Final Draft, 4 May 16

Guide for the EMC Directive 2014/30/EU

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Disclaimer

These guidelines are intended to be a manual for all parties directly or indirectly affected by the "new" Electromagnetic Compatibility Directive 2014/30/EU (EMCD). 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 Union. The legally binding provisions are those transposing the EMCD at the national level.

Finally, the reader's attention is drawn to the fact that all references to the CE marking and EU Declaration of Conformity relate only to the EMCD 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

This EMC Guide should always be read in conjunction with the 'Blue Guide' on the implementation of EU product rules[1].

The purpose of this EMC Guide is to give guidance on certain matters and procedures of the Directive 2014/30/EU[2] on the harmonisation of the laws of the Member States relating to electromagnetic compatibility[3] (EMCD). References in this EMC Guide to the Union or the single market are, accordingly, to be understood as referring to the EEA, or to the EEA market. The EMC sector is falling under the Mutual Recognition Agreement on Conformity Assessment between the EU and Switzerland [4], therefore, they are to be understood also to apply to Switzerland.

The Electromagnetic Compatibility (EMC) Directive 2014/30/EU (EMCD) repeals the previous EMCD 2004/108/EC and maintains the same objectives - to guarantee the free movement of equipment [5] and to create an acceptable electromagnetic environment in the Union territory[6].

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[1] The Blue Guide is the main reference document explaining how to implement the legislation based on the New Approach, now covered by the New Legislative Framework. The latest version of the Blue Guide can be found via http://ec.europa.eu/growth/single-market/goods/index_en.htm

[2] OJ No L96, 29.3.2014

[3] 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 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.

[4] The consolidated version of the agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment (OJ L 114, 30.4.2002, p. 369–429). can be found at http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02002A0430(05)-20150414

[5] "equipment' means any apparatus or fixed installation c. Article 3(1)(1)

[6] 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 EMCD, in the same right as of the Union territory. When the term, "Union" territory, is used in this guide, the same applies to the EEA territory. EMCD is also applicable in other territories where a suitable international agreement is in operation.

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

- equipment shall comply with the requirements of the EMCD when it is made available on the market and/or put into service when properly installed, maintained and used for its intended purpose;

- the application of good engineering practice is required for fixed installations, with the possibility for the competent authorities of Member States to request evidence of compliance of the fixed installation, and, when appropriate, initiate an evaluation if non-compliances are established.

After 2010, the Blue Guide was updated to the New Legislative Framework[7] (NLF). The New Legislative Framework (NLF) is a flexible regulatory framework for the marketing of products. In 2014 a set of Directives (including the EMCD and Low Voltage Directive (LVD)) were aligned according to NLF. Also in 2014, the Radio Equipment Directive (RED) entered into force and has to be implemented into national legislation from 13 June 2016.

The EMCD 2014/30/EU has to be applied from 20 April 2016 on. More and detailed guidance on the date of applicability and their transitional period (if any) for the new Directives of the electrical sector i.e. RED (Directive 2014/53/EU), new LVD (Directive 2014/35/EU) and new EMCD (Directive 2014/30/EU) is given in Annex 4 and also online available here.

The main changes in Directive 2014/30/EU as compared to the Directive 2004/108/EC are the following:

- definitions
- obligations of economic operators
- conformity assessment procedures
- administrative and documentation requirements
- notification and obligations of notified bodies
- Union market surveillance and border control
- Safeguard clause procedure

The harmonised standards for apparatus will not change due to the application of the new EMCD.

[7] OJ No L 218, 13.8.2008

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

1. **Scope**: allows economic operators to quickly decide whether their equipment falls under the scope of the EMCD and if so, if it is apparatus or a fixed installation.

2. **Essential requirements**.

3. **Obligations of economic operators**

4. **Conformity assessment procedure for apparatus:** gives information including: the steps of an EMC assessment; information and documentation requirements; EU 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 essential requirements.

5. **Procedures for fixed installations**: on the relevant requirements and documentation needed for fixed installations, including the use of apparatus specifically for incorporation into a particular fixed installation.

6. **Market surveillance**: relates to the duties of the national authorities ensuring only compliant apparatus circulates in the Union.

7. **Notified Bodies**: their role, selection, coordination and the treatment of complaints.

1 SCOPE

1.1 General

The EMCD applies to a vast range of equipment encompassing electrical and electronic appliances, systems and installations.

The main objective of the EMCD is to guarantee the free movement of equipment and to create an acceptable electromagnetic environment whilst ensuring that equipment will function as intended in that environment. 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 Union.

The level of protection requested is further specified in the EMCD by protection aims in the field of electromagnetic compatibility as defined in Annex I of the EMCD.

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 EMCD only describes the essential requirements along general lines.

Essential requirements include both general requirements for equipment as well as specific requirements for fixed installations.

When compliant with the provisions of the EMCD, equipment may be made available on the market and/or put into service in the Union territory and operated as designed and intended in the expected electromagnetic environment.

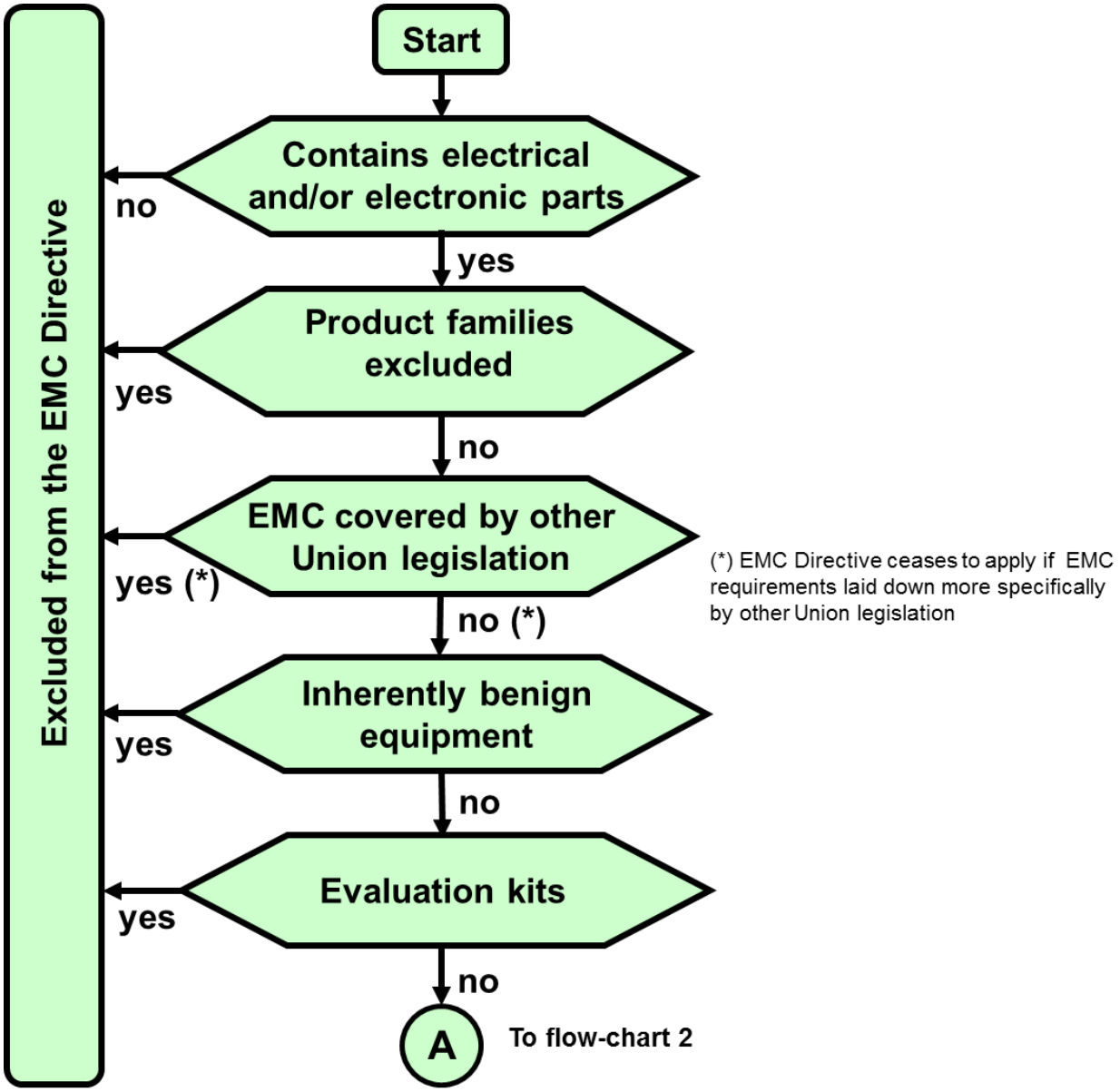
The EMCD does not regulate the safety of equipment in respect of people, domestic animals or property[8]. According Article 1, the EMCD covers exclusively the electromagnetic compatibility of equipment. However, it should be noted that other directives may require higher requirements for EMC phenomena in order to satisfy their specific safety provisions.

The EMCD is therefore not a safety related Directive.

Functional safety aspects based on electromagnetic disturbances are regulated for instance by the Machinery Directive 2006/42/EC and the Low Voltage Directive 2014/35/EU and General Product Safety Directive 2001/95/EC.

