

BERR Department for Business Enterprise & Regulatory Reform

GUIDE TO THE ELECTROMAGNETIC COMPATIBILITY (EMC) REGULATIONS 2006

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Guide to the Electromagnetic Compatibility (EMC) Regulations 2006

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This guide is intended to assist manufacturers and suppliers of electronic and electrical equipment, and persons responsible for fixed installations, to understand the effect of the Regulations. It is not an authoritative interpretation of the Regulations, which is a matter for the Courts.

The guide seeks to explain the requirements of the Regulations in general terms and does not attempt to address detailed issues. You should refer to the Regulations themselves for a full statement of the requirements. A copy of the EMC Regulations can be downloaded using the link in Annex 4. Alternatively a paper copy can be obtained from the Stationery Office, Publications Office, details in Annex 4.

1 The EMC Regulations 2006 - the law in brief

1.1 Introduction

The Electromagnetic Compatibility Regulations 2006 (SI 2006/3418) ("the Regulations") apply to electrical and electronic equipment liable to cause electromagnetic disturbance or the performance of which is liable to be affected by such disturbance.

The purpose of the Regulations is to ensure that the electromagnetic disturbance generated by electrical or electronic equipment does not exceed a level above which radio and telecommunications equipment and other equipment cannot operate as intended, and that the equipment itself has an adequate level of immunity to electromagnetic disturbance.

These Regulations do not deal with safety-related matters.

In respect of the Regulations, equipment may be categorised as apparatus or a fixed installation.

Apparatus

Apparatus, in the context of the Regulations, means any finished appliance or combination of appliances made commercially available as a single functional unit, intended for the end user and liable to create electromagnetic disturbance, or the performance of which is likely to be affected by such disturbance. In some circumstances, mobile installations (see 5.2 of this guide) and components (see 5.3 of this guide) may also be considered to be apparatus. Some types of apparatus are excluded (in whole or in part) from the scope of these Regulations because they are within the scope of other Directives. Further guidance on this is given in Annex 2.

Fixed installation

A fixed installation, in the context of the Regulations, 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 pre-defined location.

The Regulations provide for separate regimes for apparatus and fixed installations; these are dealt with separately in this guide.

1.2 Basis of legislation

The Regulations implement in the UK EMC Directive 2004/108/EC. The Regulations came into force on 20 July 2007 and the previous EMC Regulations 2005, SI 2005 No. 281, were revoked and replaced from that date. The primary legislation under which the Regulations are made is the European Communities Act 1972.

1.3 Transitional arrangements

The previous EMC Regulations, SI 2005 No. 281, were revoked on 20 July 2007 as a consequence of the repeal of Directive 89/336/EEC on that date.

Apparatus

No new declarations of conformity to 89/336/EEC may be issued from 20 July 2007. Apparatus that has a valid declaration of conformity issued on or before 19 July 2007 may continue to be manufactured and placed on the market before 20 July 2009 and may subsequently be put into service at any time.

Any change to such apparatus within this two-year transitional period (20 July 2007 – 19 July 2009) that requires a new declaration of conformity will require compliance with the Regulations and the apparatus must have a declaration of conformity to the EMC Directive, 2004/108/EC. This requirement also applies to apparatus for which a referenced harmonised standard has reached its date of cessation of presumption of conformity. A new declaration of conformity referencing the new standard will consequently be required.

All apparatus placed on the market from 20 July 2009 must have a declaration of conformity to EMC Directive 2004/108/EC.

Fixed installations

The Regulations apply in respect of fixed installations that are are put into service on or after 20 July 2007.

They also apply to a fixed installation that was put into service before 20 July 2007 if it is modified after that date in a way that may affect its electromagnetic compatibility. The obligation to document good engineering practices relating to such installations will be limited to consideration of subsequent changes or additions that could affect their electromagnetic compatibility characteristics.

2 Essential requirements

The essential requirements for all equipment are set out in Regulation 4. These require that equipment shall be designed and manufactured, having regard to the state of the art, so as to ensure that

- the electromagnetic disturbance it generates does not exceed a level above which radio and telecommunications equipment or other equipment cannot operate as intended; and
- 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 specific essential requirements for fixed installations, which apply in addition to those of Regulation 4, are set out in Regulation 5. A fixed installation shall be installed

- applying good engineering practices, and
- respecting the information on the intended use of its components,

with a view to meeting the essential requirements set out in Regulation 4.

