

Draft Guide for the EMC Directive 2004/108/EC

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INTRODUCTION

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

The Directive 2004/108/EC (hereafter called the EMC Directive or EMCD) repeals the previous EMC Directive 89/336/EEC and has maintained the same general objective, e.g. to guarantee the free movement of apparatus and to create an acceptable electromagnetic environment in the EEA territory. The protection requirements are not changed in practice and apply for apparatus and for fixed installations.

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

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

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

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

- The new legal text is closer to the EC EMC Guide 1997, by making a clear distinction between the requirements and assessment procedures for apparatus and for fixed installations respectively.
- Definitions are included for apparatus and fixed installations.
- Fixed installations require neither an EC Declaration of Conformity (DoC) nor the CE marking. Fixed installations include networks and large machines.
- Mobile installations are considered as apparatus.
- For apparatus, there are changes in the documentation and information requirements.
- The conformity assessment procedure for apparatus has been simplified to a single procedure. There is no compulsory involvement of a third party, however the manufacturer has the option of submitting the technical documentation to a Notified Body for assessment.
- When deviating from the harmonised standards or not applying them fully, the manufacturer has to perform an EMC assessment and provide detailed

documented evidence that the apparatus complies with the protection requirements of the EMC Directive.

- Apparatus intended for a given fixed installation and otherwise not commercially available may be exempted from the requirements and procedures for apparatus (e.g. EC Declaration of Conformity and CE marking), provided that special documentation requirements are met, including precautions to be taken in order not to compromise the EMC characteristics of the fixed installation.
- The regulatory role of Competent Bodies has been removed. Manufacturers have the option to consult Notified Bodies which have an advisory role. .

It is important to underline that for the vast majority of applications of the EMC Directive apparatus is assessed by using the usual and preferred method of conformity to the relevant harmonised standards. The change for the manufacturers is limited to some additional information and documentation requirements.

The harmonised standards for apparatus will not undergo changes due to the application of the new EMC Directive but only due to the normal evolution of technology needs and of the state of the art.

The present Guide should be read in conjunction with the [“Guide for the implementation of directives based on the New Approach and the Global Approach”](#)

It has been attempted to structure this Guide in a logical order suitable for users who need to ensure that their equipment is in conformity with the EMC Directive. The Guide is therefore divided into the following successive chapters:

1. **Scope:** allows manufacturers or other concerned persons to determine whether their equipment falls under the scope of the EMC Directive and if so, whether it has to be considered as an apparatus or as fixed installation.
2. **Essential requirements:** gives a brief explanation of the concept.
3. **Conformity assessment procedure for apparatus:** gives information on the conformity assessment procedure for apparatus, including the successive steps of EMC assessment, EC Declaration of Conformity; information and documentation requirements. Some more detailed guidance has been given for the EMC assessment when harmonised standards are not used. In this case the EMC assessment has been called in this Guide 'Detailed EMC technical assessment'. This new terminology is only introduced to allow a clear distinction from the usual and preferred method of EMC assessment, which refers exclusively to the use of the relevant EMC harmonised standards.
- 4 **Procedures for fixed installations:** gives information on the relevant requirements and documentation for fixed installations, including the special issue of apparatus for incorporation into given fixed installations.
- 5 **Enforcement of the EMC Directive:** gives brief indications on the enforcement by the competent authorities of Member States with emphasis on the special case of equipment for demonstration at trade-fairs.
- 6 **Notified Bodies:** gives information on their role, their selection, the co-ordination issue and the treatment of complaints concerning their role.

Annexes to this Guide give examples or more detailed information on some specific matters.