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

[8] c. Article 2(4)



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 EMCD

The EMCD excludes the following types of equipment:

1.1.2.1 Radio equipment

The Radio and Telecommunication Terminal Equipment Directive (R&TTE) 1999/5/EC and its successor, the Radio Equipment Directive 2014/53/EU cover most radio equipment and include EMC essential requirements identical to those of the EMCD 2014/30/EU. This means that the essential requirements in the EMCD 2014/30/EU are obligatory for that radio equipment. However, radio equipment falling under the scope of R&TTED and/or RED does not fall under the scope of EMCD. Consequently, reference to the EMCD shall not be made in the EU Declaration of Conformity of a radio product under the R&TTED and or the RED. Guidance on the Radio Equipment Directive can be found in the RED Guide, which will be made available on the website of the European Commission.

It shall be noted that the RED will replace the R&TTE-D on 13th June 2016. As the RED does not include Telecommunication Terminal Equipment (TTE) in its scope, the EMCD applies to TTE placed on the EU market from 13th June 2016 on, except from TTE that intentionally emits and/or receives radio waves (which is radio equipment). For a detailed explanation see also Annex 4.

1.1.2.2 Aeronautical products

There is a RED group on aeronautical products, await outcome of this group,
State of play: await outcome of discussion in TCAM WG08 and amend the following text if necessary:

Aeronautical products, parts and appliances as referred to in (EC) No 216/2008 (as amended) of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC are excluded from the EMCD. 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 EMCD.

1.1.2.3 Radio equipment intended for use by radio amateurs

The EMCD excludes in article 2 (2a) products which are covered by the R&TTED 1999/5/EC and its successor RED 2014/53/EU. Furthermore the EMCD excludes in article 2(2c) radio equipment used by radio amateurs within the meaning of the Radio Regulations adopted in the framework of the Constitution of the International Telecommunication Union and the Convention of the International Telecommunication Union.

If radio equipment is made available on the market (including cases where the intended use is for radio amateurs) then it is covered by the R&TTED

1999/5/EC and its successor RED 2014/53/EU. Detailed information may be found in the RED guide.

If not containing any radio equipment, kits of components to be assembled by radio amateurs as well as equipment made available on the market and modified by and for the use of radio amateurs are not regarded as equipment made available on the market.

1.1.3 Equipment covered by other specific Union legislation

According to Article 2(3) of the EMCD, if the EMC requirements for equipment are wholly or partly laid down more specifically by other Union legislation, the EMCD shall not apply, or shall cease to apply, to that equipment in respect of such requirements from the date of implementation of that Union legislation.

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

- Motor vehicles equipment: Regulation (EC) 661/2009, as amended, (UNECE Regulation 10).

  Hence the following are excluded from the scope of the EMCD:

  A. Vehicle and equipment subject to type approval under UNECE Regulation 10;

  B. Equipment brought to the market as spare parts which is obviously identified as a spare part by an identification number and is identical and from the same manufacturer as the corresponding original equipment manufacturer (OEM) part for an already type-approved vehicle (see Paragraph 3.2.8 of UNECE Regulation 10);

  C. Equipment sold as aftermarket equipment, if within the scope of UNECE Regulation 10 (see diagram in paragraph 3.2.1 of UNECE Regulation 10), which shall ensure the immunity of the driver;

  It is noted that equipment not stipulated in paragraphs A, B, C (above) is covered by the EMCD (example: devices connecting to the cigarette lighter interface inside a car), unless it is excluded by another provision (exclusion) of the EMCD; This equipment, intended for the installation in motor vehicles and which is not subject to type approval, shall meet the essential requirements of Directive 2014/30/EU in addition to the relevant/appropriate requirements of the EMC Vehicle legislation; to assist manufacturers, the references of

harmonised standard(s)[9], addressing these requirements, are listed in the EU Official Journal under 2014/30/EU (EMCD);

<For equipment intended for use in vehicles as well as for use not in vehicles, both the EMC-D and the Regulation (EC) 661/2009, as amended, (UNECE Regulation 10) shall apply to that equipment. Some examples of equipment for which both regulations / directives can apply in parallel are:
- a stereo-amplifier which can be built into a car, but which may also be foreseen as normal battery operated mobile stereo equipment
- It may also be an electronic ballast used for headlights in cars as well as in a search light for a diver
- Other lighting devices that are normally built into a car and are also foreseen for battery operated use in a garden shed.

Other devices like mobile phones, mp3-player are not subject to the cases A,B or C described in the guide and therefore not dual use in this respect.>

THIS TEXT IN YELLOW MUST BE CHECKED BY EUROPEAN COMMISSION IN RELATION TO THE TEXT ONDER a,b AND c ABOVE, OR IT MUST BE DELETED

– Active implantable Medical Devices: Covered by Directive 90/385/EEC [10];

– Medical Devices: Covered by Directive 93/42/EEC[11];

– In vitro Diagnostic Medical Devices: Covered by Directive 98/79/EC[12];

– Marine equipment: Covered by Directive 2014/90/EU[13];

– Agricultural and forestry tractors covered by Regulation (EU) No 167/2013[14];

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[9] Such as EN 55012:2007.

[10] OJ No L 189, 20.7.1990 amended by Directives 93/42/EEC, OJ No L 169, 12.7.1993, 93/68/EEC, OJ No L 220, 30.08.1993 and 2007/47/EC, OJ No L 247, 21.9.2007

[11] OJ No L 169, 12.7.1993, amended by Directive 93/68/EEC, OJ No L 220, 30.8.1993, 98/79/EC, OJ No L 331, 7.12.1998, 2000/70/EC, OJ No L 313, 13.12.2000, 2001/104/EC, OJ No L 6 10.1.2002 and 2007/47/EC, OJ No L 247, 21.9.2007

[12] OJ No L 331, 07.12.1998 amended by Directive 2011/100/EU, OJ No L 341, 22.12.2011

[13] OJ L 257, 28.8.2014, p. 146. Until 18 September 2016, covered by Directive 96/98/EC, as amended.

– Two or three-wheel motor vehicles within scope of Regulation 168/2013[15];

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

– Measuring instruments; Covered by Directive 2014/32/EU[16]

– Non-automatic weighing instruments: Covered by Directive 2014/31/EU [17].

1.1.4 Inherently benign equipment

Equipment which is inherently benign in terms of electromagnetic compatibility is excluded from the scope of the EMCD[18].

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 products (not exclusive) from the application of the EMCD, provided that they include no active electronic part(s):

– Cables and cabling[19], cables accessories, considered separately;

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[14] OJ L 60, 2.3.2013, amended by Commission Delegated Regulation (EU) No 1322/2014, OJ L 364, 18.12.2014

[15] OJ No L 60, 2.3.2013, amended by Commission Delegated Regulation (EU) No 134/2014, OJ No L 53, 21.2.2014

[16] OJ No L 96, 29.3.2014, amended by Commission Delegated Directive (EU) 2015/13, OJ L 3, 7.1.2015

[17] OJ L 96, 29.3.2014, p. 107. Until 20 April 2016, covered by Directive 2009/23/EC, as amended.

[18] C. Article 2(2d)

– 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);

– Corded headphones, loudspeakers without amplification, guitar inductive sensors without active electronic parts;

– Pocket lamps (including those containing LEDs) without active electronic circuits;

– Protection equipment which only produces transitory disturbances of short duration during the clearing of a short-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:

– Induction motors without electronic circuits;

– 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;

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

– Plugs-, sockets-, terminal blocks- etc. that do not have surge protectors).

If the product under assessment is not included in the list of examples above and the EMC assessment establishes that the apparatus concerned is inherently benign in terms of electromagnetic compatibility (both for emission and immunity) according to Article 2(2d), the EMCD shall not apply. However, it is recommended to document the results of the assessment and its conclusion.

1.1.5 Custom built evaluation kits

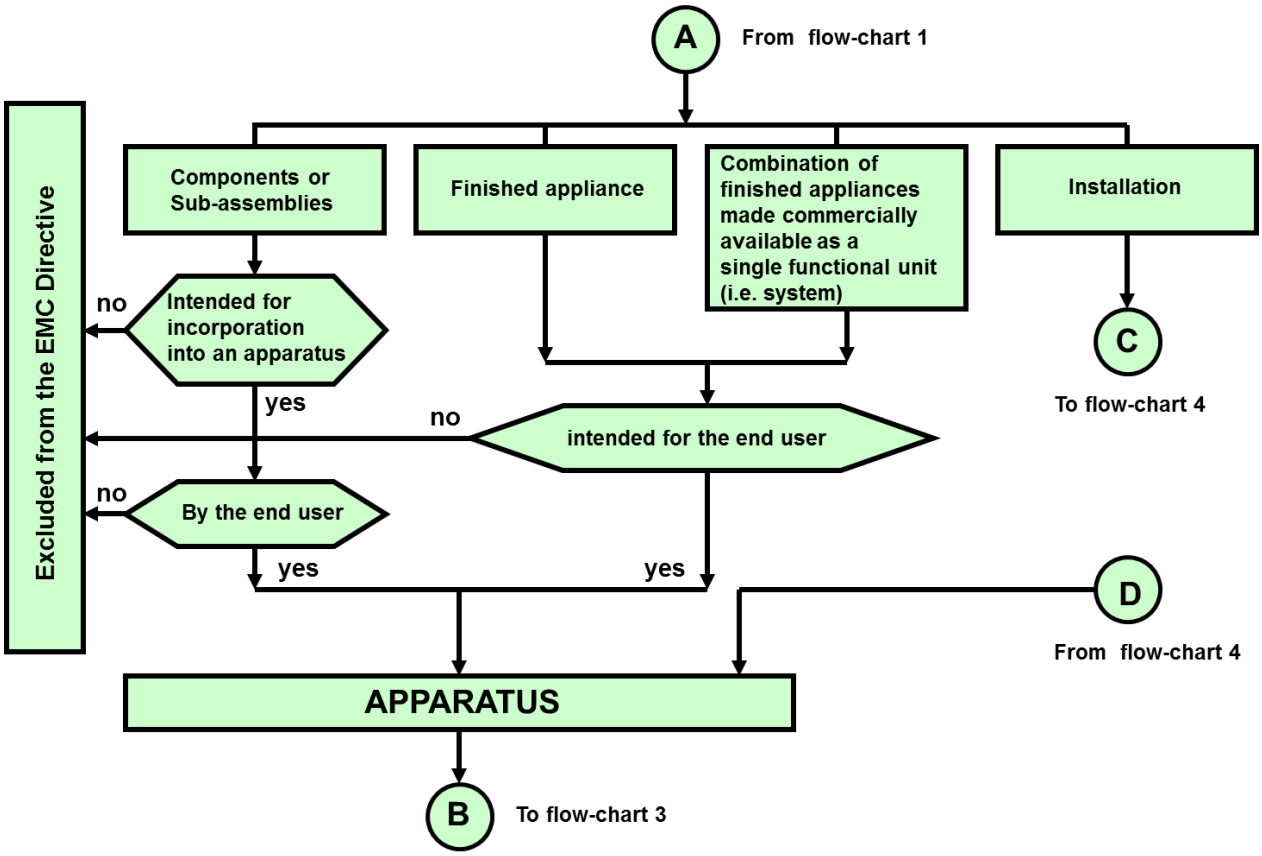
The EMCD shal not apply to custom built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes. Detailed explanation is given in Annex 5 and also available here

