

Guide for the EMC Directive 2004/108/EC
(8th February 2010)

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Disclaimer

These guidelines are intended to be a manual for all parties directly or indirectly affected by the “new” EMC (ElectroMagnetic Compatibility) Directive 2004/108/EC. They assist in the interpretation of the Directive but do not substitute for it; they explain and clarify some of the most important aspects related to its application. The Guide is also intended to ensure the free movement of products in the EU Single Market by agreement of these explanations and clarifications, reached by consensus amongst Member States and other stakeholders

These Guidelines are publicly available, but they are not binding in the sense of legal acts adopted by the Community. The legally binding provisions are those transposing the EMC Directive at national level.

Finally, the reader’s attention is drawn to the fact that all references to the CE marking and EC Declaration of Conformity relate only to the EMC Directive and that the freedom to place an apparatus on the market in the EU Internal Market is only guaranteed when applying all relevant legislation.

INTRODUCTION

The purpose of this document is to give guidance on certain matters and procedures of the Directive 2004/108/EC¹ on the approximation of the laws of the Member States relating to electromagnetic compatibility².

The Electromagnetic Compatibility (EMC) Directive 2004/108/EC repeals the previous EMC Directive 89/336/EEC³ (as amended by Directives 91/263/EEC⁴, 92/31/EEC⁵, 93/68/EEC⁶ and 93/97/EEC⁷) and maintains the same objectives - to guarantee the free movement of apparatus and to create an acceptable electromagnetic environment in the Community territory⁸. The original protection requirements are not changed in practice and apply to apparatus and to fixed installations.

The main objective of the EMC Directive is thus to regulate the compatibility of equipment regarding EMC. In order to achieve this objective, provisions have been put in place so that:

¹ OJ No L390, 31.12.2004

² The European Commission will undertake to maintain this guide. It is our goal to ensure that the information provided is both timely and accurate. If errors are brought to our attention, we will try to correct them. However, the Commission accepts no responsibility or liability whatsoever with regard to the information in this guide.

This information is:

- of a general nature only and is not intended to address the specific circumstances of any particular individual or entity;
- not necessarily comprehensive, complete, accurate or up to date;
- sometimes refers to external information over which the Commission services have no control and for which the Commission assumes no responsibility;
- not professional or legal advice.

³ OJ No L 139, 23.5.1989

⁴ OJ No L 128, 23.5.1991

⁵ OJ No L126, 12.5.1992

⁶ OJ No L 220, 20.8.1993

⁷ OJ No L 290, 24.11.1993

⁸ According to the agreement related to the European Economic Area (EEA) (Council and Commission Decision 94/1/EC of 13 December 1993 (OJEC n° L 1 of 3 January 1994, p. 1) the territories of Liechtenstein, Iceland and Norway have to be considered, for the implementation of Directive 94/9/EC, in the same right as of the Community territory. When the term, "Community" territory, is used in this guide, the same applies to the EEA territory. Directive 2004/108/EC is also applicable in other territories where a suitable international agreement is in operation.

- equipment (apparatus and fixed installations) needs to comply with the requirements of the EMC Directive when it is placed on the market and/or taken into service;
- the application of good engineering practice is required for fixed installations, with the possibility for the competent authorities of Member States to impose measures if non-compliances are established.

In 1997 the European Commission released a “Guide to the Application of Directive 89/336/EEC”. This was well received and widely used, however it had no legal status, one of the purposes of the revision of the EMC Directive has been to incorporate many of the elements from the 1997 Guide.

The main modifications made in Directive 2004/108/EC as compared to the Directive 89/336/EEC are the following:

- The new legal text makes a clear distinction between the requirements and assessment procedures for apparatus and for fixed installations respectively (fixed installations can include networks and large machines);
- Definitions are included for apparatus and fixed installations;
- Fixed installations, **although they must comply with the protection requirements,** require neither an EC Declaration of Conformity (DoC) nor CE marking;
- Mobile installations are considered apparatus;
- For apparatus, there are changes in the documentation and information requirements;
- The conformity assessment procedure for apparatus has been simplified to a single procedure. There is no compulsory involvement of a third party, but the manufacturer has the option of presenting his technical documentation to a Notified Body for assessment;
- When deviating from the European harmonised standards or not applying them fully, the manufacturer has to perform an EMC assessment and provide detailed documentary evidence that the apparatus complies with the protection requirements of the EMC Directive;
- Apparatus intended for a given fixed installation and not otherwise commercially available may be exempt from the requirements and procedures for apparatus (e.g. EC Declaration of Conformity and CE marking), provided that certain documentation requirements are met, including precautions to be taken in order not to compromise the EMC characteristics of the fixed installation;
- The regulatory role of Competent Bodies has been removed.

For the vast majority of apparatus, EMC compliance is assessed by using the usual and preferred method of conformity to the relevant European harmonised standard(s). The change for the manufacturers is limited to a few additional information and documentation requirements. Most things remain unchanged.⁹

The European harmonised standards for apparatus will not change due to the application of the new EMC Directive.

The present Guide should be read in conjunction with the “Blue Guide”.

⁹ For readers who wish only to view the limited number of changes we recommend reading sections 3.4.3 and 3.4.5.

This Guide has been structured in a logical way suitable for users who need to ensure that their equipment is in conformity with the EMC Directive. It is divided into the following Chapters:

1. **Scope**: allows manufacturers or others to quickly decide whether their equipment falls under the scope of the EMC Directive and if so, if it is apparatus or a fixed installation.
2. **Essential requirements** provide an overview of the mandatory requirements.
3. **Conformity assessment procedure for apparatus**: gives information including: the usual steps of an EMC assessment; information and documentation requirements; EC Declaration of Conformity and CE marking. More detailed guidance is provided for an EMC assessment where harmonised standards are not used or do not cover all protection requirements.
4. **Procedures for fixed installations**: on the relevant requirements and documentation needed for fixed installations, including the use of apparatus specifically for incorporation into a given fixed installation.
5. **Enforcement of the EMC Directive**: relates to the duties of the national competent authorities in ensuring only compliant apparatus circulated in the Community, with further information on apparatus intended for demonstration at trade-fairs. In parallel, to ensure that fixed installations meet the essential requirements.
6. **Notified Bodies**: their role, selection, coordination and the treatment of complaints.

1 SCOPE

1.1 General

The EMC Directive 2004/108/EC applies to a vast range of equipment encompassing electrical and electronic appliances, systems and installations.

The main objective of the Directive is to guarantee the free movement of apparatus and to create an acceptable electromagnetic environment in the Community. In order to achieve it, a harmonised and acceptable level of protection is requested in the Directive, based on Article 95 of the Union Treaty, leading to full harmonisation in the Community.

The level of protection requested is further specified in the EMC Directive by protection aims in the field of electromagnetic compatibility. The main goals are:

(1) To ensure that the electromagnetic disturbances produced by equipment¹⁰ does not affect the correct functioning of other apparatus as well as radio and telecommunications networks, related equipment and electricity distribution networks.

(2) To ensure that equipment has an adequate level of intrinsic immunity to electromagnetic disturbances to enable them to operate as intended.

Obviously, the goal of the essential requirements is not to guarantee absolute protection of equipment (e.g. zero emission level or total immunity). These requirements accommodate both physical facts and practical reasons. To ensure that this process remains open to future technical developments, the EMC Directive only describes the essential requirements along general lines.

In the “new” Directive essential requirements includes both protection requirements for equipment as well as specific requirements for installations.

When compliant with the provisions of the EMC Directive, equipment may be placed on the market and/ or put into service in the Community territory, freely moved and operated as designed and intended in the expected electromagnetic environment.

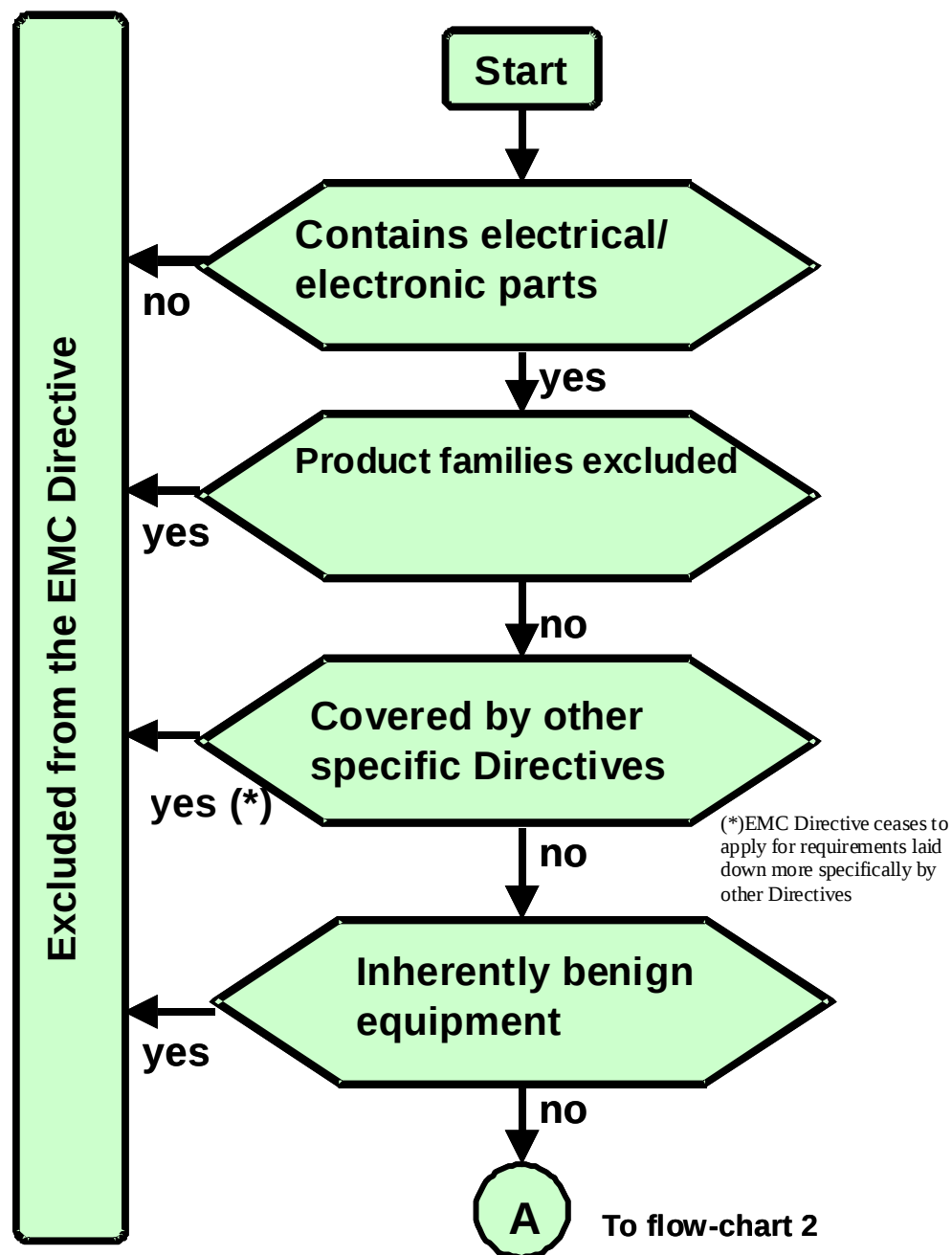
The EMC Directive does not regulate the safety of equipment in respect of people, domestic animals or property¹¹. According to the definition given in Article 2 the EMC Directive is only concerned with the electromagnetic compatibility of equipment. However, it should be noted that other directives may require higher requirements for EMC phenomena in order to satisfy their specific safety provisions.

The EMC Directive is therefore not a safety related Directive.

In order that the reader may easily decide whether his/ her equipment falls within the scope of the Directive, and if so the procedures that are to be applied, a series of decision flow-charts have been incorporated into the Guide. Flowchart 1 overleaf deals with the first step in this process.

¹⁰ “equipment” means any apparatus or fixed installation c. Article 2(1)(a)

¹¹ c. Article 1(5)



Flowchart 1 – Scope

1.1.1 Equipment without electrical and/or electronic parts

Equipment which does not contain electrical and/or electronic parts will not generate electromagnetic disturbances and its normal operation is not affected by such disturbances. Hence, equipment without electrical and/or electronic parts is not in the scope of the Directive.