1 SCOPE

1.1 General

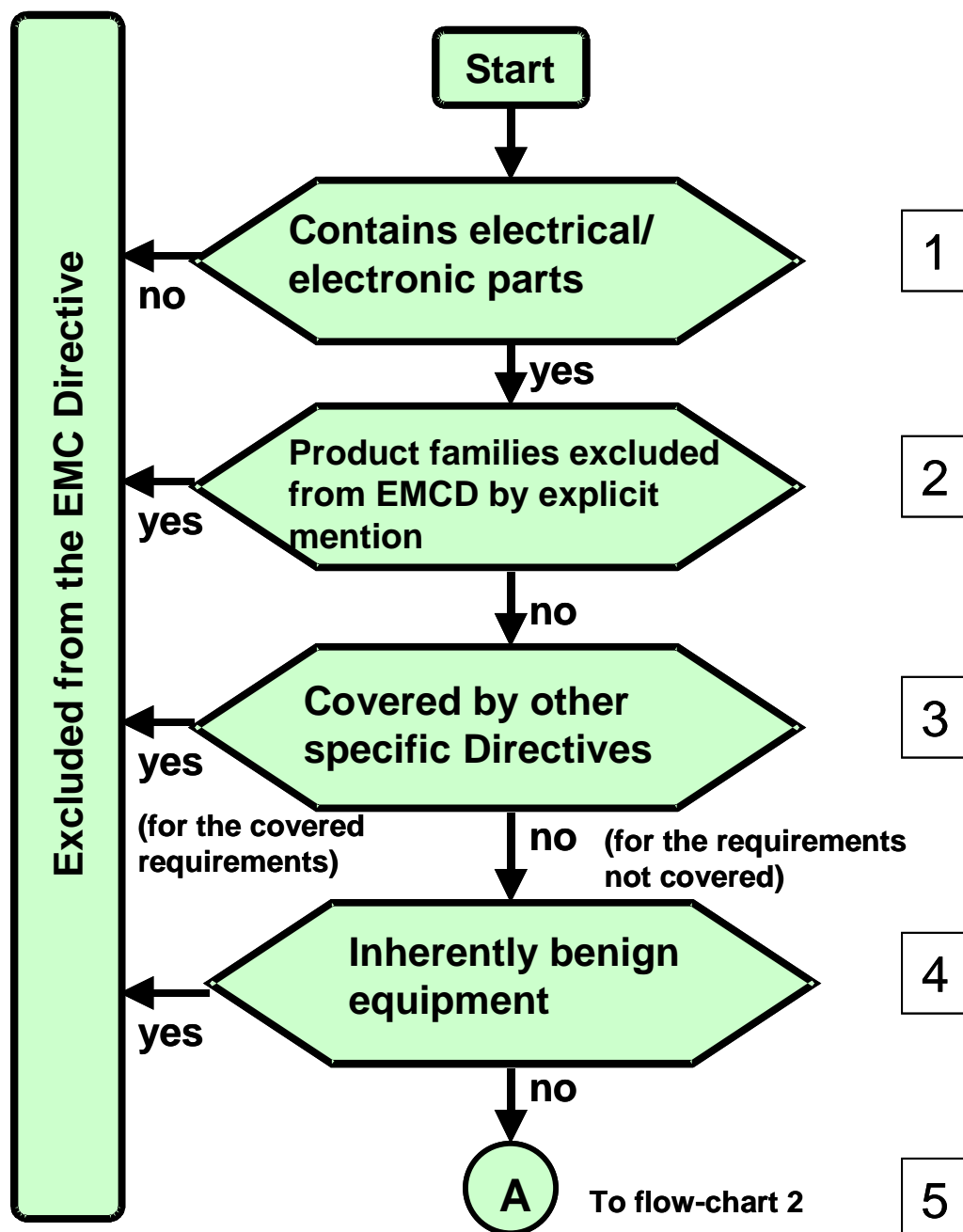
The EMC Directive 2004/108/EC¹ applies to a vast range of equipment encompassing broadly all electrical and electronic appliances, systems and installations

Article 1(5) of the EMC Directive confirms that the EMC Directive does not regulate the safety of equipment for persons or other living beings. Further according to the definition given in Article 2 the EMC Directive is only concerned with the electromagnetic compatibility between equipment.

Note: Other directives may require in some cases higher requirements for EMC phenomena in order to satisfy their specific needs regarding safety aspects.