These good engineering practices are required to be documented, and the responsible person in relation to a fixed installation is required to hold this documentation at the disposal of the enforcement authority for inspection purposes for as long as the fixed installation is in operation.

There are no conformity assessment or CE marking requirements for fixed installations.

The following provides some specific guidance on aspects of the essential requirements.

2.1 Electromagnetic disturbance

An electromagnetic disturbance is any electromagnetic phenomenon which may degrade the performance of equipment. It may be, for example, electromagnetic noise or an unwanted signal.

2.2 State of the art

Regulation 4(2) requires that equipment be designed and manufactured, having regard to the state of the art, so as to meet the essential requirements. A helpful definition of the expression "state of the art" is given in ISO/IEC Guide 2 (eighth edition 2004) where it is described as the "developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience."

In the context of Regulation 4(2), it may be considered to have two aspects: the performance requirements, and the design and construction technique. It may not be necessary to employ the highest degree of design and construction technique in order to fulfil the performance requirements; the regulation requires only that regard is taken of them. A manufacturer may choose any design and manufacturing process that results in equipment meeting the essential requirements.

If a manufacturer applies the relevant harmonised standard(s) in full, this fulfils the requirement to have regard to the state of the art in the essential requirements of the EMC Directive 2004/108/EC. However, where harmonised standards are not employed, or not applied in full, a manufacturer should have regard to the state of the art in terms of the

services to be protected, and the electromagnetic disturbances to which their apparatus may be subjected.

2.3 Unacceptable degradation

A manufacturer may chose to determine whether or not their equipment suffers unacceptable degradation on the basis of whether their equipment complies with harmonised standards covering immunity requirements which set limits for acceptable degradation.

In some cases (for example, the generic standards) the scope of a standard is so wide that detailed performance criteria cannot be included. In such cases the manufacturer should make a judgement on how the criteria in the standard apply to their apparatus.

Where harmonised standards have not been employed in respect of any aspect of immunity, the manufacturer should take into account the intended purpose of the equipment, and the reasonable or stated customer expectations in assessing the immunity of their equipment.

3 Requirements for apparatus

There are a number of requirements that must be fulfilled before apparatus within the scope of the Regulations can be placed on the market:

- the apparatus must be compliant with the essential requirements
- compliance must be demonstrated by a documented conformity assessment process
- technical documentation must be prepared and available to the enforcement authority on request
- a declaration of conformity must be drawn up
- the CE marking must be applied
- manufacture of the apparatus must take place in accordance with the technical documentation drawn up by the manufacturer
- each individual apparatus placed on the market must be accompanied by the appropriate information to ensure that when put into service, the apparatus complies with the essential requirements

Attention is drawn to the need for conformity to be demonstrated, and documented in the technical documentation, and for appropriate information to be supplied with each apparatus.

Before setting out to comply with the Regulations, the manufacturer should check whether their apparatus is covered by them. Some information on excluded apparatus is provided in Annex 2 of this guide.

If the apparatus is covered by the Regulations, and is intended for supply only to a given fixed installation, and it is not otherwise commercially available, the manufacturer has the *option* of using the exemption from conformity assessment as described in 4.4 of this guide (since apparatus covered by 4.4 of this guide need not meet the essential requirements for emission and immunity in isolation from the fixed installation).

3.1 Conformity assessment

The manufacturer may choose to demonstrate compliance with the Regulations by:

- the internal production control procedure set out in Regulation 19 (see 3.2 of this guide), or
- the internal production control procedure set out in Regulation 19 followed by the involvement of a notified body as set out in Regulation 20 (see 3.3 of this guide).

These regulations do not require the involvement of a notified body even where harmonised standards are not employed in full. However, the full application of harmonised standards evidenced by a test report is the most straightforward option, and provides a presumption of conformity with the protection requirements for emission and immunity. Where harmonised standards are not employed in full, the manufacturer has to justify the compliance of the apparatus with these protection requirements by carrying out an electromagnetic compatibility assessment as described below.

A flowchart providing a summary of the process is provided in Figure 1 below.