1.1.2 *Explicit exclusions from the EMC Directive*

Article 1.2 of the EMC Directive explicitly excludes three types of equipment:

- Radio equipment and telecommunications terminal equipment covered by Directive 1999/5/EC¹² (the “R&TTE Directive”);
- Aeronautical products, parts and appliances referred to in Regulation 1592/2002;
- Radio equipment used by radio amateurs as defined in International Telecommunication Union (ITU) Radio Regulations.

1.1.2.1 Radio equipment and telecommunications terminal equipment

The EMC Directive excludes equipment covered by Directive 1999/5/EC from the EMC Directive¹³. The R&TTE Directive covers most radio equipment and telecommunication terminal equipment and includes EMC protection requirements identical to those of the EMC Directive. This means “de-facto” that the protection requirements of 2004/108/EC are obligatory for R&TTE equipment. However, the conformity assessment procedures for apparatus are no longer an alternative to the conformity assessment procedures of the R&TTE Directive.

Radio and telecommunications terminal equipment not covered by Directive 1999/5/EC remains subject to the provisions of the EMC Directive. A typical example of radio equipment not covered by Directive 1999/5/EC is “receive-only” radio equipment intended to be used solely for the reception of sound and TV broadcasting services. Other examples of equipment not covered by the R&TTE Directive are transmitters operating below 9 kHz or above 3000 GHz and non-radio telecommunication network infrastructure equipment.

1.1.2.2 Aeronautical products

Aeronautical products, parts and appliances referred to in Regulation (EC) N° 1592/2002 of the European Parliament and of the Council of 15 July 2002 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency¹⁴ are excluded from the EMC Directive.

¹² Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity OJ L 91, 7.4.1999, p. 10–28

¹³ c. Article 1(2)(a)

¹⁴ OJ No L240, 7.9.2002, p.1 Regulation as amended by Commission Regulation (EC) No 1701/2003 (OJ L243, 27.9.2003, p.5).

This regulation and other relevant International Conventions and Regulations ensure that EMC requirements for aeroplanes and equipment intended for incorporation into aircraft are at least equivalent to those found in the EMC Directive.

1.1.2.3 Radio equipment intended for use by radio amateurs

Radio equipment used by radio amateurs is excluded unless the equipment is available commercially¹⁵. This exclusion has been included because of the specific nature of the activities of radio amateurs. Radio amateurs are people carrying out experimental activities within the field of radio communications, according to the definitions of the ITU Radio Regulations. However, amateur radio equipment which is available commercially comes within the scope of the R&TTE Directive.

Commercial equipment which is modified by and for the use of radio amateurs and kits of components to be assembled by radio amateurs are not regarded as commercially available, and are therefore outside the scope of both the EMC and R&TTE Directives.

1.1.3 *Equipment covered by other specific Community Directives*

According to Article 1(4) of the Directive, if the EMC requirements for equipment are wholly or partly laid down more specifically by other Directives, the EMC Directive shall not apply, or shall cease to apply, to that equipment in respect of such requirements from the date of mandatory application of those Directives.

The following list contains examples of equipment **excluded for both emission and immunity purposes** from the EMC Directive:

- Motor vehicles: covered by specific Directive 72/245/EEC¹⁶ and 2004/104/EC;

Specific EMC protection and safety requirements applicable to motor vehicles are laid down by the Directive 2004/104/EC, which amends Directive 72/245/EEC concerning the electromagnetic compatibility of motor vehicles. This concerns Electronic Sub Assemblies (ESAs) and after-market electronic equipment related to immunity related functions. For such equipment a type approval following Directive 2004/104/EC is required;

Components sold as after-market equipment and intended for installation in motor vehicles need no type approval under the

¹⁵ C. Article 1(2)©

¹⁶ OJ No L 152, 6.7.1972, amended by Directive 2005/83/EC, OJ No L 305, 24.11.2005.

motor vehicle EMC Directive 2004/104/EC if they are not related to immunity related functions (see Annex I, section 3.2.3 of Directive 2004/104/EC). This type of equipment is assessed under the EMC directive or the R&TTE directive 1999/5/EC as necessary. It carries the CE marking and an EC Declaration of Conformity must be issued.

“Equipment satisfying the requirements for exemption of type approval under the motor vehicle EMC directive must meet the essential requirements of 2004/108/EC in addition to the requirements of Annex I paragraphs 6.5, 6.6, 6.8 and 6.9 of 2004/104/EC. To assist manufacturers, a standard harmonised under 2004/108/EC and including those appropriate technical requirements of 2004/104/EC, is being produced. It will be listed in the Official Journal under 2004/108/EC only.

Equipment requiring type approval is subject only to the requirements of 2004/104/EC, and is not covered in this guide.”

- Active implantable Medical Devices: Directive 90/385/EEC¹⁷;
- Medical Devices: Directive 93/42/EEC¹⁸;
- In vitro Diagnostic Medical Devices: Directive 98/79/EC¹⁹;
- Marine equipment: if covered by Directive 96/98/EC²⁰;
- Agricultural and forestry tractors covered by Directive 75/322/EEC²¹;
- Two or three-wheel motor vehicles within scope of Directive 97/24/EC²²;

The following are examples of equipment **excluded for immunity purposes only** from the EMC Directive:

- Measuring instruments: Directive 2004/22/EC²³;

¹⁷ OJ No L 189, 20.7.1990 amended by Directives 93/42/EEC, OJ No L 169, 12.7.1993 and 93/68/EEC, OJ No L 220, 30.08.1993.

¹⁸ OJ No L 169, 12.7.1993, amended by Directive 93/68/EEC, OJ No L 220, 30.8.1993.

¹⁹ OJ N° L 331, 07.12.1998.

²⁰ OJ N° L 46, 20.12.96

²¹ OJ N° L 147, 9.6.1975, amended by Directives 82/890/EEC, OJ No L 378, 31.12.1982, Directive 2000/2/EC, OJ L 021 26.01.2000 and 2001/3/EC, OJ L 28, 30.01.2001

²² OJ N° L226, 18.8.1997

- Non-automatic weighing instruments: covered by Annex I-8(2) of Directive 90/384/EEC²⁴.

1.1.4 *Inherently benign equipment*

Equipment which is inherently benign in terms of electromagnetic compatibility is excluded from the scope of the EMC Directive²⁵.

Equipment is considered inherently benign in terms of electromagnetic compatibility if:

- its inherent physical characteristics are such that it is incapable of generating or contributing to electromagnetic emissions which exceed a level allowing radio and telecommunications equipment and other equipment to operate as intended; and,
- it will operate without unacceptable degradation in the presence of the electromagnetic disturbance normally present in its intended environment.

Both conditions need to be met in order to classify equipment as inherently benign.

The application of the above enables the exclusion of the following equipment (not exclusive) from the application of the EMC Directive, provided that they include no active electronic part(s):

- Cables and cabling²⁶, cables accessories, considered separately;
- Equipment containing only resistive loads without any automatic switching device; e.g. simple domestic heaters with no controls, thermostat, or fan;
- Batteries and accumulators (without active electronic circuits);
- Headphones, loudspeakers without amplification;
- Pocket lamps without active electronic circuits.
- Protection equipment which only produces transitory disturbances of short duration during the clearing of a short-

²³ OJ No L 135, 30.4.2004.

²⁴ OJ No L 189, 20.7.1990, amended by Directive 93/68/EEC, OJ No L 220, 30.8.1993.

²⁵ C. Article 1(3)

²⁶ Manufacturers should be aware that the characteristics and installation of cables and cabling can have a significant impact upon the EMC performance of equipment.

circuit fault or an abnormal situation in a circuit and which do not include active electronic components, such as fuses and circuit breakers without active electronic parts or active components;

- 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 under the control of other technical measures included in non-EMC product standards, and which do not include active electronic components.

Illustrative examples:

- High voltage inductors;
- High voltage transformers.

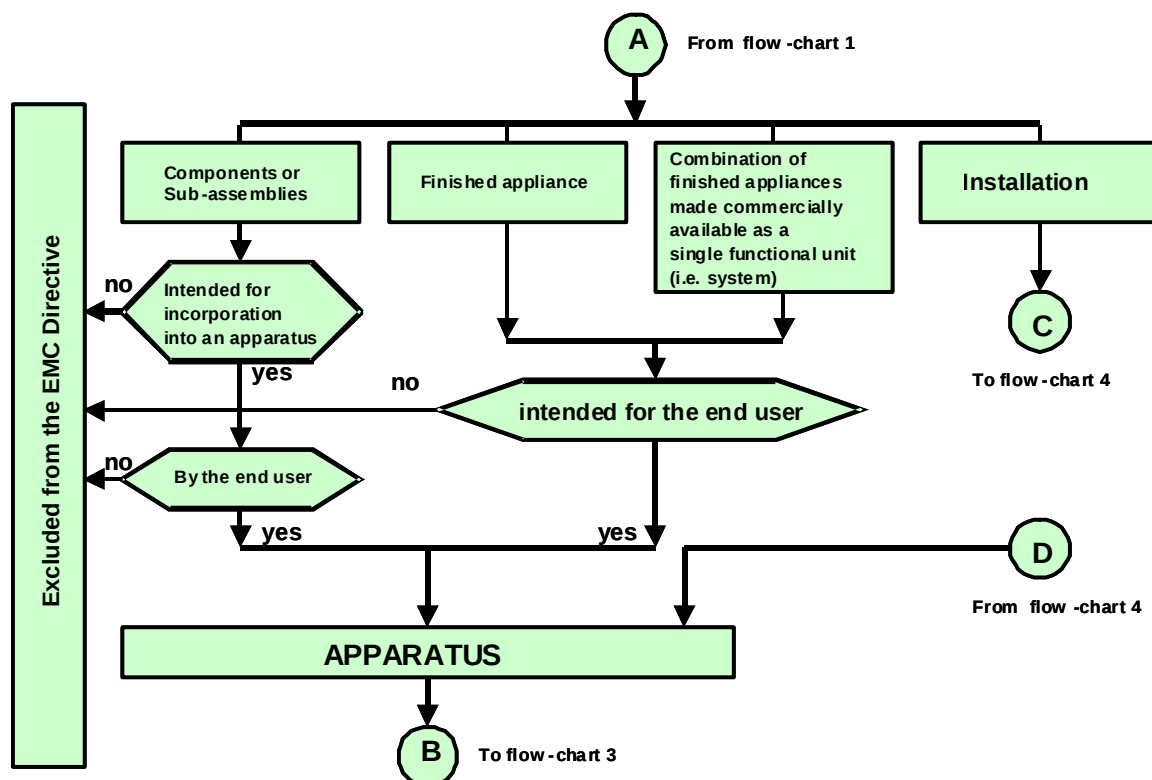
Other equipment fulfilling the criteria above:

- Capacitors (e.g. power factor correction capacitors);
- Induction motors;
- Quartz watches (without additional functions, e.g. radio receivers);
- Filament lamps (bulbs)
- Home and building switches which do not contain any active electronic components;
- Passive antennas used for TV and radio broadcast reception.
- Plugs, sockets, terminal blocks, etc.

1.1.5 Classification as apparatus or fixed installation

The EMC Directive defines equipment as any apparatus or fixed installation. As there are separate provisions for apparatus and fixed installations, it is important that the correct category of equipment be identified.

Flowchart 2 - Classification as apparatus



For guidance on the applicability of the EMC Directive to components, sub-assemblies, finished appliances, combinations of finished appliances and mobile installations the reader is referred to section 1.2, which defines the scope of apparatus. For fixed installations the reader should consider section 1.3.

1.2 Defining the scope of apparatus

The EMC Directive²⁷ defines "apparatus" as any finished appliance, or combination thereof made commercially available (i.e. placed on the market) as a single functional unit²⁸, intended for the end-user, and liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such a disturbance.

²⁷ c. Article 2(1)(b)

²⁸ The International Electrotechnical Committee (IEC)'s Vocabulary – (IEV) 702-09-03 or 714-01-30 - defines "functional unit" as follows: "An entity of hardware or software, or both together, capable of accomplishing a specified purpose. For EMC purposes this can only be hardware or combination of hardware & software"

According to Article 2(2) of the Directive "components", "sub-assemblies" and "mobile installations" are also deemed to be apparatus.