The decision flowcharts 1, 2, 3 and 4 are practical tools to determine whether types of equipment are within or outside the scope of the EMC Directive. The complete overall flowchart 6 grouping flowcharts 1, 2, 3 and 4 is given in Annex 1. The flowcharts also assist with determining whether pieces of equipment should be considered as apparatus or as fixed installations.

¹ OJ No L390, 31.12.2004



Flowchart 1 - Exclusions for equipment

The successive steps and criteria of the decision **flowchart 1** are described hereafter, with references to the relevant sections of this Guide where more precise explanations are developed:

- (1) To determine whether the equipment contains electrical and/or electronic parts. (section **1.1.1**)

- (2) To examine whether the equipment belongs to the product families which are explicitly quoted as exclusions in the EMC Directive under Article 1.2 (section 1.1.2)
- (3) To examine total/partial inclusions/exclusions due to the coverage by other specific Community Directives within the meaning of Article 1.4. (section 1.1.3)
- (4) To determine whether the equipment may be considered as inherently benign in terms of electromagnetic compatibility (section 1.1.4)
- (5) To determine whether the equipment is an apparatus or a fixed installation in the context of the EMC Directive (Section 1.1.5)
(Note: addressed in [flowchart 2](#))

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 EMC Directive.

1.1.2 *Explicit exclusions from the EMC Directive*

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

- [Radio equipment and telecommunications terminal equipment](#) covered by [Directive 1999/5/EC](#) (R&TTE Directive) (section 1.1.2.1).
- [Aeronautical products, parts and appliances](#) referred to in Regulation 1592/2002 (section 1.1.2.2).
- [Radio equipment used by radio amateurs](#) within the meaning defined in ITU's Radio Regulations. (section 1.1.2.3)

1.1.2.1 Radio equipment and telecommunications terminal equipment

The EMC Directive exempts equipment covered by [Directive 1999/5/EC](#) on radio equipment and telecommunications terminal equipment (i.e. so called "R&TTE Directive") from the EMC Directive (Article 1.2.(a) of the EMC Directive). The R&TTE Directive covers most radio and telecommunication terminal equipment and includes EMC protection requirements identical to those of the EMC Directive. This means that the protection requirements of 2004/108/EC have mandatory effect for R&TTE equipment[and that the conformity assessment procedures for apparatus are available as an alternative to the conformity assessment procedures of the R&TTE Directive] *Statement under legal scrutiny.*

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

The special case of measurement equipment using radio frequency signals to measure and test the performance of other equipment is covered in the Annex 2.

1.1.2.2 Aeronautical products

Aeronautical products, parts and appliances referred to in Regulation (EC) N° 1592/2002 of the European Parliament and of the Council of 15 July 2002 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency² are excluded from the EMC Directive (Article 1.2.(b) of the EMC Directive). This regulation and other relevant International Conventions and Regulations ensure that EMC requirements for aeroplanes and equipment intended for incorporation into aircraft are at least equivalent to those found in the EMC Directive.

1.1.2.3 Radio equipment used by radio amateurs

Radio equipment used by radio amateurs is excluded unless the equipment is available commercially (Article 1.2 (c) of the EMC Directive). This exclusion has been included because of the specific nature of the activities of radio amateurs. Radio amateurs are persons carrying out experimental activities within the field of radio communications, according to the definitions of the ITU (International Telecommunication Union) Radio Regulations. Amateur radio equipment which is commercially available comes within the scope of the R&TTE Directive.

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

1.1.3 *Equipment covered by other specific Community Directives*

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

² OJ No L240, 7.9.2002, p.1 Regulation as amended by Commission Regulation (EC) No 1701/2003 (OJ L243, 27.9.2003, p.5)

Directives. The following list contains examples of equipment excluded (emission and immunity) from the EMC Directive:

- Motor vehicles: covered by specific Directive 72/245/EEC³ and 2004/104/EC

Specific EMC protection and safety requirements applicable to motor vehicles are laid down by the Directive [2004/104/EC](#), which amends the Directive 72/245/EEC concerning the electromagnetic compatibility of motor vehicles.