(insert Hyperlink to Commission doc on Commission website>

1.1.6 Classification as apparatus or fixed installation

The EMCD 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



1.2 Defining the scope of apparatus

The EMCD [20] defines "apparatus" as any finished appliance, or combination thereof made available (i.e. making available) on the market as a single functional unit[21], 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.

According to Article 3(2) of the Directive "components" or "sub-assemblies" intended for incorporation into an apparatus by the end-user and "mobile installations" are also deemed to be apparatus.

One of the pre-conditions in order to be considered apparatus in the sense of the EMCD 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

[20] c. Article 3 (1.2)

[21] 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

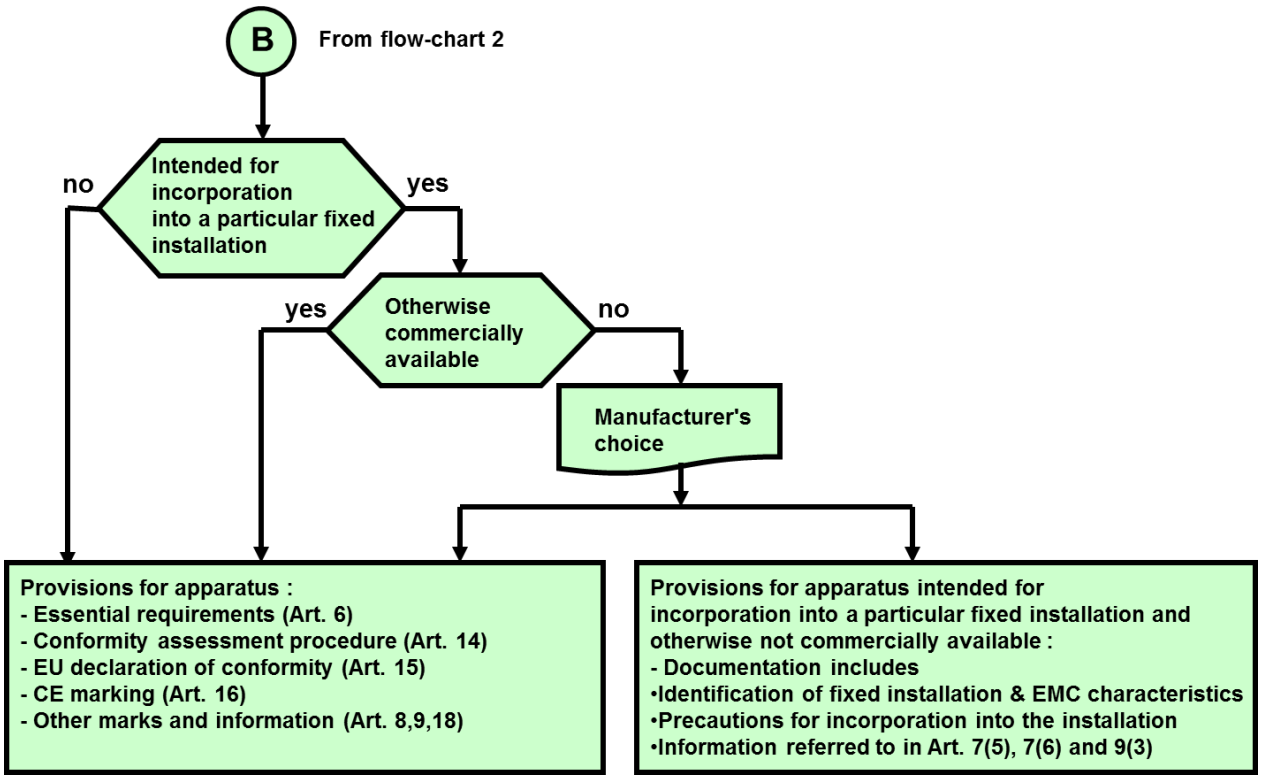
(e.g. enterprise) using or intending to use the apparatus for its intended purpose.

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 EMCD does not apply (see section 1.1.4).

Flowchart 3 summarises the provisions applicable to apparatus (see chapter 4 and section 5.4).

Flowchart 3 - Provisions applicable to apparatus



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 EMCD, if it is **intended for the end-user** and thus has to fulfil all the applicable provisions of the Directive. If the finished appliance is made available on the market for everybody the requirements of the EMCD has to be fulfilled.

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 EMCD and consequently the EMCD does not apply[22].

1.2.2 Combination of finished appliances (systems)

A combination of several finished appliances which is made available as a single functional unit intended for the end-user is considered to be apparatus[23]. Such a system, within the sense of the EMCD, is combined, and/or designed and/or put together and marketed under one name or trade mark 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 EMCD, 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 essential 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;

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[22] 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.

[23] C. Article 3(1b)

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

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 without electronic circuits, see section 1.1.4);

Computer disk drives;

USB sticks, SD cards;

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 EMCD[24]. 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;

- electromagnetic relays without active electronic parts,

- electromagnetic locks without active electronic parts,

[24] See footnote 20

- LEDs,

-Simple thermostats,

-Cathode ray tubes.

1.2.4 Mobile installations

Mobile installations(e.g. mobile LED videowalls) 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 EMCD, as defined for apparatus, apply to mobile installations.

1.2.5 Second-hand apparatus

Please see the “Blue Guide” section 2.1 about ‘product coverage’.

1.2.6 Equipment for own use

Where equipment is manufactured for own use and put into service; the obligation to comply with the Directive begins with first use. More guidance can be found in the Blue Guide section 2.5.

1.2.7 Equipment put into service

The Directive applies to equipment when placed on the market and to equipment when put into service.

Placing on the market is considered not to take place where a product is manufactured for one’s own use or bought by a consumer in a third country while physically present in that country. Equipment which is not placed on the market but is only put into service (for example for own use), needs to comply only with the essential requirements of the Directive. The obligations of the economic operators (e.g. CE Marking, identification, technical documentation, EU Declaration of Conformity) are not applicable to this equipment not placed on the market. According to the Blue Guide, putting into service takes place at the moment of first use within the Union by the end user.

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 EMCD 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.

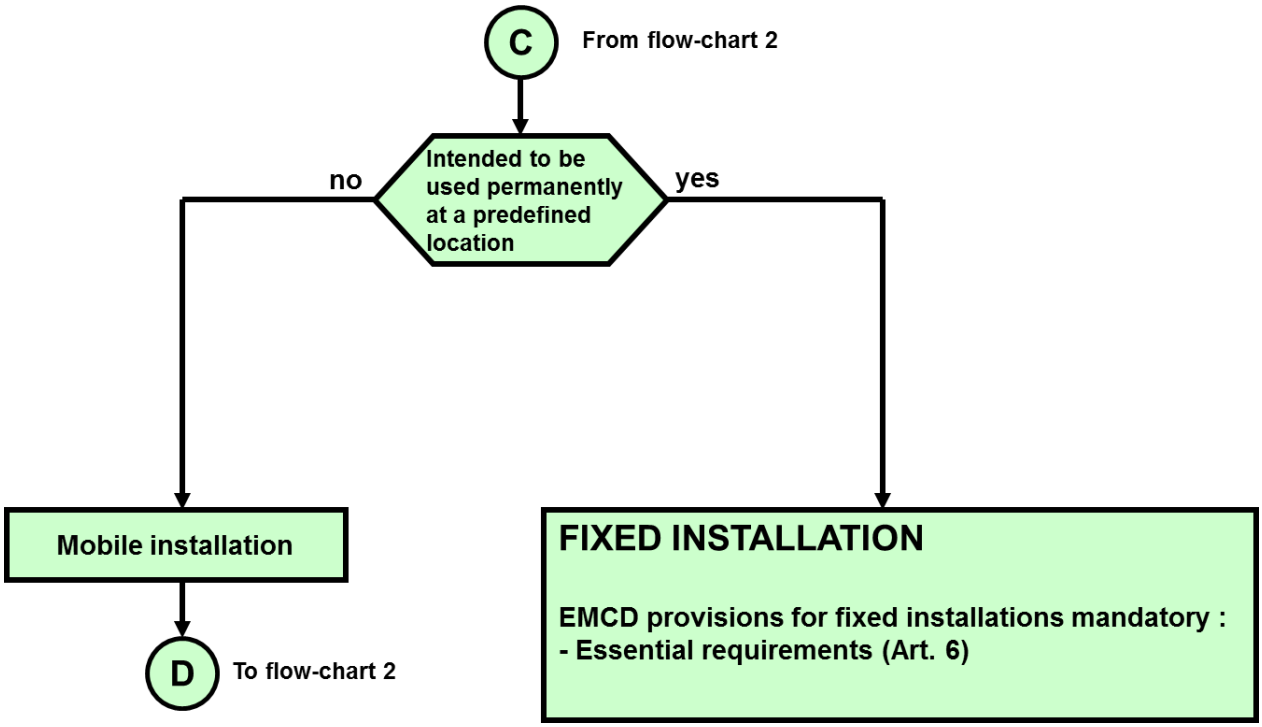
Examples of fixed installations:

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 5.