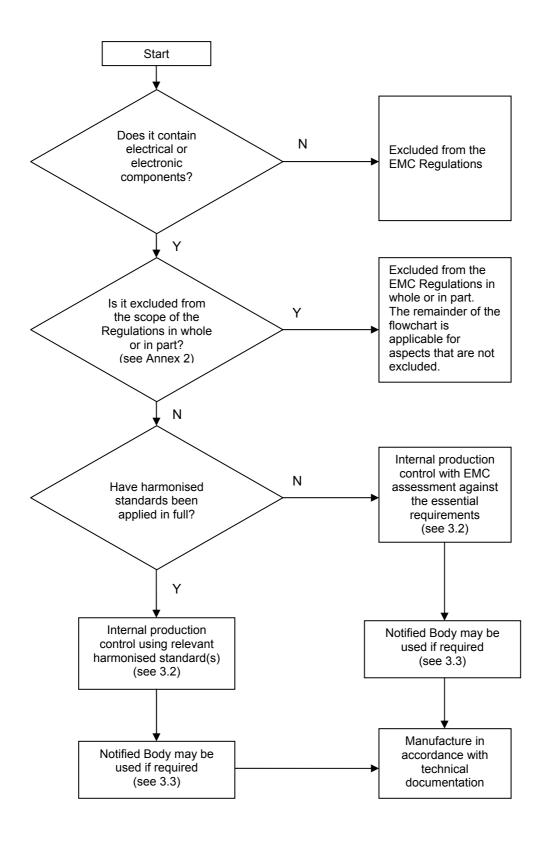


Figure 1 Conformity assessment process for apparatus

3.2 Internal Production Control (Regulation 19)

The manufacturer has to perform an electromagnetic compatibility assessment of the apparatus by

- demonstrating that the apparatus complies with all relevant harmonised standards (see 3.4), or
- performing their own assessment against the essential requirements, taking into account all normal intended operating conditions and all possible configurations that they identify as representative of intended use, or
- a combination of the above. Compliance with a harmonised standard provides a
 presumption of conformity with those parts of the essential requirements that are
 covered by the standard, so partial application of the relevant harmonised standard(s)
 provides a presumption of conformity only with those aspects covered by the part(s)
 of the standard(s) applied

The manufacturer must then draw up technical documentation in accordance with Schedule 3 of the Regulations. This must provide evidence of compliance with the essential requirements.

The manufacturer or their authorised representative must then draw up a declaration of conformity in accordance with Regulation 22.

The manufacturer must then take all steps necessary to ensure that the apparatus is manufactured in accordance with the technical documentation.

3.3 Involvement of a notified body (Regulation 19 followed by Regulation 20)

A notified body is someone appointed by the Secretary of State. Their role is to assess technical documentation to the extent required by the manufacturer. Further information is provided in Annex 3 of this guide. Under the Regulations, there is always a choice whether or not to involve a notified body.

Under Regulation 20 a manufacturer or their authorised representative may choose to involve a notified body in order to demonstrate compliance with all or some of the essential requirements relating to emission and immunity.

If a notified body is to be involved, the manufacturer completes the internal production control procedure in accordance with Regulation 19. They, or their authorised representative, then presents to the notified body the technical documentation for the aspects of the essential requirements that the manufacturer wishes to be assessed.

The notified body will review that part of the technical documentation identified for assessment. If satisfied that compliance has been demonstrated with those aspects of the essential requirements that it has been asked to assess, it will issue a statement to that effect.

The manufacturer will then add this statement to their technical documentation.

Where a notified body is minded to refuse a statement of compliance, it must inform the manufacturer in accordance with Regulation 33. This procedure also applies if the notified body wishes to vary or withdraw a statement.

3.4 Use of harmonised standards

The correct use of all relevant harmonised standards is equivalent to having performed the full electromagnetic compatibility assessment of Regulation 19(1) and 19(2). Where

harmonised standards have been applied only in part (for example for emission but not immunity) they provide this exemption only in respect of those aspects covered.

Depending on the apparatus type, there may be more than one harmonised standard applying simultaneously to provide complete coverage of the essential requirements, for example one for emission and one for immunity, and for apparatus intended to be connected directly to the public mains electricity supply network, a standard covering limits for harmonics and another for limitation of flicker.

Guidance on the selection of harmonised standards is contained in a CENELEC publication Guide 25 which is available free of charge from the CENELEC website, and the list of applicable harmonised standards and their titles, together with their dates of application may be viewed at the European Commission's website, via links provided in Annex 4.

3.5 Technical documentation, EC Declaration of Conformity and CE marking

Technical documentation

Schedule 3 of the Regulations sets out the requirements for technical documentation. There are no requirements for the format or style of the documentation, but it must enable the conformity of the apparatus with the essential requirements to be assessed.