The EMC Directive gives requirements for apparatus when placed on the market and/or put in service²⁹.

One of the pre-conditions in order to be considered apparatus in the sense of the EMC Directive is that it is intended for the end-user. In the context of this Guide end-user means any natural person (e.g. consumer) or legal entity (e.g. enterprise) using or intending to use the apparatus for its intended purpose.

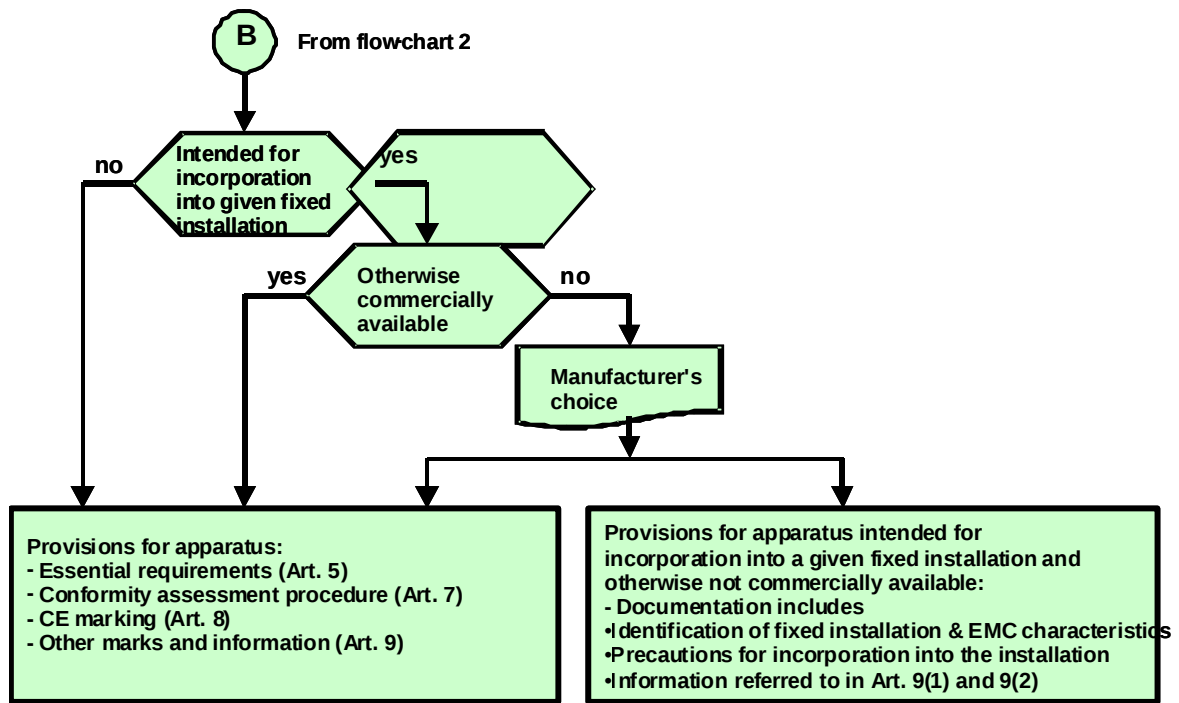
Generally an end-user is deemed to have no qualifications in the field of electromagnetic compatibility.

Another caveat is that the apparatus should be liable to cause electromagnetic disturbances, or its normal operation may be affected by such disturbances. If both of these conditions are not fulfilled due to inherent characteristics of the apparatus, then the apparatus may be considered as inherently benign in terms of electromagnetic compatibility, and hence, the EMC Directive does not apply (see section 1.1.4).

Flowchart 3 summarises the provisions applicable to apparatus (see chapter 3 and section 4.4).

Flowchart 3 - Provisions applicable to apparatus

²⁹ "Placing on the market" and "putting into service" are further explained in the "Blue Guide" ("Guide to the implementation of directives based on the New Approach and the Global Approach")



1.2.1 Finished appliances

A finished appliance is any device or unit that delivers a function and has its own enclosure.

A finished appliance is considered as apparatus in the sense of the EMC Directive, if it is **intended for the end-user** and thus has to fulfil all the applicable provisions of the Directive.

When the finished appliance is intended exclusively for an industrial assembly operation for incorporation into other apparatus, it is not apparatus in the sense of the EMC Directive and consequently the EMC Directive does not apply³⁰.

³⁰ For finished appliances outside of scope it would be reasonable to suggest that these are provided with a statement on their EMC characteristics and the nature of their incorporation.

1.2.2 *Combination of finished appliances (systems)*

A combination of several finished appliances which is made commercially available as a single functional unit intended for the end-user is considered to be apparatus³¹. Such a system, within the sense of the EMC Directive, is combined, and/or designed and/or put together by the same person (the “manufacturer”) and is intended to be placed on the market for distribution as a single functional unit for end-use and to be installed and operated together to perform a specific task. All provisions of the EMC Directive, as defined for apparatus, apply to the combination as a whole.

It should be noted that combining two or more CE marked finished appliances does not automatically produce a “compliant” system e.g.: a combination of CE marked Programmable Logic Controllers and motor drives may fail to meet the protection requirements.

1.2.3 *Components/Sub-assemblies*

In contrast to finished appliances, components /sub-assemblies do not, in general, have a proper enclosure intended for their final use. Components/sub-assemblies are often intended to be fitted into or added to an apparatus in order to add an additional function.

1.2.3.1 *Components/sub-assemblies within scope*

Components or sub-assemblies on the market which are:

- for incorporation into an apparatus by the end-user;
- available to end-users;

are to be considered as apparatus with regard to the application of the EMC Directive.

The instructions for use accompanying the component or sub-assembly should include all relevant information, and should assume that adjustments or connections can be performed by an end-user not aware of the EMC implications.

Illustrative examples:

Plug-in cards for computers;

Programmable logic controllers;

Electric motors (except for induction motors, see section 1.1.4);

Computer disk drives;

³¹ C. Article 2(1)(b)

Power supply units where they take the form of autonomous appliances or sold separately for installation by the end-user;

Electronic temperature controls.

1.2.3.2 Excluded components/sub-assemblies

Components and sub-assemblies intended for incorporation by persons other than the end user into apparatus and/or a subsequent sub-assembly are not considered to be "apparatus" and are therefore not covered by the EMC Directive³². This may also be applied to the examples in 1.2.3.1.

Illustrative examples:

-Electrical or electronic components forming part of electrical or electronic circuit:

-Resistors, capacitors, inductors, filters,

-Diodes, transistors, thyristors, triacs, etc,

-Integrated circuits;

-Simple electromagnetic relays,

- LEDs,

-Simple thermostats,

-Cathode ray tubes.

1.2.4 *Mobile installations*

Mobile installations (e.g. a portable broadcast studio) which are defined as a combination of apparatus (and where applicable other devices) intended to be moved and operated in a range of locations are deemed to be apparatus. All provisions of the EMC Directive, as defined for apparatus, apply to mobile installations.

1.2.5 *Second-hand apparatus*

Please see the "Blue Guide".

³² See footnote 20

1.2.6 *Products for own use*

Where an apparatus is manufactured for own use, placing on the market is considered to take place at the moment of putting into service; the obligation to comply with the Directive begins with first use.

1.3 **Defining the scope for fixed installations**

1.3.1 *Fixed installations*

"Fixed installation", is defined as "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."

"Fixed installation" is thus an all encompassing term that applies to all electrical installations that have been constructed with the intention of being permanent. The definition covers all installations from the smallest residential electrical installation through to national electrical and telephone networks, including all commercial and industrial installations.

The EMC Directive excludes "inherently benign" installations. However, "*a- priori*" application of this exclusion criterion to a predefined type of installation seems problematic and such an exclusion can only be made on a case-by-case basis.

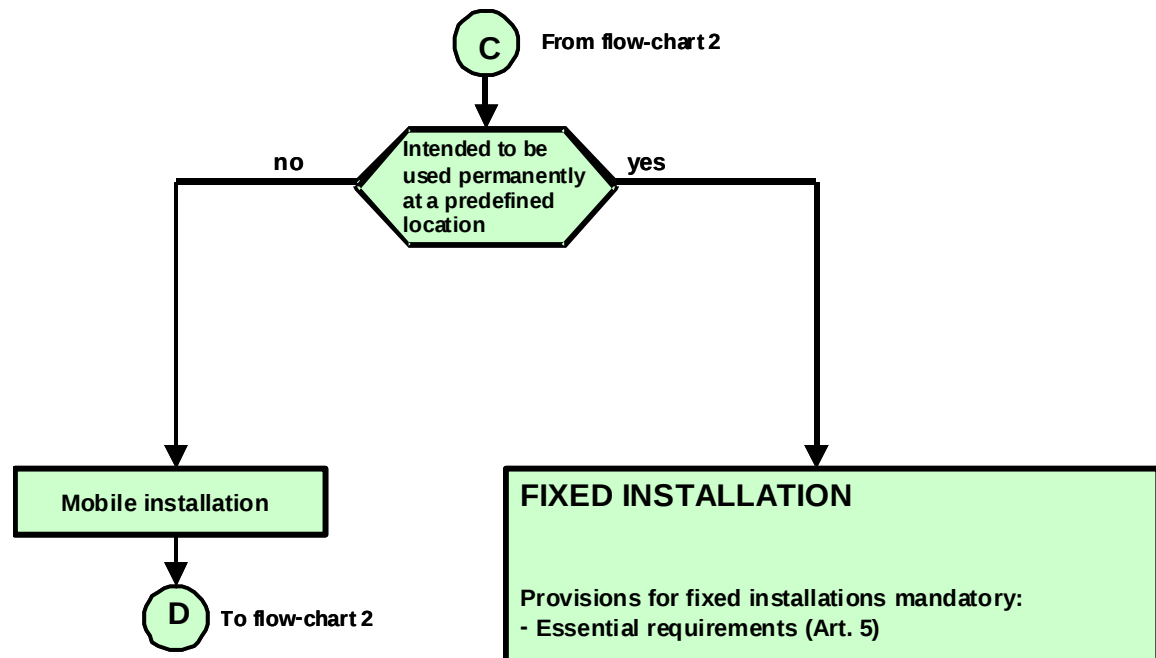
The term "fixed installation" also applies to large machines if they meet the definition given for fixed installations, such as production lines. Large machines, in the usual sense of this term, are normally apparatus and have to be treated as such.

Examples of fixed installations:

Industrial plants, power plants, power supply networks, telecommunication networks, cable TV networks, computer networks, airport luggage handling installations, airport runway lighting installations, automatic warehouses, skating hall ice rink machinery installations, storm surge barrier installations (with the control room etc), wind turbine stations, car assembly plants, water pumping stations, water treatment plants, railway infrastructures, air conditioning installations.

Further guidance on fixed installations is provided in Chapters 2 and 4.

Flowchart 4 - Installations



1.3.2 Specific apparatus for fixed installations

In general, apparatus that will be incorporated into fixed installations need to comply with all of the provisions of the EMC Directive. However, the EMC Directive provides an exception for apparatus intended for incorporation in a **given fixed installation** and otherwise not commercially available.

Additional information on the requirements for specific apparatus is given in section 4.4.

2 ESSENTIAL REQUIREMENTS

The EMC Directive sets out mandatory “essential requirements” formulated in a general manner for all equipment (e.g. apparatus and fixed installations) within its scope. These essential requirements define the results to be attained, but do not specify the detailed technical requirements. It also allows adapting the equipment and product design as a result of technological progress. The appropriate technical solutions to meet the requirements are not imposed as long as the equipment complies with the essential requirements.

The essential requirements lay down the necessary elements for protecting public and general interest.

Compliance with the essential requirements is mandatory. These are legally-binding for all equipment in the scope of the EMC Directive. Only compliant equipment may be placed on the market and/ or put in service in the Community.

The EMC Directive does not contain any additional requirements (e.g. concerning product quality). On occasion, commercial contracts specify additional EMC requirements, which are outside the legislation and are strictly business agreements negotiable between the two parties concerned. However, these provisions cannot be contrary to the essential requirements of this Directive.

The essential requirements are split into two parts:

“Protection requirements” for all equipment (e.g. apparatus and fixed installations). These protection requirements cover all relevant EMC phenomena for both emission and immunity.

“Specific requirements” for fixed installations.