Large machines (systems, see 1.2.2) are often produced in series and can be used /installed in more than one different location. Manufacturers may want to apply all the requirements for apparatus to large machines instead of the requirements for fixed installations and thus have the advantage of the EU Declaration of Conformity and CE marking, apply only the EMC assessment once and have free movement for the machine within the EU.

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 EMCD. However, the EMCD provides an exception for apparatus intended for incorporation in a **particular fixed installation** and otherwise not made available.

Additional information on the requirements for specific apparatus is given in section 5.4.

2 ESSENTIAL REQUIREMENTS

The EMCD 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 EMCD. Only compliant equipment may be placed on the market and/ or put in service in the Union.

The EMCD 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:

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

“Specific requirements for fixed installations”.

3 OBLIGATIONS OF ECONOMIC OPERATORS

Guidance on the basic obligations of economic operators can be found in the Blue Guide chapter 3 “the actors in the product supply chain and their obligations”. EMC specific obligations are to be found in chapter 4 of this EMC Guide.

4 CONFORMITY ASSESSMENT PROCEDURE FOR APPARATUS

4.1 Introduction

Apparatus shall comply with the essential requirements referenced in Article 6 and detailed in Annex I of the EMCD. Compliance with these essential requirements shall be demonstrated by applying one of the conformity assessment procedures referenced in Article 14 and detailed in Annex II and Annex III of the EMCD.

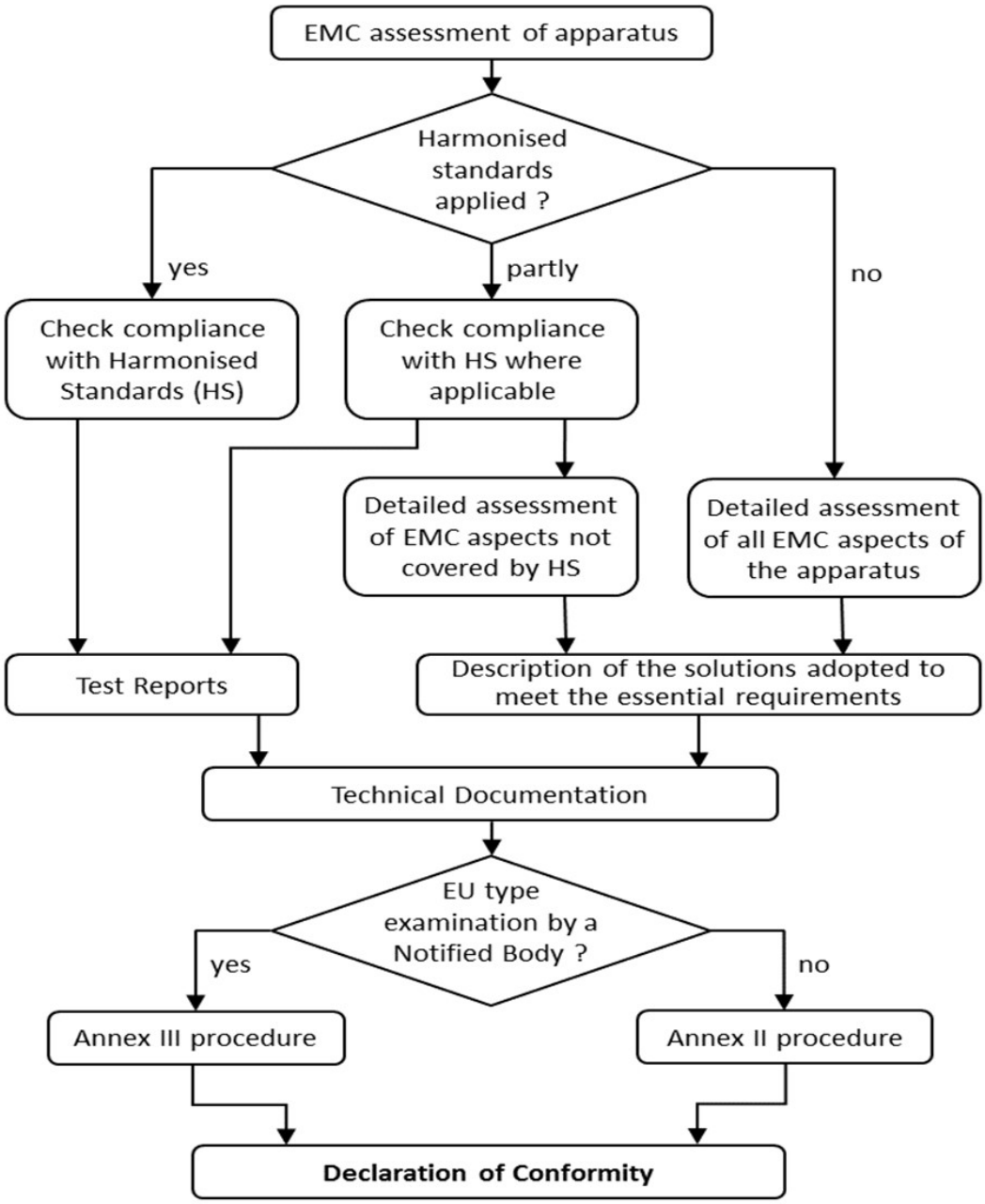
Technical documentation shall be prepared by the manufacturer to demonstrate evidence of compliance with the essential requirements. This includes evidence that the apparatus complies with the relevant harmonised standards or, if harmonised standards are not used or only used in part, a detailed technical justification.

The manufacturer shall take all measures necessary to ensure that the apparatus are manufactured in accordance with the technical documentation[25]. The manufacturer may involve a Notified Body during the conformity assessment procedure (of Annex III).

The manufacturer shall also complete an EU Declaration of Conformity and affix the CE marking on the product or, if not possible due to the nature or the size of the product, on the packaging and accompanying documentation.

Flowchart 5 - Conformity assessment procedure for apparatus

[25] C. Annex II.4 and Annex III part B.2


EMC assessment of apparatus
Harmonised standards applied ?
yes
partly
no
Check compliance with Harmonised Standards (HS)
Check compliance with HS where applicable
Detailed assessment of EMC aspects not covered by HS
Detailed assessment of all EMC aspects of the apparatus
Test Reports
Description of the solutions adopted to meet the essential requirements
Technical Documentation
EU type examination by a Notified Body ?
yes
no
Annex III procedure
Annex II procedure
Declaration of Conformity

4.2 Risk analyses and risk assessment

The conformity assessment procedures for apparatus require the manufacturer to establish technical documentation. This documentation shall make it possible to assess the conformity of the apparatus to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). In EMCD the concept of risk refers to risks in relation to the electromagnetic compatibility protection aims specified in Annex I "Essential Requirements" and not to safety. On basis of the knowledge of the relevant EMC phenomena for the apparatus and its intended operating environments the EMC assessment according to chapter 4.3 can be performed. This EMC assessment is considered to be an adequate analysis and assessment of the risk(s). See also Blue Guide section 4.1.1.

4.3 EMC Assessment

4.3.1 General Concept

The manufacturer shall perform an EMC assessment of the apparatus[26] based on the relevant phenomena in order to ensure that he meets the essential requirements. As noted above the EMCD 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 2(2d), the apparatus is excluded from the scope of EMCD and no further actions are 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 essential requirements, "in all possible configurations identified by the manufacturer as representative of its intended use". [27]

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[26] Recital 30 and Annex II

[27] Annex II.2

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 having checked whether the chosen harmonised standard(s) covers all the phenomena relevant to the product.

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.

Harmonised standards (see the definition in paragraph 4.2.2) provide a recognised methodology to demonstrate compliance to the essential requirements and are usually the preferred way to demonstrate compliance. Use of the relevant EMC harmonised standards (method a) to cover all essential requirements is equivalent to performing an EMC assessment. If this is not the case, the manufacturer will have to substantiate that the steps taken are adequate to ensure compliance with the EMCD.

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 laboratory[28].

Where a manufacturer assembles a final apparatus using components from other manufacturers, the manufacturer of the final apparatus must retain overall control and is responsible for the compliance of the final apparatus[29].

