifetime, this means that the documentation should keep pace: as is necessary in any case, you will need to assess engineering changes for their EMC implications. Any that ripple through to affect the content of the technical documentation should result in appropriate changes to it.

Whilst the purpose of the documentation is clear enough, what is not clear is who will be doing the assessment of conformity with the essential requirements – in other words, who is the documentation being written for? Will it be an enforcement officer who has just a sketchy knowledge of EMC technicalities, or will it be an EMC consultant who is prepared and able to pick holes in even the densest material? Presumably, this will depend on the context of whatever enforcement action is being taken; so it is up to you as technical author to anticipate this context and set the technical level of the documentation appropriately.

2.3.2 The notified body

A substantial change between the first and second editions of the Directive is the removal of the old Technical Construction File route to compliance, and the concomitant disappearance of Competent Bodies. Instead, we now have Notified Bodies (NBs) and their use by the manufacturer is entirely voluntary.

Annex III of the Directive describes the use of Notified Bodies (Annex II is the self certification/internal production control procedure discussed above):

> 1. This procedure consists of applying Annex II, completed as follows:
>
> 2. The manufacturer or his authorised representative in the Community shall present the technical documentation to the notified body referred to in Article 12 and request the notified body for an assessment thereof. The manufacturer or his authorised representative in the Community shall specify to the notified body which aspects of the essential requirements must be assessed by the notified body.
>
> 3. The notified body shall review the technical documentation and assess whether the technical documentation properly demonstrates that the requirements of the Directive that it is to assess have been met. If the compliance of the apparatus is confirmed, the notified body shall issue a statement to the manufacturer or his authorised representative in the Community confirming the compliance of the apparatus. That statement shall be limited to those aspects of the essential

requirements which have been assessed by the notified body.

4. The manufacturer shall add the statement of the notified body to the technical documentation.

There are a number of features to point out here.

2.3.2.1 The primacy of the manufacturer

Not only is it entirely at the manufacturer's discretion whether or not to use an NB, but the manufacturer tells the NB what to do, not *vice versa* (Annex III.2). You may choose to ask an NB to assess the documentation as a whole, covering the totality of the essential requirements, or only in part. Of course, the statement that the NB issues will only cover those aspects that it has reviewed. So, for instance, you may be entirely comfortable with your compliance with emissions limits but you may want an opinion on how the product complies with the immunity requirements.

The NB only provides a "statement", and only if the compliance is confirmed. The statement has to be included with the technical documentation, but there is no indication that there is any responsibility on or ability of the NB to prevent the manufacturer placing the product on the market if it believes that compliance is not confirmed; that remains firmly the responsibility of the manufacturer. Manufacturers are free to choose any NB. There is no need to choose an NB located in the country where the apparatus is manufactured, nor in the country to which the apparatus will be shipped, marketed or taken into service. If the manufacturer has used the services of an NB for one of his products there is no obligation to use the same NB for another one, or for modifications of the originally assessed product.

A manufacturer may consult more than one NB simultaneously in respect of any apparatus: there is no prohibition on this, and the NB's opinion is not binding. In other words, it is apparently legitimate to "shop around", should you so desire, until you get a favourable opinion.

The Directive at Article 12 specifies how NBs are to be appointed. The requirements are similar to those for Competent Bodies under the first Directive, but sufficiently different that it is unclear as to whether all such existing Competent Bodies will choose to or be able to convert to NB status. An NB can only render services within its scope of designation which may be limited to certain categories of apparatus, certain essential requirements or certain other specific aspects. But for the time being there are no agreed criteria within the EU for the definition of "scope of designation"; different countries are likely to have different ideas.

2.3.2.2 When would a manufacturer use an NB?

At first sight, there seems to be little point in consulting an NB. It adds expense, but has no teeth and is not a requirement of the process.

A common use of the TCF route and the involvement of a Competent Body under the first edition Directive was to certify the compliance of a fixed installation. As we have seen, the requirements for installations have changed drastically, and Notified Bodies have no role in assessing the good practice documentation that is required, even though that would be one of their most useful functions, and one in which (as Competent Bodies) they actually have gained some experience. Their role is limited entirely to assessing the compliance of *apparatus*.

The NB cannot perform the product's EMC assessment or generate the technical documentation itself: in no way does it supplant the Annex II procedure, which remains firmly in the hands of the manufacturer. The NB is, in fact, required to be independent in the process of "preparing the reports and performing the verification function". (This

may not stop you contracting one NB to create the documentation and another to assess it, if you are prepared to sign up to the result.)