3 CONFORMITY ASSESSMENT PROCEDURE FOR APPARATUS

3.1 Introduction

Apparatus is required to comply with the protection requirements referenced in Article 5 and detailed in Annex I of the EMC Directive.

Compliance with these protection requirements is demonstrated by applying the conformity assessment procedure detailed in Article 7 and Annex II (and Annex III on a voluntary basis) of the Directive.

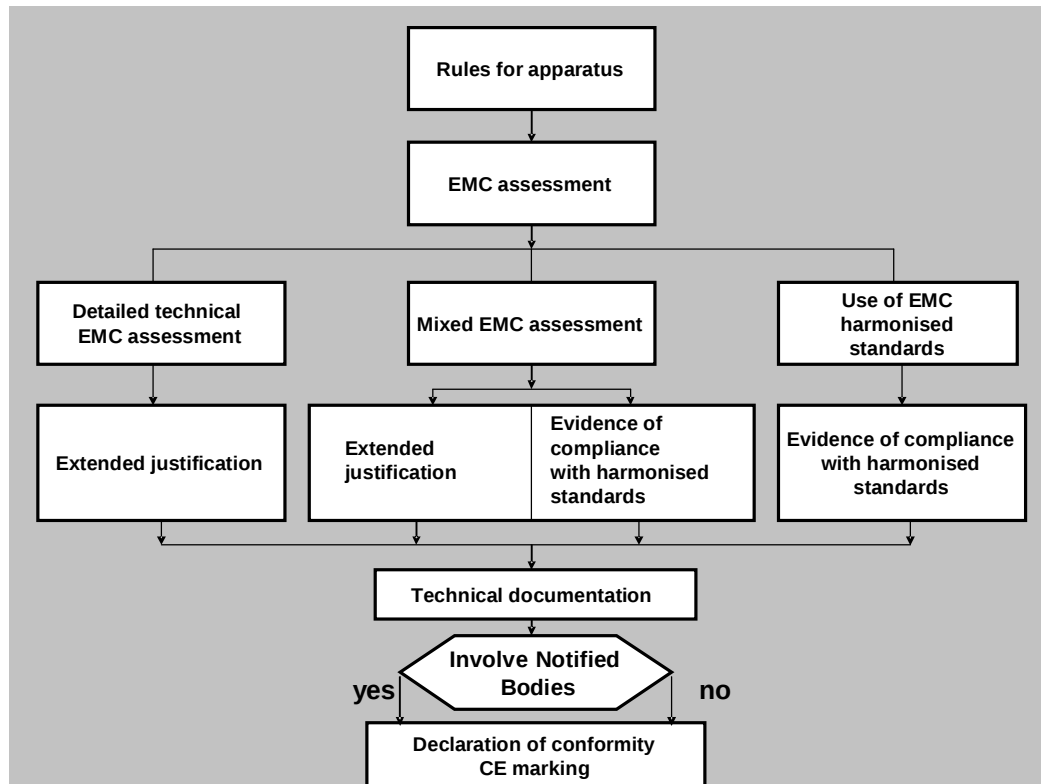
Technical documentation has to be prepared by the manufacturer to demonstrate evidence of compliance with the protection requirements. This includes evidence that the apparatus complies with the relevant harmonised standards or, if harmonised standards are not used or only used in part, a detailed technical justification. The manufacturer must take all measures necessary to ensure that the apparatus are manufactured in accordance with the technical documentation³³.

The manufacturer is also required to complete an EC Declaration of Conformity and affix the CE marking.

He/ She may opt on a voluntary basis to involve a Notified Body during the conformity assessment procedure.

³³ C. Annex II.8

Flowchart 5 - Conformity assessment procedure for apparatus



3.2 EMC Assessment

3.2.1 General Concept

The manufacturer needs to perform an EMC assessment of the apparatus³⁴ based on the relevant phenomena in order to ensure that he meets the protection requirements. As noted above the EMC Directive does not require the **mandatory** intervention from a third party when carrying out the assessment.

The manufacturer is fully responsible for applying the appropriate method of assessment. Recommendations are given in this Guide to help in this process.

Where the EMC assessment establishes that the apparatus concerned is inherently benign in terms of electromagnetic compatibility (both for emission and immunity) according to Article 1(3), the apparatus is excluded from the scope of EMC Directive and no further actions are

³⁴ Article 7 and Annex II

necessary. However, it is recommended to document the results of the assessment and its conclusion.

The EMC assessment needs to take into account all normal intended operating conditions of the apparatus.

In cases where the apparatus can take different configurations, the electromagnetic compatibility assessment confirms that the apparatus meets the protection requirements, “in all possible configurations identified by the manufacturer as representative of its intended use”.³⁵

In practice, this EMC assessment has to be performed following a defined methodology.

Three methods are possible for the EMC assessment:

- a) Application of EMC harmonised standards;
- b) An EMC assessment where no harmonised standards have been applied and the manufacturer applies his own methodology.
- c) Mixed assessment, combining the two previous methods. For example, one could use the harmonised standards to cover emission phenomena and a detailed technical EMC assessment for immunity aspects.

European harmonised standards provide a recognised methodology to demonstrate compliance to the protection requirements and are usually the preferred way to demonstrate compliance. Use of the relevant EMC harmonised standards (method a) to cover all protection requirements is equivalent to performing an EMC assessment. If this is not the case, he/she will have to substantiate that the steps taken are adequate to ensure compliance with the EMC Directive.

The manufacturer may ask a third party to perform the EMC assessment for him or help him with part of it, but the manufacturer is and remains fully responsible the compliance of his apparatus with the provisions of the Directive.

To re-iterate - **the EMC assessment is the sole responsibility of the manufacturer**; it is never the responsibility of a third party such as a Notified Body or an EMC test laboratory³⁶.

Where a manufacturer assembles a final apparatus using components from other manufacturers, the manufacturer must retain overall control. The manufacturer is responsible for the compliance of the final apparatus³⁷.

³⁵ Annex II.2

³⁶ The specific services and operation of Notified Bodies are described in chapter 6

3.2.1.1 The “Worst Case” approach

Where apparatus can take different configurations, the EMC assessment should confirm that the apparatus meets the protection requirements in all of the configurations foreseeable by the manufacturer as representative of normal use in intended applications.

In such cases it is considered sufficient to perform an assessment on the basis of the configuration most likely to cause maximum disturbances and the configuration most likely to be susceptible to disturbances.

This method is often referred to as the “worst case” scenario and aims to minimise the costs of the assessment.

It applies to apparatus that derive from a series all having similar characteristics such that it would be excessive to have all apparatus separately assessed/tested. It also applies to apparatus that may be placed on the market in different configurations with different permutations of apparatus and function, examples may include:

- Computer with external displays, CD-ROM devices, etc.;
- Apparatus of the same type with different power inputs where the source of disturbances or of possible immunity problems is independent of the power input.

Recommended procedure:

1. Identify the worst case apparatus in respect to the EMC characteristics;
2. Perform an EMC assessment for the worst case; this should cover all relevant phenomena;
3. Declare the selected worst case apparatus representative for the whole series;
4. Document the selection of the worst case(s).

The manufacturer is responsible for identifying the possible configurations and the choice of the worst case(s). The use of the worst case approach needs to be documented in the technical documentation³⁸.

³⁷ It is therefore recommended that any manufacturer of apparatus incorporating components and sub-assemblies from other sources should request information on their EMC characteristics and method of incorporation as part of the commercial process.

³⁸ Within the immunity and emission phenomena to be covered, different worst case selections may occur (because of non-related phenomena). This may increase the number of cases to be investigated

3.2.2 Use of EMC European harmonised standards

The correct application of the relevant European harmonised standards, whose references have been published in the relevant section of the OJEU, covering all the essential requirements of the EMC Directive is equivalent to the carrying out of the detailed technical EMC assessment. It is the most frequently used and recommended way to demonstrate EMC compliance.

When an individual apparatus is placed on the market, that complies with the EMC requirements of the relevant harmonised standards, as listed in the **current** consolidated list published in the OJEU, for use with the EMC Directive it has a **Presumption of Conformity** to the protection requirements of the EMCD.

The EMC Directive refers to the moment of placing on the market for each individual apparatus. This means that for apparatus which is continuously produced over a long period, the applicable standards may change in the course of time. In this case the provisions explained at 3.2.2.3 concerning the date of cessation of Presumption of Conformity should be taken into account. The Date of Cessation ensures that a transition period (usually three years) is foreseen during which the old and new standards are both valid.

After this time if the manufacturer wishes to continue to benefit from the Presumption of Conformity a new Declaration of Conformity is required to the later valid edition of the harmonised standard. This will require an EMC evaluation to the later version of the published harmonised standard and may require re-testing. However, it may be that the manufacturer wishes to continue to meet the essential requirements by continuing use of the “old” edition (that has ceased to be harmonised) plus other technical solutions if necessary. As harmonised standards are voluntary this is of course an acceptable solution but would not give the presumption of conformity that application of the later edition would confer. In addition, it will require amendment to the text of the Declaration given that the method of conformity assessment has now changed.

Where new editions become available and are to be applied it does not necessarily mean that a complete EMC re-assessment of an existing product is necessary. The evaluation may be restricted to those modifications directly affecting the apparatus concerned. For example, the change may only relate to a small range in scope, or one particular clause or phenomenon.

European Harmonised standards under the EMC Directive are drawn up and adopted by the three following European Standardisation Organisations:

- European Committee for Electro technical Standardization (CENELEC)
- European Telecommunications Standards Institute (ETSI)

- European Committee for Standardization (CEN)

Detailed information on the general EU policy regarding European harmonised standards is available at the following web-sites:

http://ec.europa.eu/comm/enterprise/electr_equipment

<http://www.newapproach.org>

3.2.2.1 List of European harmonised standards

The list of European harmonised standards published in the OJEU is regularly updated and is available on the following European Commission web-site:

<http://ec.europa.eu/comm/enterprise/newapproach/standardization/harmstds/reflist/emc.html>

Information on standards is also available on the CENELEC, ETSI and CEN web-sites:

www.cenelec.org

www.etsi.org

www.cen.eu

In order to obtain the text of the standards, you should contact the national members of CEN or CENELEC or the standardisation body of your country if you are located outside the territory of CEN/CENELEC members.

A list of members of CENELEC is available at:

<http://www.cenelec.org/Cenelec/About+CENELEC/Our+organization/CENELEC+Members/Default.htm>

ETSI standards are freely available on the ETSI web-site above.

Further guidance for the application of European harmonised standards is given in Annex 2.

3.2.2.2 Relevant European harmonised standards

The selection of the appropriate European harmonised standards is the responsibility of the manufacturer.

In many cases it is necessary to apply several such standards to cover all of the EMC protection requirements of the Directive.

Generally the three main aspects to be covered are:

- high frequency emission (related to radio protection);
- low frequency emission on the mains supply (harmonics, voltage fluctuations);
- Immunity to permanent and transient EMC phenomena.

Applying several standards may also be necessary for multi-function apparatus, for example those combining a radio broadcast receiver and another non-radio function, for example an alarm.

Alternative test and measurement methods, when introduced into a harmonised standard for the same purpose are considered, together with their associated limits, as equivalent regarding the provision of a presumption of conformity with the protection requirements.

Useful practical information on the selection of the appropriate standards may be found in the CENELEC Guide 25 "Use of EMC standards for the application of the EMC Directive" which is available on the Commission and CENELEC web-sites. The CENELEC Guide 24 also available on the same web-sites explains the general structure of the EMC standardisation and the respective roles of EMC standards, e.g. basic standards, generic and product (family) standards.

The ETSI TR 102070-1 for the application of harmonised standards to multi-radio and non-radio equipment for EMC (part 1: EMC) is available on the ETSI web site.

3.2.2.3 Date of cessation of Presumption of Conformity of the superseded standard

The OJEU provides the following information for each harmonised standard:

- the reference;
- the title;
- the reference of the superseded standard;
- The date of cessation of Presumption of Conformity of the superseded standard.

This date of cessation of Presumption of Conformity of the superseded standard should not be confused with the date of withdrawal (dow) of a superseded standard indicated by a standards organisation, although normally both these dates are identical. The "dow" has no meaning within the concept of the EMC Directive.

Any version of a standard taken from the latest valid OJEU list may be used as a harmonised standard until the date of cessation of Presumption of Conformity is reached.