Components sold as aftermarket equipment and intended for the installation in motor vehicles need no type approval under the motor vehicle EMC Directive [2004/104/EC](#) if they are not related to immunity related functions (see Annex I, section 3.2.3 of Directive [2004/104/EC](#)). In this case, when the EMC requirements of the Motor Vehicles Directive are complied with, an EC Declaration of Conformity according to the procedures of the EMC Directive or R&TTE Directive must be issued. During a transition period of four years after coming into force (i.e. until 3 December 2008) of the Motor Vehicles EMC Directive 2004/104/EC the person responsible for placing on the market of such a product has to submit all relevant information and/or a sample to a technical service which will determine if the equipment is immunity-related or not.

In the special cases of equipment, where EMC phenomena not covered by the Motor Vehicles Directive 2004/104/EC are relevant, the EMC Directive 2004/108/EC continues however to apply and thus equipment for which such phenomena are relevant should also carry a CE marking.

- Active implantable Medical Devices: covered by specific Directive 90/385/EEC⁴
- Medical Devices: covered by specific Directive 93/42/EEC⁵
- In vitro Diagnostic Medical Devices: covered by specific Directive 98/79/EC⁶

³ OJ No L 152, 6.7.1972, amended by Directive 2005/83/EC, OJ No L 305, 24.11.2005

⁴ OJ No L 189, 20.7.1990 amended by Directives 93/42/EEC, OJ No L 169, 12.7.1993 and 93/68/EEC, OJ No L 220, 30.08.1993.

⁵ OJ No L 169, 12.7.1993, amended by Directive 93/68/EEC, OJ No L 220, 30.8.1993.

⁶ OJ N° L 331, 07.12.1998.

- Marine equipment: if covered by the specific Directive 96/98/EC⁷
- Agricultural and forestry tractors covered by Directive 75/322/EEC,⁸
- Two or three-wheel motor vehicles, covered by Directive 97/24/EC⁹

The following examples of equipment excluded only for immunity from the EMC Directive (for this equipment the EMC Directive covers the emission requirements):

- Measuring instruments: covered by specific Directive 2004/22/EC¹⁰
- Non-automatic weighing instruments: covered by Annex I-8(2) of Directive 90/384/EEC¹¹.

1.1.4 *Inherently benign equipment*

Equipment which is inherently benign in terms of electromagnetic compatibility is excluded from the scope of the EMC Directive according to Article 1(3).

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 that it will operate without unacceptable degradation in the presence of the electromagnetic disturbance normally present in its intended environment. Both conditions shall be met to classify the equipment as inherently benign.

The application of the above enables, for example, the exclusion of the following equipment from the application of the EMC Directive, on the clear understanding that they include no active electronic part:

- Cables and cabling¹², cables accessories, considered separately.

⁷ OJ N° L 46, 20.12.96

⁸ OJ N° L 147, 9.6.1975, amended by Directives 82/890/EEC, OJ No L 378, 31.12.1982, Directive 2000/2/EC, OJ L 021 26.01.2000 and 2001/3/EC, OJ L 28, 30.01.2001

⁹ OJ N° L226, 18.8.1997

¹⁰ OJ No L 135, 30.4.2004.

¹¹ OJ No L 189, 20.7.1990, amended by Directive 93/68/EEC, OJ No L 220, 30.8.1993.

¹² Manufacturers should be aware that the characteristics and installation of cables and cabling can have a significant impact upon the EMC performance of equipment.

- Equipment containing only resistive loads without any automatic switching device; e.g. simple domestic heaters with no controls, thermostat, or fan.
- Batteries and accumulators (without active electronic circuits)
- Headphones, loudspeakers without amplification.
- Pocket lamp without active electronic circuits.

Also the following equipment is considered benign:

- Protection equipment which only produce 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.-
- Fuses, circuit breakers, home and building switches which do not contain any active electronic 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 anyway under the control of other technical measures included in non-EMC product standards, and which do not include active electronic components.