The main driving force for involving an NB will be where the manufacturer requires reassurance by a third party to increase his confidence in the compliance process, or where the equipment is so complex that its assessment requires expert guidance. In most cases, this could be done by any competent EMC consultant; the use of an NB merely gives the imprimatur of appointment by the statutory authority. However, the NB statement can be seen as a shield against future enforcement action, and some manufacturers will be prepared to pay for such insurance. It may also be viewed in a few cases as an extra marketing tool.

2.3.3 Testing

Except in the case of benign products, which it is clear will intrinsically not cause interference or be susceptible to it, such as an electric fire or pocket torch, each manufacturer will need to submit products to some degree of EMC testing to be sure that they comply with the Directive. Later chapters consider EMC test methods in detail. To cover the eventual requirements of the standards, the scope of the tests will need to include mains harmonic, conducted and radiated RF emissions, plus immunity to RF, transients, electrostatic discharge and supply disturbances. A test facility to address all these phenomena at compliance level is beyond the budget of all but the largest companies. Not only are a screened room and/or an open area test site and all the test equipment needed, but also the staff to run the facility – which itself requires a level of skill, experience and competence not usually found in most development or test departments. A large company may have the product volume and available capital which allows investment (of the order of £1m) in an in-house facility of this nature, and there are several such companies throughout Europe who have taken this step. The EMCD places no external constraints on the operation of these in-house test facilities. The management options for, and approaches to, testing are discussed in section 16.3.

2.3.4 Using standards

Compliance with harmonised standards is “equivalent to” the performance of the EMC assessment (see 2.3.1.2). This mechanism depends on the availability of standards which can be applied to the product in question. The detail of the appropriate standards is covered in Chapter 4; this section will discuss their general availability and applicability.

Prior to the adoption of the first EMC Directive, the EMC standards regime had developed in a somewhat piecemeal fashion. The existing standards fell into a number of categories:

- RFI: intended to protect the radio spectrum from specific interference sources, such as information technology equipment, motor vehicle ignition, household appliances or fluorescent lights
- mains emissions: specifically harmonic currents and short-term variations, to protect the low-voltage power distribution network
- product- and industry-specific: to ensure the immunity from interference of particular types of product, such as process instrumentation or legal metrology, or to regulate emissions from equipment that will be used in a specific environment, such as marine equipment

These standards are not over-ridden by the Directive; those which have been harmonised by CENELEC may be applied to products within their scope and are regarded as adequate to demonstrate compliance, at least as far as their scope and coverage of the essential requirements allows.

2.3.4.1 The generic standards

In the early days of the EMC Directive, there were many industry sectors for which no product-specific standards had been developed. This was especially so for immunity, which was a new concept for many products. In order to fill this gap wherever possible, CENELEC gave a high priority to developing the Generic Standards. 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. They are divided into two groups, one for immunity and one for emissions, each of which has separate parts for different environment classes (Table 2.2).

Table 2.2 The generic standards

Environment	Residential, commercial and light industry	Industrial
Emissions	EN 61000-6-3	EN 61000-6-4
Immunity	EN 61000-6-1	EN 61000-6-2

Where a relevant product-specific standard does exist, this takes precedence over the generic standard. It is quite common, though, for a particular product to need a variety of standards. For instance, a fire alarm may be covered by one product standard for mains harmonic emissions, another for immunity, and the generic standard for emissions. All these standards must be satisfied before compliance with the Directive can be claimed. Although a comprehensive range of product standards has been developed, other mixed combinations still occur and there will always be unusual products that "fall through the cracks".

Environment classes

The distinction between environmental classes is based on the electromagnetic conditions that obtain in general throughout the specified environments [128]. The inclusion of the "light industrial" environment (workshops, laboratories and service centres) in class 1 has been the subject of some controversy, but studies have shown that there is no significant difference between the electromagnetic conditions at residential, commercial and light industrial locations. 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.

2.3.4.2 Performance criteria

A particular problem with immunity is that the equipment under test may exhibit a wide variety of responses to the test stimulus. This can range from a complete lack of response, through a degradation in the accuracy of measured variables to total corruption of its operation. The same problem does not exist for emissions, where comparison with a defined test limit is possible. To account for this variety, the generic immunity standards include three generalized performance criteria for the purpose of

evaluating test results. In the test report, you must include a functional description and a specific definition of performance criteria based on these, during or as a consequence of the EMC testing. The definitions of these criteria can be found in section 9.3. Most noteworthy is that the criteria are grounded on what performance the user may reasonably expect *or is told to expect*. In other words, if you specify a given performance loss during application of the immunity test and write this into the user documentation, then provided the equipment does not actually become unsafe as a result of the test, you have met the requirements of the generic standards.