Explanations are provided as notes attached in the list of European harmonised standards published in the OJEU and in the CENELEC guide 25.

3.2.3 An EMC assessment where no harmonised standards have been applied

A manufacturer may wish to declare the conformity of his apparatus directly to the protection requirements, without reference to harmonised standards, by making his own EMC assessment. This assessment needs to follow a technical methodology to ensure that the requirements of the EMC Directive are met.

The manufacturer will need to provide clear evidence of compliance.

This option allows flexibility for technical development, crucial when manufacturers of new or innovative apparatus for which standards do not exist, or cannot be used, want to assess their apparatus according to the protection requirements.

This is usually the case where:

- There are no European harmonised standards or where they do not cover all the protection requirements applicable to the apparatus;
- The apparatus uses technologies, incompatible with or not yet taken into account by European harmonised standards, and generic standards are not applicable;
- The manufacturer uses test facilities not yet covered by the European harmonised standards;
- The manufacturer may want to apply any other standards or specifications not harmonised in the context of the EMC Directive;
- The apparatus is physically too large to be tested in the facility described in the European harmonised standard or where “in-situ” testing is foreseen and not adequately covered by a harmonised standard.

The assessment required for a particular apparatus will depend on several factors, such as:

- Nature of the apparatus (apparatus characteristics);
- Intended use;

- Location of use; EMC environment
- Types of disturbances created by or affecting the apparatus;
- Environmental conditions;
- Performance criteria for immunity.

The EMC Directive requires the manufacturer to document all steps taken and decisions made to check the conformity of the apparatus for those aspects for which the manufacturer has chosen this method of assessment. It may encompass (but is not limited to) the following:

- Description and definition of the apparatus operating conditions and its intended purpose. This should also cover the power supply voltage and frequency aspects relevant to the apparatus;
- Specification, descriptions and classification of the environments in which the apparatus will be used. This may cover also aspects relevant for apparatus that may be moved and must have emission and immunity characteristics appropriate for several environments. This selection is the responsibility of the manufacturer based on knowledge of the electromagnetic environment and awareness of the statistical aspects involved;
- Clear specification of relevant sources and effects of the electromagnetic phenomena covered and compatibility levels applied;
- Specification of the performance criteria of the apparatus. These should be set taking into account of the reasonable expectations of the user;
- Test levels with regard to the immunity of the apparatus;
- Limits adopted for emission, etc.;
- Reference to available documents such as any European harmonised standards, recommendations;
- Indication of any deviations made to available reference documents. These deviations may concern the phenomena considered, tests methods, test facilities or test levels, etc.;
- EMC design considerations and/or calculation results;
- Statistical evaluations, theoretical studies or other examinations carried out, presenting background theory, arguments, results and conclusion. This may include information on the levels of occurrence and statistical distribution of the disturbances;
- Description on how components are selected;

- Information on shielding, cable screening and routing, filters, ferrites etc;
- Any description of the solutions adopted in order to comply with the protection requirements;
- Any specification of general or specific requirements taken to limit emission of disturbances;
- Assessment of whether compliance with the protection requirements is ensured in residential areas or not. If this is not the case the restriction of use shall be clearly established;
- Assessment of whether any specific precautions have to be taken when the apparatus is assembled, installed, maintained or used, in order to ensure that, when put into service, the apparatus is in conformity with the protection requirements;
- Worst case selection criteria for series of apparatus with similarities.

Detailed guidance on the selection of electromagnetic phenomena to be assessed in the EMC assessment is given in Annex 3 to this Guide.

Reference sources of information for the manufacturers undertaking this method of assessment continue to include European harmonised standards, their drafts as well as standards related to EMC but not harmonised under the Directive e.g. basic EMC standards.

To-reiterate, where this route is chosen the apparatus does not benefit from a presumption of conformity.

3.3 Documentation required by the EMC Directive

The documentation required by the EMC Directive comprises of the technical documentation and the EC Declaration of Conformity

3.3.1 Technical documentation

The manufacturer draws up technical documentation providing evidence of the conformity of the apparatus with the essential requirements of this Directive³⁹.

The purpose of the technical documentation is to enable the conformity of the apparatus with the protection requirements to be assessed. It must contain all necessary practical (technical) details, including the following:

³⁹ Annex II.3 and Annex IV

- An identification of the product covered by the technical documentation. This identification should allow unambiguously linking between the technical document and the product;
- A general description of the apparatus. The amount of information required will depend on the complexity of the apparatus, simple apparatus may be fully defined in one line whereas more complex apparatus may need a complete description (a picture may be included);
- If European harmonised standards have been applied then evidence of compliance is required. At a minimum this will be a dated list of the European harmonised standards applied and the results obtained on their application;
- If European harmonised standards have not been applied or have been applied only in part then a description of the steps taken to meet the essential requirements – an EMC Assessment described in Annex II of the Directive - must be included. The documentation includes test reports, design calculations made, examinations carried out etc.;
- If a manufacturer is using the procedure of Annex III of the EMCD, then the Notified Body statement shall be included.

As the directive does not provide for any rule regarding the linguistic regime of the technical documentation, one should refer to the horizontal guidance provided by the “Blue Guide”

3.3.2 *EC Declaration of Conformity*

The compliance of apparatus with all relevant essential requirements is declared by an ‘EC’ Declaration of Conformity (DoC) issued by the manufacturer - inside or outside the Community - or his authorised representative in the Community⁴⁰. As the DoC is an "official" Declaration is must be signed by a person: "empowered to bind the manufacturer or his authorised representative.

The Directive specifies the mandatory minimum content of the DoC as follows.⁴¹

- a reference to the Directive;
- an identification of the apparatus to which it refers, as set out in Article 9(1);

⁴⁰ If the manufacturer is outside and has an agreement with the authorised representative to this effect. See the Blue Guide for more details

⁴¹ Annex IV, 2

- the name and address of the manufacturer and, where applicable; the name and address of his authorised representative in the Community;
- a dated reference to the specifications under which conformity is declared to ensure the conformity of the apparatus with the provisions of this Directive;
- the date of that declaration;
- the identity and signature of the person empowered to bind the manufacturer or his authorised representative.

In most cases, the dated references to the specifications under which conformity is declared, will be those of the European harmonised standards that are applicable to the apparatus in question as listed in the OJEU. If European harmonised standards have not been used or only partially, a reference to the manufacturer's technical documentation needs to be included and a reference to any identifiable non-harmonised standards or specifications that have been applied.

The layout of the DoC can take any form as long as the minimum required relevant information is provided. If any of the minimum required content is missing, the DoC is considered not complete and thus not valid and may lead to an appropriate action from the competent authorities of a Member State.

The following standards have been drawn up with the objective of providing the general criteria for the EC Declaration of Conformity:

- EN ISO/IEC 17050-1:2005 Conformity assessment. Supplier's Declaration of Conformity. General requirements;
- EN ISO/IEC 17050-2:2005 Conformity assessment. Supplier's Declaration of Conformity – Part 2: Supporting documentation

.CENELEC has published a specific guide for the 'EC' Declaration of Conformity:

“CENELEC Guide n° 16 on the implementation of New Approach directives and the Low Voltage Directive with respect to the EC Declaration of Conformity”

It is left to the discretion of the manufacturer to add any information that could be useful in order to make the DoC applicable to areas outside the EU, provided that it does not conflict with the requirements of the EMC Directive.

Furthermore, in the case where several Directives apply simultaneously to the apparatus the manufacturer or the authorised representative is free to

decide whether it might be worthwhile to merge all the DoCs into a single document. However, this may not be possible if a Directive provides for a specific form of the DoC (such as the Directive relating to Personal Protective Equipment) that are not aligned with the DoC for the EMC Directive.

All information regarding the concept of making the DoC available for the authorities, as well as where to keep the DoC is given in section 3.3.3.

For examples see Annex V. Further information is provided in the Blue Guide.

3.3.3 *The Concept of “holding at the disposal”*

The Directive requires that:

“The manufacturer or his authorised representative in the Community shall hold the technical documentation and the EC Declaration of Conformity at the disposal of the authorities for a period of at least ten years after the date on which such apparatus was last manufactured. If neither the manufacturer nor his authorised representative is established within the Community, the obligation to hold the EC Declaration of Conformity and the technical documentation at the disposal of the competent authorities rests with the person who places the apparatus on the Community market.”

“Hold at the disposal” covers the obligation of “Making documentation available to the competent authority”.

The concept of holding at the disposal of means:

1. There shall be one person in the Community responsible for making available the EC Declaration of Conformity and the technical documentation;
2. This person must present the EC Declaration of Conformity and the technical documentation upon request by the competent authorities, within a reasonable time. He has to take positive actions to make it actually available to those authorities (send a copy of the file, email, etc.);
3. Failure to present the information within a reasonable period in response to a request by the authorities constitutes an infringement of one of the administrative requirements of the EMC Directive.
4. This person does not need to be in material possession of the documents. The documents can be kept on the manufacturer's premises, even if the manufacturer is outside the Community. However the authorities, who have limited geographical jurisdiction, cannot be expected to go beyond their frontiers to

examine the technical documentation at the manufacturer's premises. The manufacturer or his authorised representative in the Community is obliged to hold the required documents in such a way that they can be presented to the authorities upon first request and within a reasonable time. The onus rests with the manufacturer or his authorised representative in the Community to ensure that the documentation is provided.

5. Where neither are present in the Community, the responsibility for the provision of this information rests with the person first placing the products onto the Community market.
6. The manufacturer has to provide the documentation and cannot use the argument that it contains confidential information (e.g. commercial confidentiality).
7. It has been agreed by those concerned that the information to be made available on request needs not to be an original document but can be a copy. In addition, the technical documentation can be kept in any format (for example as a hard copy or CD-ROM or any other electronic storage method), which allows it to be made available within a reasonable period of time.

Neither the technical documentation nor the EC Declaration of Conformity has to accompany the apparatus. Nor is it a legal obligation under the Directive for manufacturers to make available technical documentation to their customers.

3.4 CE Marking and information

3.4.1 CE marking

The EMC Directive requires that the apparatus bears the CE marking as an attestation of compliance with the EMC Directive⁴².

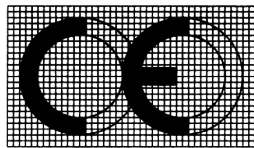
When use is made of the exemption provided by Article 13(1) for apparatus intended for incorporation into a given fixed installation and otherwise not commercially available (see section 3.4.4), it is not allowed to affix the CE marking to this apparatus to attest compliance with the EMC Directive. CE marking may however be required to show conformity to other Directives.

⁴² Article 8 and Annex V

The procedures specified in Article 8 and Annex V of the EMC Directive are in accordance with the “CE Marking Directive” (93/68/EEC).

The EMC Directive also forbids affixing of marks that are similar to the CE marking, and also those that are likely to mislead third parties in relation to the meaning of the CE marking, e.g. by giving the impression that they are needed in order to have free access to a Member State’s market.

For apparatus under the EMC Directive, the CE marking is the only marking having regulatory effect regarding EMC within the European Community.



The CE marking is affixed to the apparatus or to its data plate. For most apparatus this poses no difficulties to achieve whilst observing the requirement on minimum height of 5 mm.

The EMC Directive (as with most New Approach Directives) recognises that there are circumstances where it is “not possible or warranted on account of the nature of the product” to have the marking affixed to the apparatus or to its data plate. In such cases it is allowed to have the CE marking’ affixed on the packaging if such exists and in addition on the accompanying documents. Although the word “documents” is in plural, the intention is that the CE marking is in the “primary” documentation and is easily identified by the user and/or the surveillance authorities.

The Blue Guide (Chapter 7.3) gives more information as to which circumstances this exemption is allowed.

The EMC Directive does not forbid affixing the CE marking to more than one place, for example, on the packaging as well as the apparatus inside.

Affixing the CE marking denotes compliance with all applicable EC “New Approach” Directives. As a consequence, a product neither falling under the scope of the EMC Directive nor under the scope of other Directives providing for CE marking cannot bear this sign.

3.4.1.1 CE marking of systems

A system which is only placed on the market as a whole need carry only one CE marking, which may be placed on any one of the constituent parts or units. However the manufacturer may, if he wishes, place additional CE marking on the other parts of the system. This could be appropriate, for example, if the user were able to easily separate the constituent parts and make use of them separately. Additional CE marking does not incur the

need for separate conformity assessment or additional declarations of conformity for the constituent parts.