The technical documentation must cover the design and manufacture of the apparatus in particular -

- a general description of the apparatus
- evidence of compliance with the relevant harmonised standards, if any, applied in full or in part (typically, a test report)
- where the manufacturer has not applied relevant harmonised standards, or has applied them only in part, a description and explanation of the steps taken to meet the essential requirements, including a description of the electromagnetic compatibility assessment set out in Regulation 19(1), results of design calculations made, examinations carried out, test reports, etc; and
- a statement from the notified body, when the procedure in Regulation 20 has been followed

The responsible person (the manufacturer established in the Community or their authorised representative or where the manufacturer is not established in the Community and he has not appointed an authorised representative, the person who places the apparatus on the market or puts it into service) must hold the technical documentation and where applicable, a statement from a notified body. Copies of these documents and the EC Declaration of Conformity ("DoC") must be retained by the responsible person for a period of ten years after the date on which the apparatus to which it relates was last manufactured. During this period the responsible person must make the documents available to the enforcement authority on request.

Declaration of Conformity

The manufacturer or their authorised representative must draw up a DoC that indicates that the apparatus is compliant with the essential requirements. There is no standard format for the DoC, but the information that must be provided is set out in Regulation 22 and consists of the following:

- a reference to the EMC Directive;
- identification of the apparatus to which it refers
- the name and address of the manufacturer and where applicable, the name and address of their authorised representative
- a dated reference to the specifications under which conformity is declared to ensure the conformity of the apparatus with the provisions of the EMC Directive
- the date of that declaration; and
- the identity and signature of the person empowered to bind the manufacturer or their authorised representative

Note that the fourth bullet point uses the word "specifications" rather than "standards". This is deliberate, and the requirement includes any identifiable specification employed by the manufacturer, not just harmonised standards.

CE marking

The affixing of the CE marking to apparatus is a declaration by the manufacturer that it meets all the appropriate provisions of the relevant legislation implementing certain European Directives. For many electrical products, the CE marking indicates compliance with both the EMC and Low Voltage Directives.

CE marking gives companies easier access into the European market to sell their products without adaptation or rechecking.

Apparatus covered by the Regulations must carry CE marking before it can be placed on the market. Regulation 21 sets out the requirements for this and Schedule 2 of the Regulations shows how the CE Marking must be applied.

3.6 Information requirements

The Regulations require that each apparatus placed on the market shall have the following information for the user and/or enforcement authorities.

- identification in terms of type, batch, serial number or any information allowing for identification of the apparatus
- the name and address of the manufacturer and if he is not established in the Community, the name and address of the responsible person
- 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 essential requirements
- apparatus for which compliance with the essential requirements is not ensured in residential areas is accompanied by a clear indication of this restriction of use and where appropriate this indication is also on the packaging (see 5.1)
- instructions accompanying the apparatus contain the information required to enable the apparatus to be used in accordance with its intended purpose

3.7 Enforcement for apparatus

Enforcement Authorities

For the vast majority of apparatus, the following applies:

Enforcement is carried out by the Trading Standards Departments of Local Authorities, or the Department of Enterprise, Trade and Investment in Northern Ireland.

Ofcom may enforce the Regulations where the action relates to the protection and management of the radio spectrum.

The Secretary of State for Business, Enterprise and Regulatory Reform may enforce the Regulations

Responsibilities of responsible persons

The person responsible for placing the apparatus on the market must make available copies of the DoC, technical documentation, and notified body statement where applicable, when requested to do so by an enforcement authority.

3.8 Putting into service

Regulation 16 requires that no person shall put into service apparatus unless it complies with the essential requirements when properly installed, maintained and used for its intended purpose.

4 Requirements for fixed installations

Fixed installations must meet the essential requirements described in section 2 of this guide in respect of emissions and immunity, but they need not be subjected to conformity assessment, or have a declaration of conformity, and they are not required to be CE marked.

These requirements for fixed installations allow an optional relaxation for the requirements for apparatus that is intended for incorporation into a given fixed installation and is not otherwise commercially available (see 4.4).

A fixed installation (or modification to a fixed installation that was installed before 20 July 2007) may only be put into service if it meets the requirements of Regulation 35.

The following provides some specific guidance on some aspects of fixed installations.

4.1 Fixed installations

The Regulations do not define the size or extent of a fixed installation. It is for the responsible person to define the extent of a fixed installation for which he is responsible, but he cannot exclude any part that is within their control, unless it forms part of another fixed installation.

The definition of a fixed installation includes the requirement "intended to be used permanently". There are two important elements to this: intent and duration. This requirement would be fulfilled if it were intended that the constituent parts were to be used in the defined location for their expected lifetime(s).