2.3.4.3 Basic and product standards

The tests defined in the generic standards are based only on internationally approved, already existing standards. For each electromagnetic phenomenon the test procedure given by such a standard is referenced, and a single test level or limit is laid down. No new tests are defined in the body of any generic standard.

Those standards which are referenced in the generic standards, for example the various parts of EN 61000 along with some of the CISPR standards, are known as "basic" standards. This means that such standards are entirely devoted to aspects of EMC that will prove to be of general interest and use to all committees developing other standards – for instance, product-specific standards. Generally, a product-specific standard will take a form similar to the generic standard, with similar limits, but will be more specific as regards operational modes and configurations, and about performance criteria that are considered acceptable. It will refer to the basic standards for the test methods wherever possible.

2.3.4.4 Harmonisation

The discussion in this chapter has repeatedly referred to standards as being "harmonised". This has a special meaning under the EC's New Approach, which covers the EMC and R&TTE Directives as well as many others. The meaning and structure is comprehensively outlined in the Commission's "Blue Guide" [179], which covers the implementation of New Approach Directives. In summary:

> Harmonised standards are European standards, which are adopted by European standards organisations, prepared in accordance with the General Guidelines agreed between the Commission and the European standards organisations, and follow a mandate issued by the Commission after consultation with the Member States. European standards are technical specifications adopted by European standards organisations for repeated or continuous application, with which compliance is not compulsory. According to the internal rules of these organisations, European standards must be transposed at national level. This transposition means that the European standards in question must be made available as national standards in an identical way, and that all conflicting national standards must be withdrawn in a given period.
>
> Harmonised standards in the meaning of the New Approach are deemed to exist when the European standards organisations formally present to the Commission the European standards elaborated or identified in conformity with the mandate. Harmonised standards are not a specific category amongst European standards. The terminology used in New Approach directives is a legal qualification of technical specifications existing as European standards, but to which a special meaning has been given by these directives.

From this, you can see that international (IEC) standards by themselves cannot be harmonised; only their European editions can be. Harmonised standards provide a *presumption of conformity* with the essential requirements, once their reference has been published in the *Official Journal of the EU*. The objective of publishing the reference is to set the earliest date for the presumption of conformity to take effect, and

the entry in the OJ includes this information. The OJ listing is updated at occasional intervals, and the most recent can be found via links on the EC's Europa website.

In fact, because of this system, publication in the OJ assumes a considerable importance especially when difficulties have arisen with the application of a particular standard, and it has been amended or revised to take these into account. You cannot legitimately use a new version of a standard until it has been harmonised by an OJ listing. In 2005 and 2006 a complex situation arose with the application of EN 55022 which was exacerbated by the Commission's failure to publish necessary updates in any reasonable timescale, and indeed to introduce errors when it did. It's probably fair to say that the resulting quagmire has severely tested many participants' faith in the compliance system as it now exists.

2.3.4.5 Presumption of conformity

The meaning of this term is important: it says that if you correctly apply all relevant harmonised standards, it is to be *presumed* that you comply with the Directive's essential requirements; but it doesn't *guarantee* that you do. There may be deficiencies in a standard even if you apply it correctly, which mean that it is possible for a product still to cause or suffer from interference, despite complying with its requirements. Some standards have known loopholes which still exist, although their existence has been well documented for many years. Since you are required to certify compliance with the essential requirements, there will always be some element of risk which is unavoidable. The best that can be said is that an enforcement authority is likely to have a harder time proving non-compliance if you can show correct application of the standards.

The presumption of conformity is limited to the scope of the standard, and to the relevant essential requirements that are covered by the standard, and to *compliance with* (not merely application of) the standard (see 2.3.1.2). Not many standards explicitly state which essential requirements they cover, although it is slowly becoming more common as standards are updated. Just because it is listed in the OJEU, with a title that applies to your apparatus, this does not mean it covers exactly what you want it to, wholly and completely. So you still need to carry out (and document) some analysis yourself, in order to tell whether you are using an adequate standard or group of standards, or whether you need to expand the EMC assessment to cover those aspects that the chosen standard doesn't. As we see later in Chapter 9, a test plan is still needed to interpret even a comprehensive standard in the light of your particular product, so you would have had to do some such analysis anyway.