If separate use could lead to a part or unit failing to comply with the protection requirements, a suitable warning should be included in the instructions for use, for example: *The units of this system are intended to be used together, and must not be operated separately.*

If the manufacturer places any part of the system on the market separately, the relevant provisions of the Directive, conformity assessment, documentation and CE marking, apply separately to that part or unit, in addition to the requirements for the system as a whole.

3.4.2 Other identifying marks

The EMC Directive requires that apparatus be identified by “type, batch, serial number or any other information allowing for the identification of the apparatus”. There is flexibility in this requirement, allowing for the manufacturer to choose his own philosophy for identification of an apparatus for regulatory purposes. However, the identification of the apparatus must unambiguously correlate with the DoC and the technical documentation.

Although not explicitly mentioned this information needs to be on the apparatus (or its data plate). This will establish a link to the documentation where more information is given.

Specific apparatus intended to be incorporated into a given fixed installation (using the provisions of Article 13.2) and otherwise not commercially available may have this identification information in the accompanying documentation and not on the apparatus.

3.4.3 Information for traceability

In order to facilitate traceability, the EMC Directive requires that the actual manufacturer be identified by name and address. In cases where the manufacturer is located outside of the European Community, also the name and address of the authorised representative or (where neither are in the Community) the person responsible for placing the apparatus on the Community market needs to be given.

This information has to “accompany” the apparatus. It can thus be given in the documentation accompanying the apparatus, complementing the information usually found with the apparatus itself⁴³ or printed on the packaging.

⁴³ See section 3.4.2

3.4.4 *Information regarding installation, use and maintenance*

Apparatus may need assembling or special consideration in respect of its installation for it to comply with the protection requirements of the Directive. Therefore all information necessary for correct assembly and installation has to be provided. If no information is given with the apparatus it needs to be presumed that users can install the apparatus without any special considerations regarding the EMC aspects, and it will still comply with the protection requirements of the EMC Directive.

Examples of cases where it is relevant to provide more detailed information:

- If there are any particular earthing aspects related to the apparatus for EMC purposes, recognising of course that earthing for safety purposes cannot be compromised;
- Where the apparatus is connected to other apparatus there may be a need to have specific types of cables (e.g. screened, double screened). If so this must be specified to allow for proper installation.

Furthermore, any precaution that needs to be observed for the apparatus to maintain its compliance with the protection requirements regarding use and maintenance also needs to be indicated.

Finally, information on use of the apparatus in accordance with its intended purpose has to be provided in the user's instructions.

There has been a good deal of discussion in the development of this Guide in recognition of the "state of the art" in the provision of information. This has also recognised that other relevant Directives allow for a "hyperlink" or electronic media to be used for information relating to traceability.

The Commission services have taken as a bench-mark that the information provided to the end-user has to allow him/ her to use the apparatus without any further steps on their behalf.

In short, it is recognised that the receipt of a computer with a DVD R/W function might allow specific information to be provided in DVD format with the paper copy of the information restricted to the installation, set-up and evidently operation of the DVD function.

However, it is not accepted (in other cases than those stemming from the view above) that electronic media or a hyperlink is sufficient as an alternative to information in paper copy. The end-user has an absolute right to quick and easy use of the apparatus they have purchased with no further obligations (such as access to the internet).

If apparatus is sold via the internet it is considered that all necessary information that would otherwise have been available in material form should be accessible both to the intended end-user as well as market surveillance authorities.

3.4.5 Information when compliance is not ensured with protection requirements in residential areas

The EMC Directive recognises that the electromagnetic environment of residential areas needs particular attention. In such areas, broadcast receivers may be expected to be used in close proximity to other apparatus.

The EMC Directive requires that apparatus for which compliance with the protection requirements in residential areas is not ensured by the manufacturer (for example when limits for the residential environment in standards are exceeded) has to be accompanied by a clear indication of this restriction of use, where appropriate also on the packaging. A clear indication may take one of the following forms (decided by the manufacturer on the basis of the severity of a potential problem if the apparatus is used in such locations):

- This product must not be used in residential areas.
- This product may cause interference if used in residential areas. Such use must be avoided unless the user takes special measures to reduce electromagnetic emissions to prevent interference to the reception of radio and television broadcasts.

The descriptions used in harmonised standards (for example “this is a class A product”) are not suitable without further explanation, as they are not understood by the general public.

The information should be included on the packaging (if present) and may be restricted to the languages used elsewhere on the packaging. The information should also be included in the instructions for use, in each of the languages in which instructions are provided.

Products sold via mail order or the internet may not have packaging, or instructions for use, visible to the user before purchase. In such cases, the information should be provided clearly as part of the product’s description in the catalogue or on the webpage.

4 FIXED INSTALLATIONS

4.1 Essential Requirements

"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

Owing to their characteristics fixed installations are not subject to the need for free movement within the Community. Therefore, they are not subject to the requirements for CE marking, DoC or for formal EMC assessment before putting into service. However, fixed installations have to comply with the protection requirements and other specific requirements (Annex I of the Directive) which are applicable to them.

Measures are prescribed in the EMC Directive to enable the competent authorities to handle complaints concerning disturbance generated by fixed installations⁴⁴.

A fixed installation may be assembled by the incorporation of several apparatus including specific apparatus as described in Article 13(1) and other devices outside the scope of the EMC Directive. In order to fulfil the protection and documentation requirements it may be advisable to specify the EMC characteristics of all these devices in the technical documentation.

Most apparatus making part of a fixed installation should be subject to all provisions applicable to apparatus under the EMC Directive. However, there is a possibility of exemption detailed in Article 13.1 of the EMC Directive under certain conditions (See sections 1.3.2 and 4.4 of this Guide).

The specific essential requirements specify that fixed installations need to be installed taking account of good engineering practices and of the information provided by the respective manufacturers regarding the intended use of the components that make up the fixed installation. This is to comply with the protection requirements which are expressed in an identical way for fixed installations as for apparatus.

The two basic requirements relating to the use of components and to good engineering practice can be summarised as follows:

Intended use of components

This means that all the EMC instructions given by the manufacturer for all the component sub-parts used in the fixed installation have to be taken into account. This applies to any sub-part, whether those parts are large machines, apparatus, components not subject to the EMC Directive, specific apparatus for the fixed installation, etc.

Since a fixed Installation is installed in a pre-defined location the instructions for use should ensure that the components are installed in this specific location.

⁴⁴ Article 13 (2))

For example, these instructions may concern:

- the specified environment (especially the EMC environment);
- the required use of additional auxiliary devices (protection devices, filters etc);
- the specifications and length of the cables required for external connections;
- the conditions for use;
- Any special precautions for EMC (equipotential earthing etc.).

Good engineering practice

Good engineering practice comprises of suitable technical behaviour taking account recognised standards and codes of practice applicable to the particular fixed installation. The “good engineering practices” referred to in Annex I, 2 mean practices which are good for EMC purposes, at the specific site in question

General information on good engineering practice within the context of installations is available in several EMC handbooks, courses and technical reports. For example some technical reports published by standardisation bodies deal with installation and mitigation guidelines for EMC.

Good engineering practice, particularly in the field of EMC, are in constant evolution. Whilst there is a need to have regard for the ‘state of the art’ practices it does not necessarily follow that they are relevant for all installations. Standards for installations cannot cover all specific local conditions: therefore it is necessary to be aware of some guiding principles when aiming to demonstrate installation according to good engineering practices:

- Emissions: take appropriate actions to mitigate the source of disturbances by EMC design, e.g. by the addition of filters or of absorption devices etc.
- Coupling and radiation: take appropriate actions in respect of distances, equipotential earthing, selection of cables, screening etc.
- Immunity: take appropriate actions to ensure that sensitive equipment is protected against the various types of disturbances that might be expected.

When applying the protection requirements to a defined fixed installation, it is essential to define the borderlines/geographical limits of this fixed installation in order to distinguish it clearly from the external environment.

In an analogy with apparatus, it is fundamental to identify:

- The ports/interfaces where conducted (high or low frequency) disturbances may cross the borderline from or towards the fixed installation (power supply port, control and telecommunication ports etc.);
- The coupling mechanism with the external environment;
- The radiation towards or from the external environment.

It should be noted that it is not the purpose of the EMC Directive to ensure electromagnetic compatibility between specific equipment inside the borders of the defined fixed installation.

4.2 Documentation

The level of detail of the documentation may vary from very simple information to much more detailed documentation for complex installations involving important potential EMC aspects. Where installations are comprised solely of apparatus placed on the market in conformity with the EMC Directive and carrying the CE marking, the responsible person satisfies the documentation requirements placed on him by being able to provide, on request, the instructions for installation, use and maintenance provided by the supplier of each apparatus:

4.3 Responsible person for fixed installations

Member States are responsible for establishing provisions to identify such persons who are responsible for a fixed installation.

4.4 Requirements for specific apparatus for given fixed installations

The general principle is that all apparatus are subject to all the relevant provisions of the EMC Directive. However, the EMC Directive provides at Article 13(1) the possibility of exception for apparatus intended for incorporation in a given fixed installation and which are otherwise not commercially available.

An apparatus can only benefit from this exemption if there is a direct link between the manufacturer of that specific apparatus and the owners, installers, designers, operators or responsible persons of the fixed installation for which that specific apparatus is intended. A link provider-customer is required.

For the specific apparatus which may benefit from this exemption, the protection requirements for those apparatus considered in isolation, the conformity assessment procedure for apparatus, the subsequent EC

Declaration of Conformity and the specific marks and information for apparatus are not compulsory⁴⁵.

Specific apparatus for which use is made of this exemption may not bear the CE marking for EMC purposes.

This exemption is extra-ordinary and that it is only provided on a case-by-case basis. However, the reader's attention is brought to the second part of Article 20 of the preamble which states:

“Should apparatus be incorporated into more than one identical fixed installation, identifying the electromagnetic compatibility characteristics of these installations should be sufficient to ensure exemption from the conformity assessment procedure.”

The characteristics of the identical installations, **together with their specific locations** need to be identified alongside each unit of specific apparatus intended for incorporation. The storage of “specific apparatus” units intended for more than one fixed (identical) installation is therefore permitted so long as these conditions are fulfilled

4.4.1. Obligations when the exemption clause is used for specific apparatus

In the case of such specific apparatus, the following indications are required in the accompanying documentation: the type, the batch, the serial number or any other identifying information of the apparatus as well as the name and address of the manufacturer and, if he is not established within the Community, the name and address of his authorised representative or of the person in the Community responsible for placing the apparatus on the Community market.

The accompanying documentation has to identify the fixed installation for which the specific apparatus is intended and the electromagnetic compatibility characteristics of the fixed installation.

Furthermore, the precautions to be taken for the incorporation of the specific apparatus, in order not to compromise the conformity of the given fixed installation, has to be given in the accompanying documentation.

⁴⁵ See 4.4.1

5 ENFORCEMENT OF THE EMC DIRECTIVE

The purpose of market surveillance is to ensure that the provisions of the EMC Directive are complied with across the Community. Consumers, workers and other users are entitled to an equivalent level of protection throughout the single market, regardless of the origin of the product. Further, market surveillance is important for the interest of economic operators, because it helps to eliminate unfair competition.

Member States need to take all appropriate measures to ensure that equipment is placed on the market and/or put into service only if it complies with the requirements of the EMC Directive, when properly installed, maintained and used for its intended purpose.

This obligation is complementary to that requiring Member States to allow free movement of equipment that is in compliance with the EMC Directive.

It requires thus that Member States, where applicable:

- check that equipment is meeting the requirements, that action is taken to bring non-compliant equipment into compliance, and that sanctions are applied where necessary; and,
- deal with special measures and interference complaints

The EMC Directive does not contain provisions on how surveillance should be organised and carried out in the Member States. The legal and administrative surveillance infrastructures can therefore be different from one Member State to another.

No equipment can be excluded from surveillance operations, even if they have been subject to any voluntary certification scheme or other voluntary initiatives, or have been assessed according to the procedure involving a Notified Body.