If constituent parts are expected to be moved during their expected lifetime to another location, to be taken into service at that location, the requirement would not be fulfilled. It is recognised that modifications will be made to fixed installations throughout their operational life, and such modifications would not invalidate the original intent, although such acts would be subject to the relevant provisions of the Regulations, in particular, Regulation 35.

4.2 Responsible person for a fixed installation

There must always be a person with responsibility for ensuring that, when used, the fixed installation complies with the essential requirements. That person is known as the "responsible person in relation to a fixed installation". The Regulations define this responsible person as the person who, by virtue of their control of the fixed installation is able to determine that the configuration of the installation is such that when used it complies with the essential requirements.

Such a person must therefore hold a position of responsibility sufficient to control the configuration of the fixed installation, and to be satisfied that the documentation is and continues to be sufficient to demonstrate that good engineering practices have been followed. The responsible person does not have to be an EMC expert, and may seek appropriate advice in fulfilling their obligations. However, they cannot delegate their responsibility.

There will be many types, sizes and complexities of fixed installation. The person who is responsible may be different according to the circumstances. For example, in some cases it could be the owner of a site, in others the operator of the installation, in others the maintainer of the installation, etc. In some cases control may be determined contractually between the parties concerned.

It will be necessary for operators of new fixed installations to identify the responsible person before the installation is put into service, since they are responsible for holding and providing

the documentation demonstrating the application of good engineering practices as required by Regulations 5(3) and 36 respectively. For an existing fixed installation, the obligation to identify the responsible person occurs before a modification is made that may affect the installation's electromagnetic compatibility characteristics.

4.3 Good engineering practices

Regulation 5 requires a fixed installation to be installed applying good engineering practices. Essentially, this expression means sound technical custom, based on accumulated understanding and experience.

In employing such practices in a fixed installation, it is implicit that to comply with the essential requirements for electromagnetic compatibility, good **EMC** engineering practices have to be employed, which are suitable for that site. The practices have to be sufficient to ensure that the fixed installation meets the essential requirements set out in Regulation 4. It is not possible to define these more precisely, as they will vary according to the technologies employed in the constituent parts of the fixed installation, and its surroundings, and may include mitigation measures required by the information provided for incorporation of those parts.

The fact that better engineering practices could have been employed would not invalidate sufficiently good engineering practices that allow the requirements of Regulation 4 to be met.

4.4 "Certain Apparatus" intended for incorporation into a given fixed installation

Apparatus intended for incorporation into a given fixed installation may be placed on the market as described in Section 3 of this guide, but the regime allows a relaxation when the apparatus is not otherwise commercially available The basis for the different treatment is that it is not necessary to carry out a conformity assessment, for "certain apparatus" that is intended solely for a specific fixed installation, in isolation from that fixed installation.

Regulation 34 sets out the requirements for "certain apparatus" for a "given fixed installation". It defines "certain apparatus" as apparatus which is

- intended for incorporation into a given fixed installation
- otherwise not commercially available.

It is expected that most apparatus incorporated within a fixed installations will not fall within the special "certain apparatus" category because the two conditions given above are not met.

Where the requirements set out in Regulation 34 do apply, in order that the requirements of Regulation 34(1) may be fulfilled, the manufacturer of the apparatus or their authorised representative must understand the nature of the installation in sufficient detail, to be able to determine the precautions to be taken for incorporation to avoid compromising the conformity of that installation.

The term "given fixed installation" should therefore be taken to mean a specific location of a fixed installation, rather than a type of installation, subject to the qualification of the following paragraph.

Such apparatus may be incorporated into more than one identical fixed installation. In such cases, for the manufacturer of the apparatus to be satisfied that Regulation 34 applies in place of Regulation 15, although the installations need not be identical in every detail, they must be sufficiently alike in their electromagnetic compatibility characteristics, and the interfaces with the apparatus, that identical apparatus and precautions will suffice in order not to compromise the conformity of each installation.

If these conditions are not fulfilled, each installation must be treated as a separate given fixed installation, and the apparatus designs and/or precautions must be specific to each site.

It is not the responsibility of the manufacture (or their authorised representative) to ensure that the fixed installation has an appropriate responsible person. They have only to fulfil their own responsibilities in respect of the apparatus that they supply.