Illustrative examples:

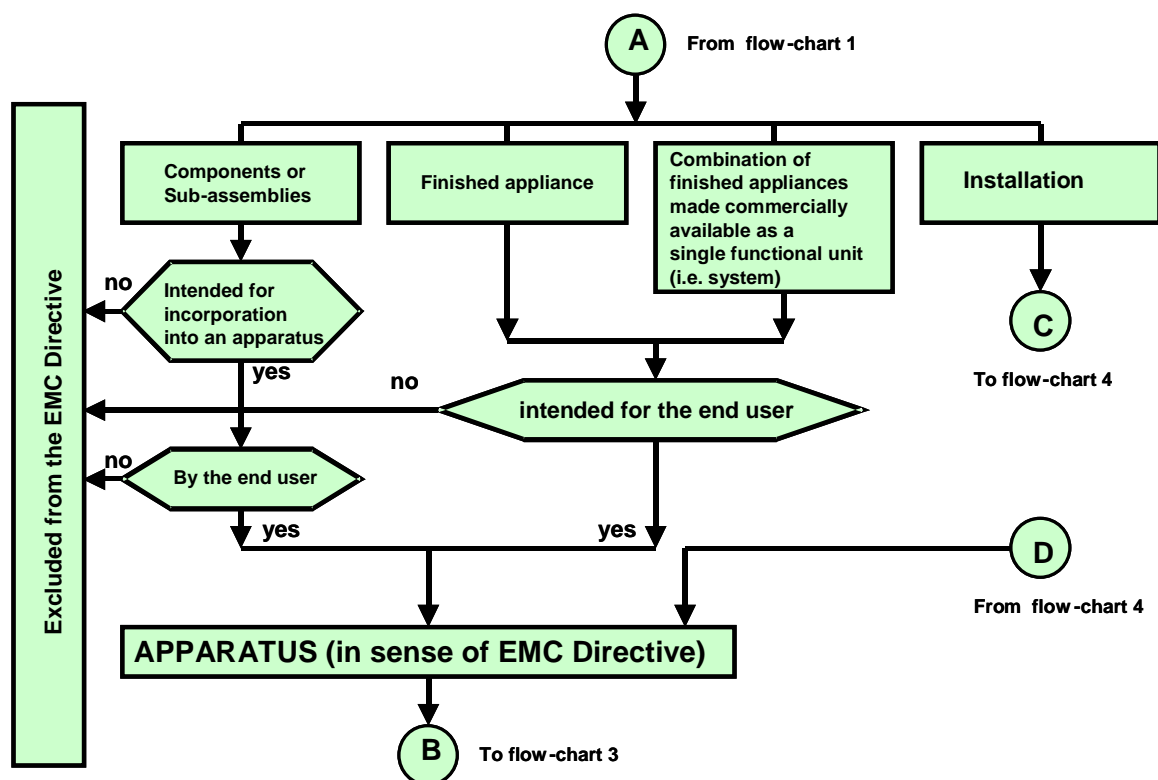
- High voltage inductors;
- High voltage transformers.
- Capacitors (e.g. power factor correction capacitors);
- Induction motors;
- Quartz watches (without additional functions, e.g. radio receivers);
- Filament lamps (bulbs);
- Passive antennas used for TV and radio broadcast reception.
- Plugs, sockets terminal blocks, etc.

1.1.5 Classification as apparatus or fixed installation

The EMC Directive defines equipment as any apparatus or fixed installation. As there are separate provisions for apparatus and fixed

installations, it is important that the correct category of the equipment is determined.

In technical-commercial classifications the following terminology is frequently used: components, sub-assemblies, finished appliances (i.e. finished products), a combination of finished appliances (i.e. a system) and installations. [Flowchart 2](#) uses this classification as a starting point for arriving at apparatus in the sense of the EMC Directive



Flowchart 2 - Scope for apparatus

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

For guidance on the applicability of the EMC Directive for fixed installations the reader is referred to section 1.3, which defines the scope for fixed installations.