The EMC Directive enables surveillance authorities to gain access to information on the equipment, the EC Declaration of Conformity and technical documentation. These must be made available by the manufacturer, the authorised representative established within the Community, or where neither is presenting the Community, by the importer or person responsible for placing onto the market, or by the responsible person for a fixed installation.

5.1 Special measures regarding equipment at trade fairs, etc.

An exception to the principle that market surveillance can only take place after the manufacturer has taken formal responsibility for the equipment, is

the case of equipment being displayed and/or demonstrated at trade fairs, exhibitions and demonstrations.⁴⁶

The Directive allows the display and/or demonstration of non-compliant equipment under specific circumstances, i.e. provided that a visible sign clearly indicates that the equipment may not be marketed or put into service until it has been brought into compliance, and that adequate measures are taken during demonstrations to ensure that electromagnetic disturbances are avoided.

Competent authorities of Member States monitor that this obligation is respected and can take appropriate measures when these pre-conditions are not followed by the persons responsible for the display and/or demonstration. This may include stopping any demonstration or having the equipment being removed from the trade fair, exhibition or similar event as well as issuing warnings.

6 NOTIFIED BODIES

6.1 General concept

In the EMC Directive the involvement of the Notified Body is **voluntary** and the purpose of the Body is to help the manufacturer (or his authorised representative within the Community) by reviewing the technical documentation for apparatus drawn up by the manufacturer.

The difference between any third party (such as an EMC test laboratory) and the Notified Body is that the Body has been designated by the competent authority of the Member State as competent to review the technical documentation.

Member States verify that these Bodies meet the criteria given in Annex VI of the EMC Directive i.e. that it can demonstrate the required level of competence, independence, impartiality and integrity. This is subject to surveillance at regular intervals.

A Body can either be established on the territory of the EEA, or established on the territory of a State that has a Mutual Recognition Agreement (MRA) in operation with the European Union, covering the EMC Directive. Within the MRA concept these Bodies are named Conformity Assessment Bodies (CAB) but they are equivalent to EEA Notified Bodies.

Mutual Recognition Agreements on conformity assessment in the area of EMC, between the EU and third countries have entered into force on: 1/12/1998 with the United States, 1/11/1998 with Canada, 1/01/1999 with

⁴⁶ Article 4(3)).

Australia and New Zealand, 1/01/2002 with Japan, 1/06/2002 with Switzerland

6.2 Role of Notified Bodies

The role of the Notified Body derives from Article 7 and Annex III of the EMC Directive. Their designation criteria are laid down in Annex VI.

The Notified Body shall:

- Only accept requests for assessment of technical documentation from manufacturers (inside or outside the Community) or their authorised representatives in the Community. The manufacturer defines which aspects of the essential requirements the Body is to assess.
- Review the technical documentation of the apparatus and assess whether the technical documentation properly demonstrates that the relevant aspects of the essential requirements of the EMC Directive have been met.
- Issue a Notified Body statement, to the manufacturer or authorised representative, if the compliance of the apparatus is confirmed for the requirements assessed. The Body will limit the statement on those aspects of the essential requirements of the apparatus that have been requested by the manufacturer and assessed by the NB.

If the compliance of the apparatus is not confirmed, the Body **has to** provide a negative response describing on what grounds the technical documentation of the apparatus fails to demonstrate compliance to the EMC Directive.

6.3 Selection of a Notified Body

The EU Commission maintains a website list of all NBs including CABs. (<http://ec.europa.eu/enterprise/newapproach/nando/>). The list includes the address of each organisation as well as the scope of the designation.

When selecting a Notified Body manufacturers should consider the following:

A Body can only render services within its scope of designation, however it should be understood that there are no agreed criteria for the definition of "scope of designation".

The Body is free to offer its services, to any manufacturer established either inside or outside the Community. Although the Body must be established on the territory of the Notifying State, it may have personnel outside that State or may carry out its activities on any territory and at any premises (for example at manufacturers' premises).

Manufacturers are free to choose any Body. There is no need to choose an Body located in the country where the apparatus is manufactured, nor in the country to which the apparatus will be shipped or where the apparatus is brought on the market or taking into service.

If the manufacturer has used the service of a Body for one of his apparatus there is no obligation to use the same NB for any of his other apparatus. This also applies to modifications of original assessed apparatus.

Although not prescribed in the Directive, it is the general principle of the “New” and “Global” Approaches to legislation that a formal application can only be made by the manufacturer to a single Notified Body. It is also the view of the member states (responsible for the operation of Notified Bodies) that the opinion given by the Bodies is binding on the manufacturer i.e. any non-compliances identified cannot be ignored.

6.4 Coordination between Notified Bodies.

To achieve a higher degree of efficiency and uniformity in their work an organisation of Notified Bodies has been set up. This organisation is the Association of Notified Bodies (**ECANB**), which provides Internet-based support to the exchange of information between the NBs.

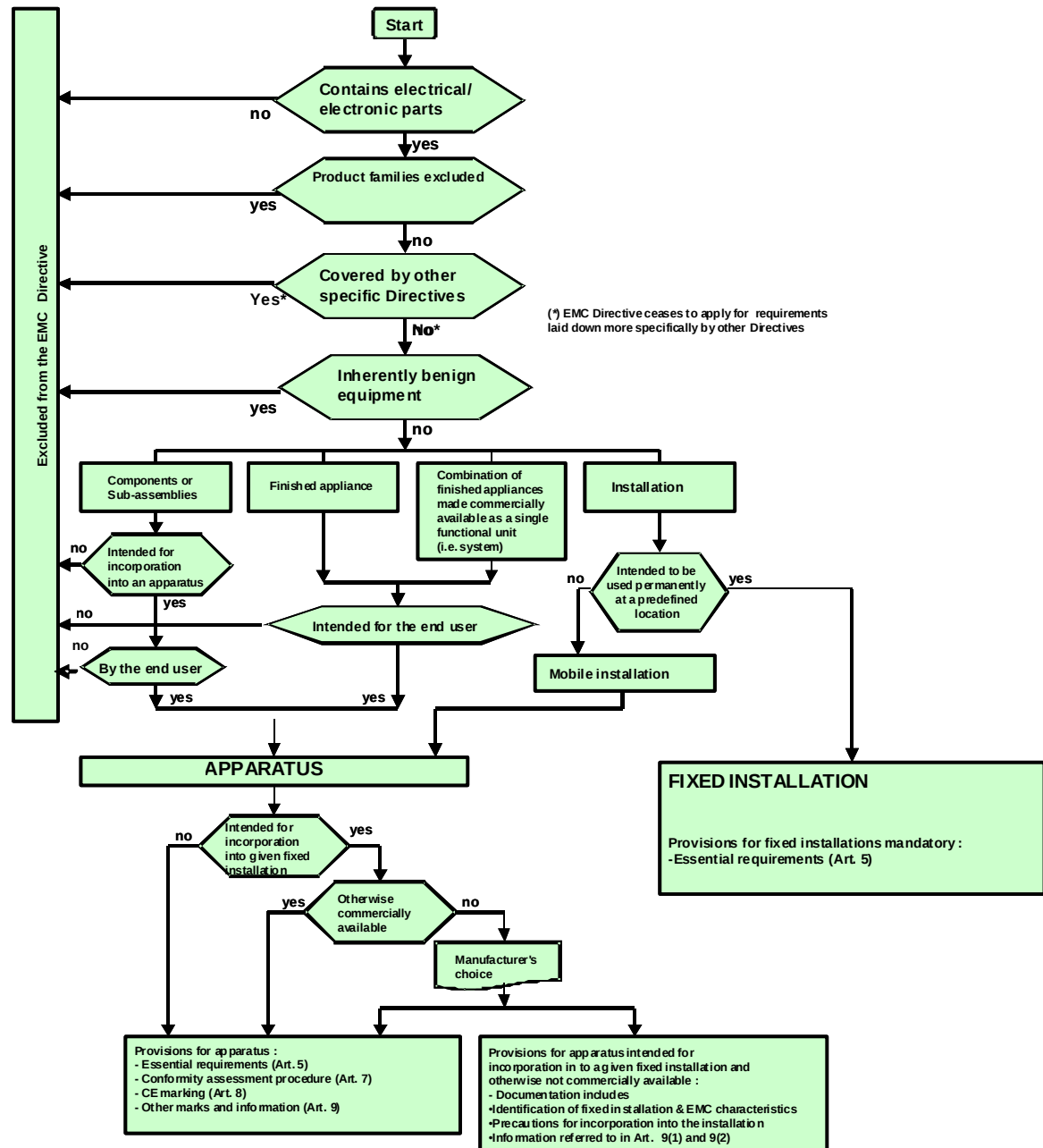
The relevant ECANB working documents, meeting reports, recommendations and guidelines are available to all Bodies. The ECANB issues information sheets, called technical guidance notes (TGNs) which have been established in order to assist the Bodies in their task. These TGNs may also contain valuable background information for manufacturers. The approved TGNs are therefore placed in the public domain (Technical Guidance Notes – TGN) and serve as general reference.

6.5 Complaints regarding the service of the NB

Where a manufacturer has a complaint regarding the service performed by a Body, he should preferably first file a complaint with the organisation in question. However, the option exists to contact the competent authority of the Member State.

Where it is confirmed by the procedure of the Directive that an apparatus is non-compliant and it has been subject to the conformity assessment procedure involving the service of a Body the Member State supervising the Body shall take appropriate action in respect of the author of the Notified Body statement, and shall inform the Commission and the other Member States accordingly.

ANNEX 1 - Overall Flowchart



ANNEX 2 - Guidance on using a (harmonised) standard

Referencing a given standard in a DoC means that the manufacturer takes responsibility of the conformity of his equipment with all the provisions of that standard and that this can be demonstrated by applying the methods (tests, measurement methods, etc.) this standard describes or refers to.

The requirements and limits of this standard are expected to be met when the equipment is tested to the standard, for example by market surveillance authorities in the case of a harmonised standard referred to by the manufacturer in the DoC.

The only secure way for the manufacturer is thus to apply, without any deviation, the standards referred to, relevant for its equipment, while making the EMC assessment. As most EMC standards include a series of tests with associated measurement methods, that implies in particular that all normative tests indicated should be done exactly as required by the standard with regard to test and measurement methods

Notes on some practices

There are circumstances where the manufacturer deviates, under his full responsibility, from the preferred way described above. The deviations described hereafter imply a risk for the manufacturer. He has to evaluate this risk when he declares conformity to a harmonised standard by allowing himself such deviations. The technical documentation should give detailed information on such deviations.

a) The manufacturer may decide in some cases not to perform some tests if he can satisfy himself by other means (e.g. design precautions, comparison with similar apparatus) with sufficient certitude that the requirements of the standard will be met, if the tests were executed. He may also decide under his responsibility not to perform some tests if the inherent physical characteristics of the apparatus are such that negligible disturbances will occur in a given frequency band.

b) The manufacturer may also have at disposal test installations not complying in all details with all the prescriptions of the standard or use simplified methods (sometimes called pre-compliance methods). He then takes a risk in declaring conformity to the standard. The risk may be minimised by taking increased margins with regard to the limits or by having performed comparison tests between his simplified method and the full compliant method.

c) A pre-scan measurement is made to quickly obtain information on the unknown emission spectrum of the apparatus in order to decide whether a

full complete measurement is considered necessary. More information may be found in EN 55016-2 (CISPR 16-2) on this particular subject.

ANNEX 3 - EMC assessment where harmonised standards have not been applied in whole or in part

Guidance for selecting the electromagnetic phenomena to be assessed

The EMC Directive requires the identification of the relevant disturbances and EMC phenomena for the apparatus and the environments where it operates in order to determine the relevant assessment to be performed.

Although the EMC Directive does not specify a frequency range, it is general practice to take account of the range of frequency encompassed in the EMC assessment from 0 Hz to 400 GHz. This does not mean there is a need to apply a full assessment within this range as certain phenomena are limited in frequency range (e.g. for conducted high frequency emission: the frequency range to take into account is usually 9 kHz to 30 MHz). For some apparatus, electromagnetic phenomena are inherently limited in frequency range by the principle of construction or the physical nature of the apparatus.

The frequency range to be applied in the assessment depends on the nature of the apparatus and its intended use. However it is important to make sure that the relevant frequency range has been covered in combination with the phenomena to be assessed.

The selection of phenomena to be assessed depends on the environment where the apparatus is being used.