4.5 Electromagnetic compatibility characteristics of a fixed installation

Regulation 34(1)(i) requires the manufacturer (or their authorised representative) of apparatus which is intended for incorporation into a given fixed installation and is otherwise not commercially available to provide in the accompanying documentation information identifying the fixed installation and its electromagnetic compatibility characteristics. It will be necessary for the manufacturer to understand the electromagnetic compatibility characteristics pertaining to such an installation in sufficient detail to enable him to design or adapt the apparatus to be suitable for incorporation, and to identify any specific precautions that must be taken during that process.

The purpose of identifying the electromagnetic compatibility characteristics of the installation is therefore to provide the basis for ensuring that that the conformity of the fixed installation is not compromised, and to provide evidence in the case of a challenge.

The level of detail required will depend on the complexity of the apparatus, the intended fixed installation, and the electromagnetic environment. For straightforward situations, the descriptions of the environment as set out in the harmonised generic or product standards may be sufficient. In more complex cases, the specific electromagnetic characteristics of the other parts of the installation and/or the environment may be required. The manufacturer of the apparatus (or their authorised representative) is responsible for this judgement.

In fulfilling their responsibilities, the manufacturer (or their authorised representative) may use any appropriate source of information, including the person responsible for the fixed installation, although it should be noted that the Regulations do not place any responsibility on the latter to supply such information. However, it remains the manufacturer's (or their authorised representative's) responsibility to obtain the necessary information because only they know the characteristics of their apparatus, and they have to provide the information required by the Directive in order to benefit from the exemption from conformity assessment. If insufficient information is available on the EMC characteristics of the fixed installation, a manufacturer has the option of following the conformity assessment procedures for placing the apparatus on the market.

4.6 Enforcement for fixed installations

The enforcement authorities for fixed installations are the same as those for apparatus (see 3.7).

In the case of indications of non-compliance of a fixed installation, for example a report of interference being caused, in the first instance it is expected that an enforcement authority will seek documentary evidence of the application of good engineering practices. Regulation 39 allows for further investigations if necessary.

An investigation into an alleged non-conformity of a fixed installation may require the supply of documentation that relates to confidential details of performance or constructional details of apparatus. In such cases, it may be appropriate for the enforcement authority to obtain such evidence directly from the manufacturer of the apparatus or their authorised representative. Where non-compliance is as a result of interaction between two or more fixed installations, that are otherwise compliant, or the disturbances originate from a shared resource, the authorities may require the responsible persons to co-operate to remedy the non-compliance.

In some cases, a fixed installation may be located physically within the boundary of another fixed installation. In such circumstances, it is possible that the fixed installations will have different responsible persons, each employed by a different organisation. There may, or may not, be a contractual arrangement between these organisations, and the installations may, or may not, be interconnected electrically, but this should not affect how the compliance of each fixed installation is considered.

The compliance of each fixed installation with the essential requirements of the Directive would be considered separately in the first instance. The responsible person for the larger fixed installation would not be responsible for the conformity of any smaller fixed installation within it unless it was agreed otherwise. However, each fixed installation will form part of the electromagnetic environment of the other, and this must be taken into account in addition to consideration of the surroundings in complying with Regulation 35.

In the case of interference being caused, the source of which is traced to a source within the boundary of the larger fixed installation, the authorities may be expected to approach the responsible person for the larger fixed installation in the first instance, but the responsible person for any smaller fixed installation would also be expected to cooperate in the investigation. Each may be required to provide evidence of compliance of the fixed installations for which they are responsible. It is likely that only by further co-operation between the responsible persons will a solution be able to be found.

5 Other issues affecting apparatus

5.1 Apparatus for which compliance is not ensured in residential areas

Residential areas may be considered to be domestic environments and locations immediately adjacent. In such locations, broadcast receivers can be expected to be in use in close proximity to other equipment. Regulation 15 requires that apparatus for which compliance with the essential requirements is not ensured in residential areas is accompanied by a clear indication of this restriction of use and where appropriate, this indication is also on the packaging.

A "clear indication" would include an indication in the user instructions, and where appropriate on the packaging, of suitable locations in which the equipment may be used. If these do not include residential areas, a suitable warning would be that use in residential areas may cause interference, and such use should be avoided unless special measures are taken by the user to restrict emissions to a level that allows the reception of broadcast transmissions.

5.2 Mobile installations

The definition of apparatus in Regulation 3 includes mobile installations which are defined, as in the Directive, as a combination of apparatus and, where applicable, other devices, intended to be moved and operated in a range of locations. This definition does not require the combination of apparatus to have an identical configuration in each location.

Installations intended to be taken down and reassembled at different locations cannot be considered to be fixed installations, since the definition of fixed installation includes the words "used permanently at a predefined location", nor can they be considered to be apparatus for a given fixed installation.