1.2 Defining the scope for apparatus

Article 2.1 (b) of the EMC Directive defines "Apparatus" ("Apparatus" means any [finished appliance](#), or [combination thereof](#) made commercially

available (i.e. placed on the market) as a single functional unit, intended for the end-user, and liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance.). According to Article 2(2) "[components/sub-assemblies](#)" and "[mobile installations](#)" are deemed to be an apparatus, under defined conditions.

Note: The IEC's International Electrotechnical Vocabulary - IEC 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"

The EMC Directive imposes requirements to apparatus when placed on the market and/or put in service.

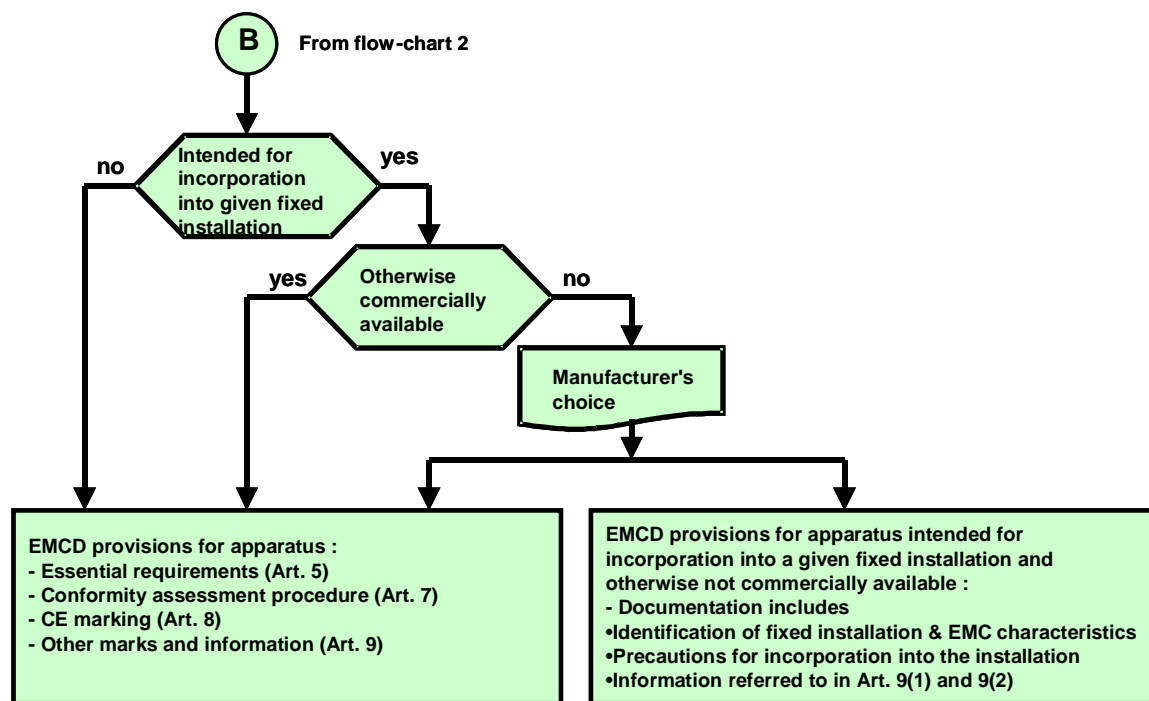
Note: "Placing on the market" and "putting into service" are further explained in the "Guide to the implementation of directives based on the New Approach and the Global Approach"

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

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

In order to be considered as an apparatus in the sense of the EMC Directive the apparatus should be liable to cause electromagnetic disturbances, or its normal operation is liable to be affected by such disturbances. If the condition is not fulfilled due to inherent characteristics of the apparatus, then the apparatus may be considered as inherently [benign in terms of electromagnetic compatibility](#), and hence, the EMC Directive does not apply (see section [1.1.4](#)).

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



Flowchart 3 - Provisions applicable to apparatus

1.2.1 Finished appliances

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

A finished appliance is considered as apparatus in the sense of the EMC Directive, if it is **intended for the end-user**.