4.3.1.1 The “Worst Case” approach

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

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[28] The specific services and operation of Notified Bodies are described in chapter 7

[29] 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.

In such cases it is sufficient to perform an assessment on the basis of the configuration considered most likely to cause maximum disturbances and the configuration considered 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 documentation[30].

4.3.2 Use of EMC harmonised standards

Harmonised standards are European standards that have been adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation (for example the EMC Directive).

The correct application of the relevant harmonised standards, whose references have been published in the OJEU in the framework of the EMCD, covering all the essential requirements of the EMCD, is equivalent

[30] 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

to the carrying out of the detailed technical EMC assessment. It is the most frequently used and recommended way to demonstrate EMC compliance.

Compliance of the harmonised standards with the EMC requirements (as listed in the current consolidated list published in the OJEU) gives presumption of conformity to the essential requirements of the EMCD, provided that the chosen harmonised standards cover all the electromagnetic phenomena relevant to that apparatus.

Each harmonised standard contains information (including a table) on how to achieve the presumption of conformity with the corresponding essential requirements of the EMC Directive.

The EMCD refers to the moment of placing on the market for each individual apparatus [31]. 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 4.2.2.3 concerning the reference of the superseded standards and the date of cessation of Presumption of Conformity should be taken into account. The Date of Cessation ensures that a transition period (usually between 18 and 36 months) is foreseen during which either the old or the new harmonised standards may be used, at the choice of the manufacturer, to benefit from Presumption of Conformity.

After this time if the manufacturer wishes to continue to benefit from the Presumption of Conformity a new EU Declaration of Conformity is required to the later harmonised standard (which is often a later edition/version with the same reference number). This will require the manufacturer to make an EMC evaluation to the later harmonised standard and he may consider it necessary to carry out some 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 this case, the manufacturer has the obligation to demonstrate that his products are in conformity with essential requirements and that the means he has chosen provide for at least an equivalent level of protection.

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

[31] See section 2.2 of the Blue Guide "Making available on the market"

change may only relate to a small range in scope, or one particular clause or phenomenon.

Harmonised standards under the EMCD are drawn up and adopted by the three European Standardisation Organisations (ESO) recognised in the Standardisation Regulation[32]:

– European Committee for Standardization (CEN)

– European Committee for Electro technical Standardization (CENELEC)

– European Telecommunications Standards Institute (ETSI)

Detailed information on the general EU policy regarding harmonised standards is available at the web-site of the European Commission.

4.3.2.1 List of harmonised standards

The list of harmonised standards published in the OJEU is regularly updated. The European Commission publish a link to the relevant edition of the OJEU on their web page relevant to the EMC Directive.

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 CEN or CENELEC 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/

ETSI standards can be downloaded from the ETSI web-site without cost and are sometimes distributed by National standards bodies or third parties.

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

[32] REGULATION (EU) No 1025/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 October 2012 (OJEU L316 14.11.2012 p.12 ff)

4.3.2.2 Relevant harmonised standards

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

When the manufacturer chooses to apply harmonised standards he shall select them in the following precedence order:

- Product-specific standards (if available)
- Product family standards (if available)
- Generic standards

Product-specific (family) standards are those written by ESO's taking into account the environment, operating and loading conditions of the equipment and are considered the best to demonstrate to compliance to the directive.

Generic standards could be used in the absence of either product-specific or product-family standards. They are divided into generic environments but do not contain specific guidance of how to operate and load equipment during the testing phase of an EMC assessment.

It may be necessary to apply several harmonised standards to cover all essential requirements of the Directive. Each harmonised standard identifies the essential requirements which it covers in an annex.

Generally the main aspects to be covered are:

- Radiated disturbances
- Conducted disturbances at mains and telecommunication ports
- Immunity to continuous radiated and conducted disturbances
- Immunity to transient phenomena

Applying several standards may be necessary to address all relevant phenomena in all relevant frequency ranges. For multi-function apparatus, it may also be necessary to select standards relevant to all primary functions.

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

4.3.2.3 Alternative methods

Some of the harmonized standards offer a choice of different methods for the measurements. All of these methods may be used by a manufacturer to provide a presumption of conformity with the essential requirements of the EMCD.

It can be assumed, that these different methods are equivalent, having been accepted in a harmonized standard. Nevertheless it is clear, that in some cases, where the results are near to a limit, an apparatus may pass with one method and fail with an alternative one.

In any situation where it is necessary to verify the original measurement, the measuring method originally chosen should be used in order to ensure consistency of the results. This should normally be done by the manufacturer.

4.3.2.4 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 EMCD.

Any version of a standard taken from the latest valid OJEU list may be used at the choice of the manufacturer 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.

4.3.3 An EMC assessment where no harmonised standards have been applied

A manufacturer may wish to declare the conformity of his apparatus directly to the essential requirements, without reference to harmonised standards, by making his own EMC assessment. If the manufacturer

chooses not to follow the harmonized standards, he has the obligation to demonstrate that his products are in conformity with essential requirements by the use of other means of his own choice that provide for at least an equivalent level of protection (BG paragraph 4.1.3). 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 essential requirements.

This is usually the case where:

– There are no harmonised standards or where they do not cover all the essential requirements applicable to the apparatus;

– The apparatus uses technologies, incompatible with or not yet taken into account by harmonised standards, and generic standards are not applicable;

– The manufacturer uses test facilities not yet covered by the harmonised standards;

– The manufacturer may want to apply any other standards or specifications not harmonised in the context of the EMCD;

– The apparatus is physically too large to be tested in the facility described in the 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 EMCD 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 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 essential requirements;

– Any specification of general or specific requirements taken to limit emission of disturbances;

– Assessment of whether compliance with the essential 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 essential 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 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.

4.4 Documentation required by the EMCD

The documentation required by the EMCD comprises of the technical documentation and the EU Declaration of Conformity

4.4.1 Technical documentation

The manufacturer draws up the technical documentation providing evidence of the conformity of the apparatus with the essential requirements of this Directive, regardless if the Annex II "internal production control" or Annex III "EU-type examination that is followed by Conformity to type based on internal production control" was chosen.

The purpose of the technical documentation is to make it possible to assess the conformity of the apparatus to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s).. It must contain all necessary practical (technical) details, including the following:

– An identification of the product covered by the technical documentation. This identification should allow unambiguously linking between the technical documentation, the EU Declaration of Conformity 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);

– conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc. Section 4.3 Blue Guide 4th paragraph.

– descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the apparatus;

– If 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 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. In that event the technical documentation shall specify which parts of the harmonised standard have been applied. 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 EU-type examination certificate shall be included.

Referring to Article 7 (9) of the EMCD Directive as well as chapter 3 of the Blue Guide the manufacturer shall, further to a reasoned request from a competent national authority, provide all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the apparatus with this Directive, in a language which can be easily understood by that authority.

4.4.2 EU Declaration of Conformity

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

By drawing up the EU Declaration of Conformity, the manufacturer shall assume responsibility for the compliance of the apparatus with the requirements laid down in this Directive.

The Directive specifies in Annex IV the model structure of the DoC as follows.

- Apparatus model/Product (product, type, batch or serial number);

- Name and address of the manufacturer or his authorised representative

- That the EU Declaration of conformity is issued under the sole responsibility of the manufacturer;

- Object of the declaration (identification of apparatus allowing traceability; it may include a colour image of sufficient clarity where necessary for the identification of the apparatus);

- That the object of the declaration described above is in conformity with the relevant Union harmonisation legislation;

- References to the relevant harmonised standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared;

- Where applicable, the notified body ... (name, number) performed … (description of intervention) and issued the certificate … (EU-type examination certificate number);

- Additional information;

- Signed for and on behalf of;

- Place and date of issue;

- Name, function and the signature.

See also section 4.4 of the Blue Guide

In most cases, the dated references to the specifications under which conformity is declared, will be those of the harmonised standards that are applicable to the apparatus in question as listed in the OJEU. If 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 model structure of Annex IV of the EMCD has followed. 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.

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 EMCD.

Where apparatus is subject to more than one Union act requiring an EU DoC, a single EU DoC shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned including their publication references. The single EU Declaration of Conformity can be made up of a dossier containing all relevant individual EU Declarations of Conformity. If national competent

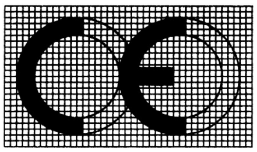
authorities are requesting a EU DoC the manufacturer has to deliver this single DoC or the full set/bundle of DoC.

4.5 CE Marking and information

4.5.1 CE marking

The EMCD requires that the apparatus bears the CE marking as an attestation of compliance with the EMCD.

The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008 and shall have the following format:



The CE marking shall be affixed visibly, legibly and indelibly to the apparatus or to its data plate.

Further details on CE marking and potential exemptions from the marking requirements on the product (like “not possible or not warranted on account of the nature of the product”) are given in the Blue Guide section 4.5.1.

When use is made of the exemption provided by Article 19(1) not to apply the requirements of articles 6 to 12 and articles 14 to 18 in the case of apparatus which is intended for incorporation into a particular fixed installation and is otherwise not made available on the market, it is not allowed to affix the CE marking to this apparatus to attest compliance with the EMCD. In this case CE marking may however be required to show conformity to other Directives.

4.5.2 Other identifying marks

The EMCD requires that apparatus be identified by “type, batch or serial number or other element allowing their 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.

The Blue Guide gives more information as to which circumstances exemptions to the marking requirements are allowed.