There is a further question as to what is meant by "correct application" of a harmonised standard. As discussed in section 2.2.3.5, the Directive states that this means doing everything by the book, that is, in a manner fully compliant with the methods as given in the standard. You may be prepared to do this, or to get a test house to do it for you; the cost may be justified. But if it isn't, and you use only "pre-compliance" methods of test, then your EMC assessment should include an analysis of the limitations of such methods and how you have dealt with them, since you will then only have "partially" applied a harmonised standard.

In respect of the protection requirements, the EMC Directive, at recital 13, indicates that harmonised standards are understood to "reflect the generally acknowledged state of the art as regards EMC matters in the European Union". Where harmonised standards are not employed in full, the manufacturer should have regard to the state of the art in terms of the services to be protected, and the electromagnetic disturbances to which his apparatus may be subjected.

2.4 Action for compliance for a product manufacturer

The second edition EMC Directive is all about risk. The dimensions of the risk are either that you will take insufficient measures to prove compliance with the Directive, in terms of identifying, performing the EMC assessment and testing to the correct harmonised standards, and meeting their requirements; or, you will spend so much time and effort in doing this that your product will not make it to market on time or to budget.

With this in mind, the steps to take for a new product to achieve compliance with the EMC Directive and bear the CE mark can be detailed as follows.

A. Self certification

1. From the marketing specification, determine what type of product it will be and what environment it will be sold for use within, and hence which if any product-specific or product-family standards published in the OJEU apply to it. If your company only ever makes or imports products for one particular application then you will be able to use the same product standard(s) for all products.
2. If no product standards apply, or they don't cover all the essential requirements (generally: LF disturbance emissions and immunity, transient immunity, and RF emissions and immunity), check the generic standards to see if the tests specified in them are applicable. The environmental classification will depend on the intended power supply connection.
3. If you cannot apply any harmonised standards, or can only partly apply them, then you will need to do a detailed EMC assessment of the equipment to cover the essential requirements, which may or may not involve other test methods.
4. Having determined what standards you will use, decide on the test levels and to what ports of the equipment (enclosure, power leads, signal/control leads) they will apply. In some cases there will be no choice, but in others the test applicability will depend on factors such as length of cable, EUT configuration and class of environment.
5. From this information you will be able to draw up a test plan, which specifies in detail the version and configuration of the EUT and any associated apparatus, the tests that will be applied to it and the pass/fail criteria. Test plans are covered in greater depth in Chapter 9. You can discuss this with your selected test house or your in-house test facility staff, and it will form the basis for your agreement with them and also for the technical documentation required by the provisions of the Directive.
6. Knowing the requirements of the test plan will enable you to some degree to incorporate cost-effective EMC measures into the product design, since the test limits and the points to which they will be applied will have been specified.
7. As the design progresses through prototype and pre-production stages you can make pre-compliance confidence tests to check the performance of the product and also the validity of the test plan. It is normal for both design and test plan to undergo iterative modifications during this stage.
8. Once the design has been finalized and shortly before the product launch

you can then perform, or get a test house to perform, full compliance tests against harmonised standards or against your own assessment as appropriate, on one or more production samples, the results of which are recorded in the technical documentation. Provided that confidence tests were satisfactory this should be no more than a formality.

9. You are then at liberty to mark the product, and/or its packaging or documentation with the CE mark (if there is no other Directive to satisfy) and your empowered signatory can sign the Declaration of Conformity, to be kept for ten years. If other New Approach Directives apply, a parallel process needs to be followed for each. The product can be placed on the market.
10. Once the product is in series production you must take steps to ensure that any changes to its build state allow it to continue to comply with the protection requirements.

B. Involvement of a Notified Body

This approach is in addition to the steps shown above.

11. In theory, once you have produced the full package of documentation at step 8 above, you select a Notified Body capable of assessing your type of product based on their published scope of designation, hand over the documentation to them, and expect a statement confirming compliance within a few weeks.
12. In practice, you will have chosen an NB at a much earlier stage, quite possibly from step 1 above, and confirmed with them what standards and/or what test plan content would be acceptable to them in order for them to provide a positive statement; also you will have agreed what the scope of their involvement will be, i.e. what aspects of the essential requirements they will be asked to review.