Such installations are mobile installations, and the Regulations' provisions for apparatus apply, in particular Regulation 15 for placing on the market. Those using the apparatus at each location must meet Regulation 16, requirements for putting into service.

5.3 Components

Components or sub-assemblies that are intended for incorporation into an apparatus by an end user and which are liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbances are considered to be apparatus and therefore subject to the appropriate provisions of the Regulations.

The definition excludes components and sub-assemblies that are intended for incorporation into apparatus by other persons such as manufacturers, and such components and sub-assemblies are therefore outside the scope of the Regulations, although the resulting apparatus will be within the scope when placed on the market and/or put into service.

5.4 Military equipment

Article 296 of the Treaty establishing the European Community provides a derogation under which European states can protect their essential security interests connected with the production of military equipment designed for use as arms, munitions or war material. By invoking article 296, European law obligations in a directive (for example) which would otherwise bite in respect of such military equipment may be derogated from.

If article 296 is invoked in a particular case, with the effect of derogating from a European law obligation (e.g. Directive 2004/108/EC), there will as a consequence be no corresponding domestic law obligation to comply with under the Regulations (for example). The derogation covers equipment capable of other applications, but does not extend to equipment which is designed for military use and other applications (often called dual-use equipment).

5.5 Second-hand and imported apparatus

The Regulations do not deal explicitly with these issues since they are general matters. The *European Guide to the implementation of directives based on the New Approach and the Global Approach* (Blue Guide) covers these aspects. A copy of this guide may be downloaded from the European Commission website via the link provided in Annex 4

Essentially, second-hand apparatus is not subject to the Regulations if it has previously been put into service by an end user within the European Economic Area. If however it is only been used previously outside this geographical area, it is covered by the Regulations.

Apparatus imported into the European Economic Area is subject to the appropriate provisions of the legislation when it is first placed on the EEA market or put into service in the EEA.

Annex 1 - Principles of the Single Market

The free movement of goods lies at the heart of achieving an open market for business in Europe.

In May 1985, European Community Ministers agreed on a 'New Approach to Technical Harmonisation and Standards' in order to fulfil this objective.

'New Approach' Directives (in other words Community laws) set out the essential requirements (for safety or protection, for example), written in general terms, which must be met before products may be placed on the market or put into service in the United Kingdom or elsewhere in the Community. Harmonised standards, which set out technical details, are the most common means by which business can meet the 'essential requirements' for products. The Directives also say how manufacturers are to demonstrate that products conform to the 'essential requirements'. Products meeting the requirements carry CE marking, which mean they have free movement anywhere in the Community.

The Electromagnetic Compatibility Directive applies across the twenty-seven Member States of the European Union and, under the European Economic Area agreement, the states of Iceland, Liechtenstein and Norway¹.

¹ There are twenty-seven members of the European Union - Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the UK.

Annex 2 - Equipment excluded (in whole or in part) from the scope of the EMC Regulations

The Regulations cover almost all electrical and electronic equipment. However, there are a number of areas where the Regulations do not apply, or apply only in part (for example for emission only or for immunity only).

There are also special provisions for equipment displayed at trade fairs and similar events.

Benign equipment

Particular equipment is excluded from the scope of the Regulations if its inherent qualities are such that 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 it will operate without unacceptable degradation in the presence of electromagnetic disturbance normally consequent upon its intended use.

A judgement as to whether equipment is electromagnetically benign must be made by the manufacturer. Although such apparatus is outside the scope of the Regulations it would be prudent for the manufacturer to document the reasons for their decision, in case of a challenge by the enforcement authorities.

Equipment presented at trade fairs or similar events

The Regulations do not apply to equipment which is not compliant with the requirements of these Regulations and which is displayed, demonstrated or presented at any trade fair, exhibition or similar event, if a sign displayed visibly on or near the equipment clearly indicates that it is not compliant with these Regulations and cannot be placed on the market or put into service, or both, until it is made compliant with those requirements.

Demonstration of the equipment at any trade fair, exhibition or similar event may only take place if adequate measures are taken to avoid electromagnetic disturbance.

Equipment covered by other Directives and legislation, in whole or in part, or otherwise excluded from the EMC Regulations 2006

This is a non-exhaustive list. These examples include product types that are covered by other directives where some or all of the requirements for EMC are more specific. As it is beyond the scope of this guide to explain the interactions between new approach directives in a comprehensive way, manufacturers may need to take advice in specific cases.