Specific apparatus intended to be incorporated into a given fixed installation (using the provisions of Article 19(1)) and otherwise not made available may have this identification information in the accompanying documentation and not on the apparatus.

4.5.3 Information for traceability

In order to facilitate traceability, manufacturers shall indicate, on the apparatus, their name, registered trade name or registered trade mark and the postal address at which they can be contacted. The address shall indicate a single point at which the manufacturer can be contacted. Importers shall indicate on the apparatus their name, registered trade name or registered trade mark and the postal address at which they can be contacted.

The product must always bear the manufacturer's name and address. Imported products must also bear the importer's name and address. All contact details shall be in a language easily understood by end-users and market surveillance authorities.

The traceability requirements shall be affixed on the apparatus itself. In cases "where that is not possible", on its packaging or in a document accompanying the apparatus.

A comprehensive explanation and details about the traceability requirements can be found in the Blue Guide section 4.2.2...

4.5.4 Information concerning the use of apparatus

Apparatus shall be accompanied by the following:

- Information on any specific precautions that must be taken when the apparatus is assembled, installed, maintained or used, in order to ensure that, when put into service, the apparatus is in conformity with the essential requirements of the EMCD,

- A clear indication on restriction of use in residential areas, where appropriate also on the packaging, if the compliance with the essential requirements of the EMCD is not ensured in residential areas (further details in chapter 4.5.5),

- Information required to enable apparatus to be used in accordance with the intended purpose of the apparatus shall be included in the instructions accompanying the apparatus,

in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. Such instructions and information, as well as any labelling, shall be clear, understandable and intelligible.

Apparatus may need assembling or special consideration in respect of its installation for it to comply during use with the essential requirements of the Directive. Therefore all information necessary for correct assembly, installation and use has to be provided, see also Blue Guide section 3.1 under point 4. If no information is given with the apparatus it is presumed

that users can install and use the apparatus without any special considerations regarding the EMC aspects, and the apparatus will still comply with the essential requirements of the EMCD.

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 and connectors (e.g. screened, double screened, etc). If so this must be specified to allow for proper installation and use.

Any precaution that needs to be observed for the apparatus to maintain its compliance with the essential requirements regarding use and maintenance needs to be indicated.

4.5.5 Information when compliance is not ensured with essential requirements in residential areas

The EMCD 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 EMCD requires that apparatus for which compliance with the essential requirements in residential areas is not ensured by the manufacturer (for example when limits for the residential environment in standards are exceeded) shall 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, it is recommended that the information, which is of relevance for the buyer, will be given in the catalogue or on the webpage.

5 FIXED INSTALLATIONS

5.1 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 Union. 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 essential requirements and other specific requirements (Annex I of the Directive) which are applicable to them.

Measures are prescribed in the EMCD to enable the competent authorities to handle complaints concerning disturbance generated by fixed installations[33].

A fixed installation may be assembled by the incorporation of several apparatus including specific apparatus as described in Article 19.1 and other devices outside the scope of the EMCD. In order to fulfil the essential 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 EMCD. However, there is a possibility of exemption detailed in Article 19(1) of the EMCD 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 essential 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:

[33] Article 19 (2)

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 EMCD, 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.

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 essential 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 EMCD to ensure electromagnetic compatibility between specific equipment inside the borders of the defined fixed installation.

5.2 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 EMCD 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. Examples of types of installations to which these documentation requirements might apply are Solar/PV Installations and domestic heating and cooling systems.

5.3 Responsible person for fixed installations

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

5.4 Requirements for specific apparatus for given fixed installations

The general principle is that all apparatus are subject to all the relevant provisions of the EMCD. However, the EMCD provides at Article 19(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 essential requirements for those apparatus considered in isolation, the conformity assessment procedure for apparatus, the subsequent EU Declaration of Conformity and the specific marks and information for apparatus are not compulsory.

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 number 32 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

5.4.1. 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 Union, the name and address of the importer.

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.

6 MARKET SURVEILLANCE OF THE EMCD

The purpose of market surveillance is to ensure that the provisions of the EMCD are complied with across the Union. Consumers, workers and other users are entitled to an equivalent level of EMC 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 EMCD, 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 EMCD.

Procedures and details on European harmonised market surveillance can be found in the Blue Guide chapter 7 on Market Surveillance and in the "Horizontal good practices on market surveillance". <Link to be added when the document is available on Commission website>

7 NOTIFIED BODIES

7.1 Introduction

Notified Bodies can carry out tasks as a Notified Body under the EMCD only for apparatus under the scope of the Directive but not for fixed installations under the scope of the Directive.

Disregarding the fact if the manufacturer has applied harmonized standards or not, in order to cover the requirements of Article 6 of the Directive, he or his authorized representative can always request a Notified Body to help in the conformity assessment procedure of the apparatus. The procedure for this is called Module B (always followed by Module C to be performed by the manufacturer) and is described in Annex III of the Directive.

7.2 General concept

Notified Bodies are designated by the competent authorities of the EU Member States, EFTA countries (EEA members) and other countries with which the EU has concluded Mutual Recognition Agreements (MRAs) to perform the conformity assessment tasks described in the Directive.

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 Australia and New Zealand and 1/06/2002 with Switzerland.

The Commission publishes a list of Notified Bodies on his website called NANDO. The lists include the address details of each Notified Body as well as the tasks for which it has been notified.

Under the EMCD the Notified Body may perform only one conformity assessment task following the procedures in Annex III of the Directive.

EU Type Examination (Module B):

Examine the technical design of the apparatus and verifying and attesting that the technical design of the apparatus meets the essential requirements of the Directive.

Notified Bodies can be designated to deal with all or only selected types of apparatus. When designated for all types of apparatus, they must be able to assess both Article 6 essential requirements (immunity and emission). When designated for selected types of apparatus, they must be also able to assess those apparatus for both of Article 6 essential requirements (immunity and emission).

The Notified Body is free to offer its services to any manufacturer, established either inside or outside the EU. Although the Notified 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 Notified Body. There is no need to choose a Notified 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 Notified Body for one of his apparatus there is no obligation to use the same Notified Body for any of his other apparatus. This also applies to modifications of original assessed apparatus.

The Notified Body will need to have policies and procedures in place that distinguish between tasks carried out as a Notified Body and any other activity in which their organisation is engaged (for example when the organisation is operating as Test Laboratory, is providing recommendations concerning the classification of apparatus as being inherently benign or is delivering practical recommendations regarding any shortfall in the technical documentation and administrative requirements). When performing those other activities, the organisation shall not suggest in any manner that they perform these activities as Notified Body.

It should be noted that the Notified Body cannot, in its role as a Notified Body, for example:

- carry out testing of apparatus it is assessing;
- prepare test reports for apparatus it is assessing;
- design apparatus it is assessing;
- sign or issue a manufacturer's EU Declaration of Conformity;
- act as an agent for the manufacturer;
- provide consultancy;
- perform an assessment for fixed installations and /or issue EU Type Examination Certificates for fixed installations;

For the avoidance of doubt, the term 'consultancy' as referred to in the directive relates to design advice regarding the functionality of the apparatus.

The manufacturer or his representative that requests a Notified Body to perform an EU Type Examination bears complete responsibility of the complete material that is sent to the Notified Body. The material (technical documentation) may include technical justification (for example test reports) based on tests performed by the manufacturer or material supplied by a third party test laboratory to the manufacturer.
If in the course of their assessment the Notified Body finds inconsistencies in the material or doubts concerning the technical data in any other way such as incorrect standards being applied, wrong conclusions drawn, etc. the Notified Body shall inform the manufacturer or his representative about this. If an external third party has provided that material the Notified Body shall not insist or suggest in any way that the Notified Body has to inspect that party (technical facility inspection or general quality inspection) either paid or for free. It is the manufacture that needs to take any appropriate action to make sure the material is correct to prove compliance with the essential requirements of the Directive.
The Notified Body, under its Notified Body name or number shall not issue any Certificate or other documents indicating that a Laboratory or facility has been inspected and approved by the Notified Body. These activities are not a task for the Notified Body under the Directive.

Annex III procedure — Examination of technical documentation
The Directive requires compliance when apparatus is "properly installed and maintained and used for its intended purpose". The Notified Body should therefore note any inconsistencies between obvious uses of the apparatus and the stated intended purpose so that its EU Type Examination may be suitably qualified and is not open to misinterpretation.
The applicant specifies which aspects of the essential requirements the Notified Body is to assess (emission and/or immunity or just a part of one of the essential requirements, e.g. only the radiated emission requirements). In all cases the Notified Body shall assess the compliance for the aspects as requested by the applicant.

An aspect relevant to the intended purpose may be the number of units of apparatus likely to be put into service and their overall potential for harmful effects to networks or the radio spectrum or to other apparatus.

The Notified Body must prepare an evaluation report that records the technical documentation that was reviewed and the Notified Body decision(s) with regards to the technical design being adequate (or not) to meet the relevant essential

requirements. If the review concludes that the documentation demonstrates compliance with the requirements of the Directive, the Notified Body can then issue an EU Type Examination Certificate to the applicant.

In the case of the Notified Body report not coming to a positive conclusion that the apparatus concerned is satisfying the requirements of the Directive, the Notified Body shall refuse to issue an EU Type Examination certificate. The Notified Body shall inform the applicant accordingly giving detailed reasons for its refusal in the report.

Refusal by the Notified Body to issue an EU Type Examination Certification shall follow the process in Article 32 (2) of the Directive.