The technology of electromagnetic compatibility has developed over a long period of time and is a fairly complex subject. The use of the radio spectrum is subject to constant changes, applying new RF technologies that may require a different protection against disturbances. An identical situation may occur for low frequency phenomena. In the field of electromagnetic immunity the sources that may create immunity problems are also constantly changing.

There exists a finite probability that the apparatus in practice will experience disturbance levels the severity of which is above those specified as characteristic of the apparatus. On the other hand it is not feasible to aim for 100 % performance in all situations, i.e. for immunity, temporary degradation in performance may be acceptable for certain apparatus.

For emission there may be special cases, for instance when highly susceptible apparatus is being used in proximity, where additional mitigation measures may have to be employed for individual apparatus to reduce the electromagnetic emission further below any specified levels. This issue may be taken into account during the assessment.

One should be aware that the problem of electromagnetic compatibility may become worse with the trend towards smaller devices operating at higher frequencies. Higher speed switching logic increases emissions while low operating voltages and currents, with circuits packaged more closely together, decreases immunity. Furthermore the mechanisms for radiation from apparatus are complex due to the different number, nature and interaction of interference sources that are active within the apparatus.

EMC covers conducted and radiated phenomena over the whole frequency range from 0 Hz to 400 GHz and may relate to many different phenomena such as given in the following non-exhaustive list of examples. Generally the three main aspects to be covered are:

- (a) Low-frequency emission on the mains supply (harmonics, voltage fluctuations) for all apparatus intended to be connected directly to low-voltage public distribution systems.
- (b) High frequency emission aspects.
- (c) Immunity aspects.

For the detailed technical EMC assessment the phenomena in the list need to be considered, unless it can be justified that a phenomenon is not relevant for the apparatus to be assessed. It may also be necessary in some cases to consider a phenomenon that is not listed in the list of examples.

List of examples of electromagnetic phenomena

Conducted low frequency phenomena	
Emission	Immunity
Harmonics and voltage fluctuations likely to be produced on the mains supply by apparatus intended to be directly connected to the low-voltage public power distribution system.	a) harmonics, interharmonics on the mains supply This phenomenon may be relevant to apparatus sensitive to precise zero crossing in time on the a.c. mains voltage or to specific harmonic components. b) signals superimposed on power lines; May be relevant for apparatus operating at low level of sensitivity such as residual current operated protection devices. c) voltage fluctuations on the mains supply In general, voltage fluctuations have an amplitude not exceeding 10 %; therefore,

	most apparatus are normally not disturbed by voltage fluctuations. However, this phenomenon may be relevant for apparatus intended to be installed at locations where the mains have larger fluctuations. d) voltage dips and interruptions on the mains supply To be considered generally for all types of apparatus. If the principle of the apparatus requires or involves a particular sensitivity to such phenomena, this should be indicated in the user documentation. e) voltage unbalance; Only applicable in special cases for three phase apparatus f) power frequency variations of the mains supply This may apply to apparatus intended to be installed at locations where the power frequency has large variations (for example apparatus connected to an emergency power supply). g) induced low frequency voltages For sensitive low level measuring instruments; h) d.c. component in a.c. networks. For special cases as residual current circuit breakers
Radiated low-frequency field phenomena	
Emission	Immunity
Generally not relevant	a) magnetic fields 1) continuous; 2) transient;

	In general only relevant for apparatus which are susceptible to magnetic fields (for example Hall effect devices, CRT and special apparatus to be installed in high magnetic field environments). If apparatus is intended for use in a low magnetic field environment, this characteristic should be indicated in the user documentation. b) electric fields. Relevant only for special applications in measurements
Conducted high-frequency phenomena	
Emission	Immunity
Generally relevant for most electronic and for many electrical apparatus. Exceptions may occur for apparatus which do not contain any source likely to generate high frequency disturbances. a) induced voltages or currents 1) continuous waves; 2) modulated waves; 3) discontinuous waves There are two methods of assessing conducted disturbances, either as a voltage or as a current. Both methods can be used to assess the three types of conducted disturbances, i.e.: – common mode (also called asymmetrical mode) – differential mode (also called symmetrical mode) – unsymmetrical mode (combines both modes by using specific artificial test networks) <i>NOTE the unsymmetrical mode voltage is primarily measured at the mains network.</i>	a) induced voltages or currents 1) continuous waves; 2) modulated waves; b) unidirectional transients ; c) oscillatory transients. Induced high frequency voltages or currents are generally relevant for electronic apparatus, except the simplest ones. In general, fast transient aspects should be assessed for apparatus which are connected to mains or have cables (signal or control) in close proximity to mains. The surge aspects should be assessed for apparatus which are connected to networks leaving the building or mains in general.

<i>The common mode voltage (or current) is measured primarily for signal and control lines.</i> Account should be taken of the following types of disturbance: a) narrowband continuous disturbance, b) broadband continuous disturbance; and c) broadband discontinuous disturbance	
Radiated high-frequency field phenomena	
Emission	Immunity
a) magnetic fields; b) electric fields; c) electromagnetic fields 1) continuous waves; 2) modulated waves; 3) transients. Generally relevant for most electronic and for many electrical apparatus. Exceptions may occur for apparatus which do not contain any source likely to generate high frequency disturbances. Generally magnetic fields are considered up to 30MHz and electromagnetic fields above 30MHz up to 1000MHz. There may be a need to cover phenomena above 1000MHz for apparatus with fast microprocessors.	a) magnetic fields; b) electric fields; c) electromagnetic fields 1) continuous waves; 2) modulated waves; 3) transients. In general, the radiated immunity to electromagnetic fields is relevant to all apparatus. Exclusions may include non-electronic apparatus. Pulse magnetic fields. This test is mainly applicable to apparatus to be installed in electrical plants (for example telecontrol centres in close proximity to switchgear).
Electrostatic discharge phenomena (ESD)	
	Immunity

	In general, electrostatic discharge aspects are applicable to all apparatus to be used in an environment where electrostatic discharges may occur. Direct and indirect discharges should be taken into account. Exclusions may include apparatus limited for use in high humidity environments or in ESD-controlled environmental conditions and non-electronic apparatus.
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ANNEX 4 – Transitional arrangements

Date of application (Article 14) :20 July 2007

The current EMC Directive 89/336/EEC is repealed from this date. National provisions implementing the new EMC Directive 2004/108/EC must be applied from that date. As from 20 July 2007, equipment compliant with the new Directive may be placed on the market and/or put into service. The national transpositions of the new Directive cannot be put into force before this date of application. Thus equipment claiming compliance with the new EMC Directive cannot be put on the market and/or put into service before the date of application of 20 July 2007.

Transitional provisions (Article 15): date of application plus 2 years, i.e. 20 July 2009

- For apparatus in the sense of the old EMC Directive 89/336 (i.e. excluding installations in the sense of this Directive) for which the manufacturer or his authorized representative has issued a Declaration of Conformity before 20 July 2007 can continue to be manufactured and placed on the market up to 20 July 2009⁴⁷.
- Installations: installations are excluded from the scope of the transitional provisions laid down in Article 15 of 2004/108 as installations are not, as such, placed on the market and, according to its wording, Article 15 only applies to "equipment" which is "placed on the market". As a result, new installations put into service on or after 20 July 2007 have to comply with the “new” EMC Directive 2004/108.
- Installations put into service before 20 July 2007 will have been subject to Directive 89/336/EEC. The new EMC Directive 2004/108/EC introduces new requirements for fixed installations. The question arises as to how these requirements will apply to existing fixed installations. Fixed installations in service on 20 July 2007 are not subject to the provisions of Directive 2004/108/EC until they are modified in a way that may affect their electromagnetic compatibility.

⁴⁷ Provided “state of the art” remains unchanged

When such an installation is modified:

- A responsible person must be identified;
- The modifications must be carried out employing good engineering practices respecting the information on the intended use of components;
- The obligation to document good engineering practice relating to the installation is limited to consideration of the changes or additions that could affect its electromagnetic compatibility characteristics.

ANNEX 5 Examples of EC Declarations of Conformity

Example 1.

- This DoC is only applicable for the EMC Directive;
- The manufacturer is located outside the EU and he has a representative in the EU;
- The specifications applied are only all the relevant harmonised standards, applied in full;
- Use is made of the opinion of a Notified Body;
- In this example the mandatory minimum requirements according to the EMC Directive are given in **bold** and the *optional data (that the manufacturer finds useful) in italics*

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	Company Logo	
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EC Declaration of Conformity

We, the undersigned,

Manufacturer	Tokyo Apparatus Ltd.
Address, City	Nagata-cho 1-11-35, Chiyoda-ku, Tokyo
Country	Japan
Phone number	+ 81 1234567
Fax number/e-mail	+ 81 7654321
Authorised representative in Europe	Mr. E. Veen, Director TAL Europe B.V.
Address, City	Emissionstreet 2, Immunitytown
Country	Belgium

certify and declare under our sole responsibility that the following apparatus:

Description	Seminar Presentation Machine
Manufacturer	Tokyo Apparatus Ltd.
Brand	Honshu
Identification	Model De Luxe
Restrictive use	For residential and office environment only

conforms with the essential requirements of the EMC Directive 2004/108/EC, based on the following specifications applied:

EU Harmonised Standards
EN 55099:2009
EN 55099:2010
EN 55088:2008

and therefore complies with the essential requirements and provisions of the EMC Directive.

The following Notified Body has issued a positive Statement of Opinion.

Notified reference	Body	Identification of NB letter of Opinion	Name and address of NB
9999		Nr. 200700234	EMC Services BV NB street 1 EMC City The Netherlands

The Technical documentation is kept at the following address:

Company	Tal Europe B.V.
Address, City	Emission street 2, Immunity town
Country	Belgium
Phone number	+ 32 99999999
Fax number/e-mail	+ 32 88888888 veen@tal.belgium

Name and position of person binding the manufacturer or his authorised representative	
Mr. Atsushi Gotoh Manager Product Design Tokyo Apparatus Ltd.	20 August 2010

Example 2.

- In this DoC the manufacturer wants to use the worldwide SDoC model according to the ISO Guidance making sure the mandatory minimum requirements applicable for the EMC Directive are fully covered;
- The manufacturer is located inside the Community;
- This DoC is only applicable for the EMC Directive;
- The technical specifications applied are a combination of a non standard test as well as EU harmonised standards, one applied only partial;

Suppliers Declaration of Conformity (conform ISO 17050)

1. **Number of SdoC:** 23456
2. **Issuer's name:** Electronic Emission Presentation B.V.
Immunitystreet 2
Emission City
Belgium
3. **Object of declaration:** Seminar Presentation Machine
Honshu Model de Luxe
4. **The object of declaration described above is in conformity with the requirements of the following documents:**

Document No:	Title
2004/108/EC	EU EMC Directive (December 2004)
EU Harmonised standards	EN 88099:2009
	EN 99099:2010
	EN 99088:2008 Part X except Chapter Y
EEP test method: 2009	Test method XYZ. To cover the parts of EN 99088 not being applied
5. **Additional information** A technical documentation nr. Global Presentation nr. YZZ is available to document compliance of the excluded part of the harmonized standard
6. **Signed for and on behalf of:** Electronic Emission presentations B.V.
7. **Date:** 30 August 2010
8. **Name and Function:** Mr. E Veen Managing Director


ANNEX 6 Acronyms and abbreviations

a.c.	Alternative current
CEN	European Committee for Standardisation
CENELEC	European Committee for Electrotechnical Standardization
CISPR	International Special Committee on Radio interference (Comité International Spécial des Perturbations Radioélectriques)
d.c.	Direct current
DoC	EC Declaration of Conformity
ECANB	Association of Competent Bodies
EEA	European Economic Area
EMC	Electromagnetic Compatibility
EMCD.	Electromagnetic Compatibility Directive
ESD	Electrostatic discharge
ETSI	European Telecommunications Standards Institute
EU	European Union
IEC	International Electrotechnical Commission
IEV	International Electrotechnical Vocabulary
ISO	International Organization for Standardization
ITU	International Telecommunication Union
LED	Light emitting diode
MRA	Mutual Recognition Agreement
NB	Notified Body
OJEU	Official Journal of the European Union

R&TTE	Radio and Telecommunication Terminal Equipment
RF	Radio frequency
TGN	Technical_Guidance_Note
TR	Technical Report