Aeronautical products, parts and appliances referred to in Regulation (EC) No. 1592/2002 of the European Parliament and of the Council on common rules in the field of civil aviation and establishing a European Aviation Safety Agency.

Marine equipment covered by Directive 96/98/EC

Measuring instruments or sub-assemblies covered by Directive 2004/22/EC on measuring instruments, which bear the CE marking, the M marking and the identification

number of the notified body responsible for carrying out the conformity assessment of the instrument or sub-assembly.

Medical

Active implantable medical devices covered by Directive 90/385/EEC In vitro medical devices covered by Directive 98/79/EC Medical devices covered by Directive 93/42/EEC

Non-automatic weighing instruments covered by Directive 90/384/EEC

Radio amateur apparatus used by radio amateurs which is not available commercially.

Radio equipment and telecommunications terminal equipment covered by Directive 1999/5/EC

Vehicles

Agricultural or forestry tractors covered by Directive 2000/2/EC, amending Directive 75/322/EEC

Automobiles covered by Directive 2004/104/EC adapting to technical progress Directive 72/245/EEC relating to the radio interference (electromagnetic compatibility) of vehicles, as amended by Directive 95/54/EC

Two and three-wheel motor vehicles covered by Directive 97/24/EC

Annex 3 - Notified Bodies

In the UK, the Secretary of State for Business, Enterprise and Regulatory Reform has responsibility for the designation of Notified Bodies. Further details on this are available in "EMC Regulations 2006: Guidelines for the designation of Notified Bodies" URN 07/922 a copy of which can be downloaded from the link given in Annex 4.

Once a Notified Body (NB) has been designated, the Secretary of State must notify the European Commission through the NANDO website. The Commission will then issue a NB number to the organisation in question. If the designated NB has been notified under another Directive then they will use this number for the purposes of the EMC Directive and all other Directives for which they are designated.

Annex 4 - Links and contacts for further information

Legislation and guides to legislation

A copy of the Regulations may be downloaded from http://www.opsi.gov.uk/legislation/about_legislation.htm

The paper edition of the Regulations may be obtained from The Stationery Office online bookshop <u>http://www.tsoshop.co.uk/bookstore.asp?FO=1215311</u>

Copies of this guide may be downloaded from the BERR website http://www.berr.gov.uk/sectors/sustainability/regulations/ecdirect/page12469.html

The Directive may be downloaded from the European Commission website http://ec.europa.eu/enterprise/electr_equipment/emc/directiv/dir2004_108.htm

A guide to the EMC Directive has been produced by the European Commission and may be viewed at

http://ec.europa.eu/enterprise/electr_equipment/emc/directiv/dir2004_108.htm

The European Guide to the implementation of directives based on the New Approach and the Global Approach (Blue Guide) may be downloaded from the European Commission website at

http://ec.europa.eu/enterprise/newapproach/legislation/guide/index.htm

Notified Bodies

The list of UK notified bodies may be downloaded from the BERR website

http://www.berr.gov.uk/sectors/sustainability/regulations/ecdirect/page12469.html

Guidelines for the designation of Notified Bodies" URN 07/922 a copy of which can be downloaded from the link shown on the Department for Business, Enterprise and Regulatory Reform (BERR) website at:

http://www.berr.gov.uk/sectors/sustainability/regulations/ecdirect/page12469.html

Standards and guides to the use of standards

Copies of harmonised standards may be obtained from the British Standards Institution,

389 Chiswick High Road, London W4 4AL

Telephone: 020 8996 9001 Fax: 020 8996 7001 E-mail: cservices@bsigroup.com

or online at http://www.bsi-global.com/upload/Standards%20&%20Publications/shop.html

Guidance on the use of harmonised standards may be found in CENELEC Guide 25, available free of charge from the CENELEC website

http://www.cenelec.org/Cenelec/CENELEC+in+action/Horizontal+areas/EMC/default.htm

The latest list of harmonised standards that provide a presumption of conformity under the EMC Directive may be downloaded from the European Commission website

http://ec.europa.eu/enterprise/electr_equipment/emc/stand.htm

Questions relating to the EMC Regulations

Questions relating to the EMC regulations and the content of this guide may be addressed to Kevin Lane, Department for Business, Enterprise & Regulatory Reform, Bay 384, 1 Victoria Street, London SW1H 0ET E-mail: <u>Kevin.Lane@berr.gov.uk</u> Tel: 020 7215 1774 Fax: 020 7215 2635