The Notified Body must base its EU Type Examination Certificate on the requirements of the Directive and the Notified Bodies professional assessment of the technical documentation taking due account of relevant standardisation, other technical references and professional decision available at that time.

When compliance of the apparatus is confirmed by the Notified Body report, the EU Type Examination Certificate of the Notified Body can state conditions (if any) for its validity. This could be a validity period of the Certificate or conditions on technical requirements to be specified in order for the apparatus to be compliant (such as adding a specific EMC filter to the apparatus or using a specified cable).

The Notified Body should maintain records documenting the rationale used to arrive at a particular decision. The records should identify any documents referenced in the assessment and the particular parameters applied to determine compliance with the essential requirements.

Annex III of the Directive provides for the Notified Body to give an evaluation report and an EU Type Examination Certificate based on the technical documentation reviewed. Further Annex III does provide guidance on the content of the EU Type Examination Certificate. However, a Notified Body is free to choose its own format and may include additional information such as the reference standards, intended purpose and other remarks/observations.
The Notified Body should take account of the following aspects for the EU Type Examination Certificate:
Title “(Directive 2014/30/EU — Notified Body) EU Type Examination certificate” or similar text and avoiding the use of words such as “opinion” and “declaration”.
Insert on the Certificate:

- Notified Body Name, address etc., logo.
- Notified Body number.
- EU Type Examination Certificate number - this shall be the unique number of EU Type Examination Certificate. A revision number and/or copy number shall be included if applicable.
- Date of issue of the Certificate and its Validity
- Applicant details: Name, address etc. of the party requiring the EU Type Examination Certificate.
- Scope of examination whether the certificate is covering emission and/or immunity.

- Clear identification of the apparatus. The goal is to give the minimum information from the following list such that a third party would be able to uniquely identify the item in question.
    - Description of apparatus, including brand/trade name, model/type designation, hardware and software (where it affects the Directive conformity) revision.
    - Reference of any build status/design documentation taken into account.
    - Technical documentation identification
    - Unique identification of the documentation etc. taken into consideration irrespective of the actual physical format of the documentation
- Conclusions of the examination
- Certification text - the text stating that the apparatus is compliant.
- Authorised signatory (signature block including printed name of the signatory).

The manufacturer shall inform the Notified Body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the apparatus with the essential requirements of this Directive or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.
If the product has been subject to important changes having a significant impact on its compliance with the EMCD (EMC Characteristics of the apparatus, , identification details of the apparatus etc.), then the apparatus becomes a new product entering the market. The original EU Type Examination Certificate is then not valid anymore. If for the new product the manufacturer wishes to apply Module B/C again and involve a Notified Body then he is free to choose any Notified Body for this assessment. He is not obliged to choose the original Notified Body.

7.3 Subcontracting

The Notified Body can formally subcontract limited tasks, as long as these can be defined as substantial and coherent parts of its operation and are still under its control. Subcontracting does not therefore entail the delegation of powers or responsibilities. Notified Body decisions are always solely issued in the name and under the responsibility of the Notified Body (see section 5.2.5 of the Blue Guide).

7.4 Information exchange

Article 36 and Annex III of the Directive contain requirements for Notified Bodies regarding providing specific information to certain organisations such as other Notified Bodies, authorities, etc.
To comply with these requirements may create some practical difficulties. Notified Bodies should check the Notified Body Coordination Group – EUANB to see whether the EUANB has made available procedures to facilitate an easy exchange of information or refers to procedures available elsewhere.

7.5 Coordination between Notified Bodies.

Recognizing that it is necessary for the conformity assessment routes to be applied consistently by all parties in order to achieve an open and competitive market throughout Europe, the European Association of EMC Notified Bodies - EUANB has been set up. (See Annex X of this Guide)

The EUANB contributes to the effective implementation of relevant legislation in cooperation with the Working Party set up under the Directive (i.e. EMCWP) and facilitates the convergence of conformity assessment practices in the regulatory sphere. The EUANB liaises with relevant organisations such as CENELEC, ETSI and EMC ADCO.

The EUANB issues information sheets, called Technical Guidance Notes — TGNs — which have been drawn up to assist the Notified Body in its task. Furthermore EUANB provides Reference Documents solely for its members containing valuable information to support the work of the Notified Bodies.

The Notified Body should also:

- be fully aware of the (national) spectrum plans in Europe, noting these are not always harmonized.
- know other EU legislation that simultaneously is applicable to apparatus for which they are applying Module B;
- be able to interpret essential requirements on the basis of available harmonised standards.
- maintain knowledge of the current apparatus state of the art including following the developments in European standardisation.

7.6 Complaints regarding the service provided by NB

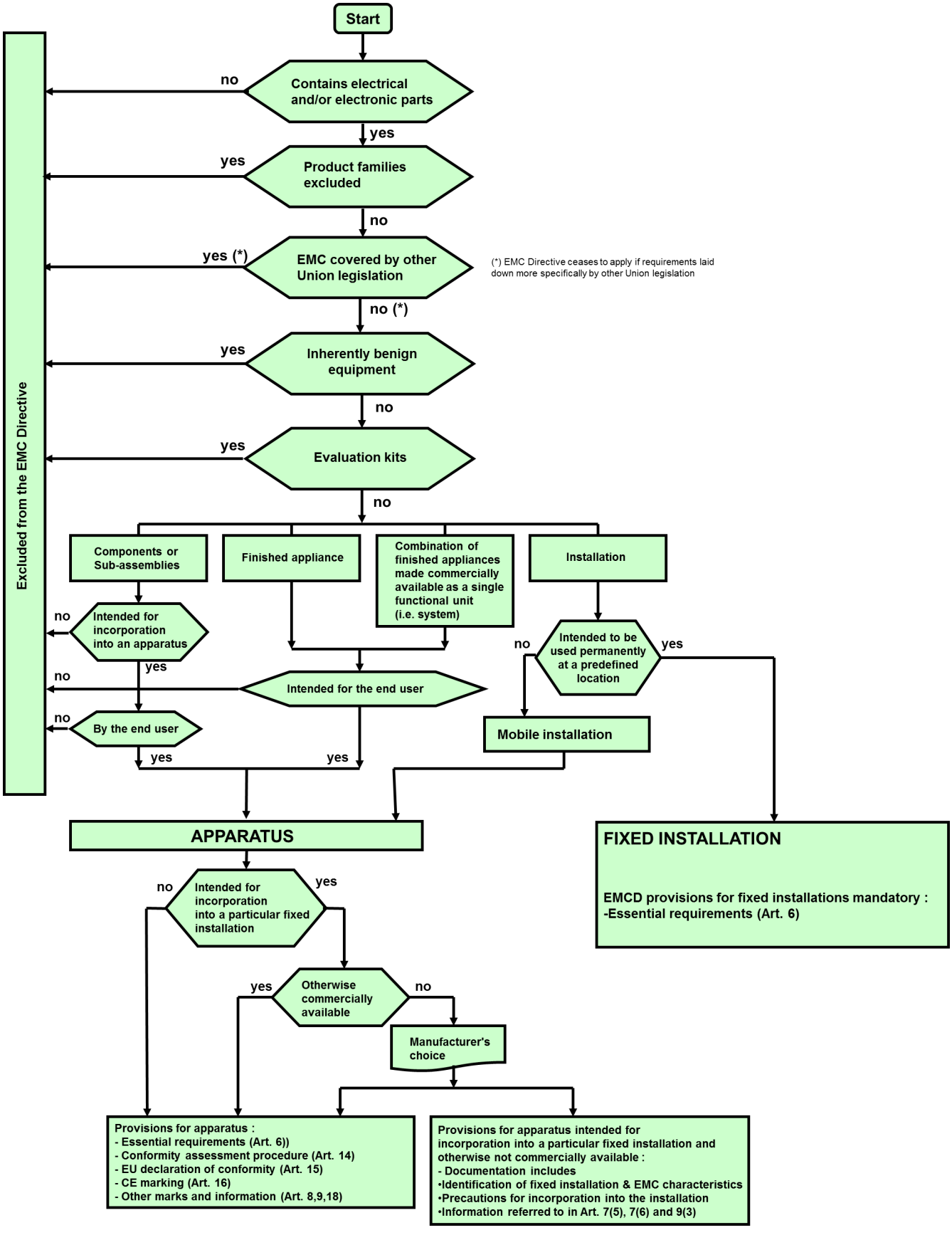
Notified Bodies are required to have a policy and procedure for the resolution of complaints received from clients or other parties.

Where a manufacturer is dissatisfied with the service performed, he should file a complaint with the Notified Body in question.

A complaint can also be filed by the manufacturer with the national notification authority.

Where non-compliant apparatus has been subject to the conformity assessment procedure involving the service provided by a Notified Body, the authority supervising the Notified Body will need to take appropriate action and inform the Commission and the other Member States accordingly.

ANNEX 1 - Overall flowchart



ANNEX 2 - Guidance on using a harmonised standard

Referencing a harmonised standard in a DoC means that the manufacturer takes responsibility of the conformity of their equipment with all the relevant provisions listed in the annex of that standard and that this can be demonstrated by applying the methods (tests, measurement methods, etc.) this standard describes or refers to. The harmonised standard may contain additional requirements that are not relevant to the presumption of conformity against the EMCD. The harmonised standard is required to contain an annex correlating its technical requirements with the essential requirements of the Directive.

The requirements and limits of the harmonised standard are expected to be met when the equipment is tested to the standard. Based on the risk analysis (see clause 4.2 of this document) and if the applied harmonised standard does not cover all the phenomena expected from the equipment, the manufacturer has to apply additional assessments to ensure that all the phenomena are considered

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 relevant 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 their full responsibility, from the way described above. The deviations described hereafter imply a risk for the manufacturer. They have to evaluate this risk when thee declare conformity to a harmonised standard by allowing themselves 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 they can satisfy themselves 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. They may also decide under their sole 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. In such cases, explanations have to be added to the technical documentation. These explanations should demonstrate on how essential requirements are met

b) 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. This possibility is depending on its availability in the applied HS.

ANNEX 3 - EMC assessment where harmonised standards do not exist or are not fully (applied)

The EMCD 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 EMCD 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 (e.g. taking into account the common use of radiocommunication products) 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 emissions 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) *NOTE the unsymmetrical mode voltage is primarily measured at the mains network.*	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.

The common mode voltage (or current) is measured primarily for signal and control lines. 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 6000MHz.	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.

ANNEX 4 - Application of Directives 2014/53/EU, 2014/35/EU and 2014/30/EU

INTRODUCTION

The purpose of this annex is to provide guidance on the date of applicability and their transitional period (if any) for the new Directives of the electrical sector i.e. RED (Directive 2014/53/EU), new LVD (Directive 2014/35/EU) and new EMCD (Directive 2014/30/EU).

Scope of RED

The new Radio Equipment Directive (RED) already entered into force (on 11/06/2014). The RED will replace Directive 1999/5/EC – the 'R&TTE Directive' - from 13 June 2016. Member States shall transpose the RED into national legislation by 12th June 2016 and apply it from 13th June 2016.

With regard to Directive 1999/5/EC (the R&TTE Directive), the RED has introduced the following changes:

(1) sound and TV receive-only equipment, which has been excluded from the R&TTE Directive, now falls within the scope of the Directive;

(2) equipment operating below 9 kHz, which has been excluded from the R&TTE Directive, now falls within the scope of the Directive;

(3) radio-determination equipment is now clearly included within the scope of the Directive;

(4) telecom terminal equipment now falls outside the scope of the Directive; this equipment will in future be covered by the LVD/EMC Directive

(5) custom built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes is explicitly excluded from the RED.

The RED contains the following transitional period (Article 48):

Member States shall not impede, for the aspects covered by this Directive, the making available on the market or putting into service of radio equipment covered by this Directive which is in conformity with the relevant Union harmonisation legislation applicable before 13 June 2016 and which was placed on the market before 13 June 2017.

It is noted that, since the R&TTED can be applicable during the transitional period, the intention is to keep valid, during the above transitional period, the references of

the harmonised standards for the R&TTE Directive, as well as the notified bodies notified under the R&TTED.

Scope of NEW LVD/EMCD

The new LVD and the new EMCD entered into force on 18/04/2014 and will be applicable as of 20/04/2016. The new LVD will replace the existing LVD (Directive 2006/95/EC) and the new EMCD will replace the existing EMCD (Directive 2004/108/EC) as of 20/4/2016.

The new LVD and EMCD did not modify the scope of the existing Directives, subject to the following new exception that has been explicitly inserted:

'custom built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes'**.**

While the revision of LVD/EMCD has not changed their scope, the changes to the scope of the current R&TTE Directive have direct consequences for the scope of the two Directives:

1) The new LVD/EMCD will apply to products that have so far been covered by the R&TTE Directive (telecommunication terminal equipment).

This is about all wireline telecommunication products as far as they have no radio function encompassed. Examples of those products are telephones, routers, switches, , home networking adapters, LAN internet access gateways, Pay telephones, Telephone exchanges, Fax machines, telephone answering machines.

2) The new LVD/EMCD will no longer apply to products covered by the RED.

Examples are: Standalone broadcast receivers (not under the control of a network) that receive radio waves (i.e. Broadcast receivers that include DVB-T modules and/or are Wi-Fi enabled), Railway applications (500Hz –2kHz), Robotic lawnmowers (1kHz –9kHz), Animal fences (1kHz –9kHz), Metal detectors (3kHz –20kHz), Stud finder (<9kHz), Electronic article surveillance –EAS (10Hz –1kHz). Consequently broadcast receivers that do not intentionally receive and/or transmit radio waves stay under the scope of the EMC-D and do not move under the scope of the RED.

GENERAL COMMENT

The RED can apply to products placed on the market on or after 13 June 2016 (not before).

The new LVD/EMCD can apply to products placed on the market on or after 20 April 2016 (not before).

OVERVIEW ON THE APPLICABILITY OF LEGISLATION

1. PRODUCTS WITHIN OLD LVD/EMCD AND CONTINUE TO BE WITHIN NEW LVD/EMCD (EVEN AFTER APPLICABILITY OF RED)

-Products placed on market before 20 April 2016: old LVD/EMCD

-Products placed on market on or after 20 April 2016: new LVD/EMCD

2. PRODUCTS WITHIN R&TTED AND REMAIN WITHIN THE SCOPE OF RED

-Products placed on market before 13 June 2016: R&TTED

-Products placed on market between 13 June 2016 and 12 June 2017: R&TTED or RED

-Products placed on market after 12 June 2017: RED

3. PRODUCTS WITHIN OLD/NEW LVD/EMCD BUT THEN FALL WITHIN RED (AFTER APPLICABILITY OF RED)-FOR EXAMPLE TELEVISION AND SOUND BROADCASTING RECEIVERS

-Products placed on market before 20 April 2016: old LVD/EMCD

-Products placed on market between 20 April 2016 and 12 June 2016 : new LVD/EMCD

-Products placed on market between 13 June 2016 and 12 June 2017: RED or new LVD/EMCD

-Products placed on market after 12 June 2017: RED

4. PRODUCTS WITHIN R&TTED AND THEN OUTSIDE RED-FOR EXAMPLE TERMINAL EQUIPMENT

-Products placed on market before 13 June 2016: R&TTED

-Products placed on market after 12 June 2016: RED is not applicable; new LVD/EMCD, if applicable to the product in question

ABBREVIATIONS

RED: Directive 2014/53/EU

R&TTED: Directive 1999/5/EC

New LVD: Directive 2014/35/EU

Old LVD: Directive 2006/95/EC

New EMCD: Directive 2014/30/EU

Old EMCD: Directive 2004/108/EC

ANNEX 5 - Custom built evaluation kits

ANNEX 6 - Acronyms and abbreviations

CEN	European Committee for Standardisation
CENELEC	European Committee for Electrotechnical Standardization
CISPR	International Special Committee on Radio interference (Comité International Spécial des Perturbations Radioélectriques)
DoC	EU Declaration of Conformity
EUANB	EU Association of Notified Bodies
EEA	European Economic Area
EMC	Electromagnetic Compatibility
EMC ADCO	EMC Administrative Co-operation Working Group of market surveillance authorities
EMCD.	Electromagnetic Compatibility Directive
ESD	Electrostatic discharge
ESO	European Standardisation Organisation
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
RED	Radio Equipment Directive
RF	Radio frequency
TGN	Technical_Guidance_Note
TR	Technical Report

ANNEX 7 - Organisations and committees

EUANB (European Union Association of EMC Notified Bodies)

EUANB provides a forum for Notified Bodies concerned with the compliance of apparatus under the Directive with regulations and technical standards in the European Economic Area, as well as in the Countries that have a Mutual Recognition Agreement with the EU covering EMC, such as the USA, Canada, New Zealand, Australia and Switzerland.

It has specific responsibilities in respect of Notified Bodies appointed under EU Directive 2014/30/EU. In this context it publishes Technical Guidance Notes and Reference Documents that are available for all Notified Bodies that have access to the CIRCABC section for Notified Bodies.

Membership of EUANB is open to any Notified Body listed in NANDO as being notified to work with the EMCD. This membership guarantees access to relevant material for Notified Bodies. To acquire membership the Technical Secretary of the EUANB should be contacted.

The Association meets twice a year in a location within the EEA. All meetings are open for members only. These meetings are ideal to discuss matters with important players in the field such as representatives of the EU Commission, CENELEC, ETSI, EMC ADCO, etc.

EUANB operates a mail server where members can ask questions that will trigger answers and comments from the experts within the Association. These discussions provide material to be stored on the protected database for future reference by the members. Furthermore the Association has a specific protected area on the CIRCABC website, operated by the EU Commission, where all working documents are stored for access by the members only.

The Technical Secretary of the EUANB is appointed by the European Commission whilst the Chairman is elected by the members.

EMC ADCO(EMC Administrative Co-operation Working Group of market surveillance authorities)

The aim of EMC ADCO is to:

− exchange information on national market surveillance activities;

− promote effective market surveillance and enforcement of the EMC Directive;

− encourage the harmonisation of market surveillance practices to ensure equitable treatment of economic operators in Europe;

− reduce the overlapping of national surveillance operations;

− stimulate the exchange of information and co-operation between members on operational issues;

− provide support and guidance for members on practical problems;

− organise regular joint cross-border EMC market surveillance campaigns to check the compliance level at European level in specific sectors and to raise economic operator and consumer's awareness of the need for conformity with the requirements of the EMC Directive;

− promote the application of the 'risk analysis' approach to maximize mutual effectiveness and make the best use of resources;

− promote the exchange of information on the regulations in the field of EMC with other economies as US, Canada and other interested countries and encourage the collaboration in the field of market surveillance in a globalised market.