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

Note: For such finished appliances outside the scope of the EMC Directive, it is however advisable that the manufacturer should provide the relevant instructions to enable their operation within the apparatus in which they will be incorporated, in accordance with the intended purpose. The instructions for use of such finished appliances should preferably indicate EMC aspects to be considered by the manufacturer of the final apparatus to help him to solve reasonably foreseeable EMC problems with the final apparatus. The manufacturer can however choose to apply all provisions of the EMC Directive related to apparatus

1.2.2 Combination of finished appliances (systems)

According to the definition in Article 2.1(b) of the EMC Directive, a combination of several finished appliances which is made commercially

available as a single functional unit intended for the end-user is considered to be an apparatus. Such a system, within the sense of the EMC Directive, is combined, and/or designed and/or put together by the same person (i.e. the system manufacturer) and is intended to be placed on the market for distribution as a single functional unit for an end-user and intended to be installed and operated together to perform a specific task. All provisions of the EMC Directive, as defined for apparatus, apply to the combination as a whole.

Note: Manufacturers of combinations described above should be aware that combining two or more CE marked finished appliances does not automatically produce a system which meets the protection requirements. e.g.: a combination of CE marked Programmable Logic Controllers and motor drives put together to be placed on the market as a system may fail to meet the protection requirements.

In normal usage, the word "system" is sometimes used with a different meaning namely for an optional combination of several finished appliances to perform a specific task where the end-user is the person who decides which finished appliances are used to construct this so-called "system". The manufacturer of each constituent finished appliance within the "system" has already fully applied the EMC Directive, and particularly taken into account the expected electromagnetic environment and the intended use. Hence, for such a so-called "system", no further conformity assessment is required.

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 Included components/sub-assemblies

When a manufacturer places components or sub-assemblies on the market which are:

- For incorporation into an apparatus by the end-user,
- Likely to be used or incorporated by end-users even if not intended directly for them,

these components or sub-assemblies are to be considered as apparatus with regard to the application of the EMC. The instructions for use accompanying the component or sub-assembly should include all relevant information, and should assume that adjustments or connections can be performed by an end-user not aware of the EMC implications.

Illustrative examples:

Plug-in cards for computers,

Programmable logic controllers,

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

Computer disk drives;

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 / or sub-assemblies intended for incorporation into an apparatus and / or sub-assembly by manufacturers or assemblers are not considered to be "apparatus" and are therefore not covered by the EMC Directive. This may also be applied to the examples in 1.2.3.1.

Note: It is advisable that the manufacturer provides with such components the relevant instructions to enable their operation within the apparatus in which they will be incorporated, in accordance with the intended purpose. The instructions for use of such components should indicate EMC aspects to be considered by the manufacturer of the final apparatus to help him to solve reasonably foreseeable EMC problems with the final apparatus.

Illustrative examples of simple components:

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

-Resistors, capacitors, inductors, filters,

-Diodes, transistors, thyristors, triacs, etc.,

-Integrated circuits;

-Simple electromagnetic relays,

-LEDs,

-Simple thermostats,

-Cathode ray tubes.

1.2.4 Mobile installations

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

Note: If such installations are however, intended to substitute temporarily for, or to extend, a fixed installation (e. g. for electricity generation or transmission in the high-voltage network) they can be treated in the same way as a fixed installation. The temporary connections to the networks of such installations should be carefully planned, and installed by experts.

Installations which are regularly dismantled and rebuilt at different locations are not considered as mobile installations. They may thus be identified as apparatus or as fixed installations according to the particular cases.

1.2.5 *Used apparatus*

At the time of drafting this guide, no more advice can be given on used apparatus than explanations already given in the [New Approach Guide](#).

1.3 Defining the scope for fixed installations

1.3.1 *Fixed installations*

"Fixed installation", is defined as "a particular combination of several types of apparatus and, where applicable, other devices, which are assembled, installed and intended to be used permanently at a predefined location."

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

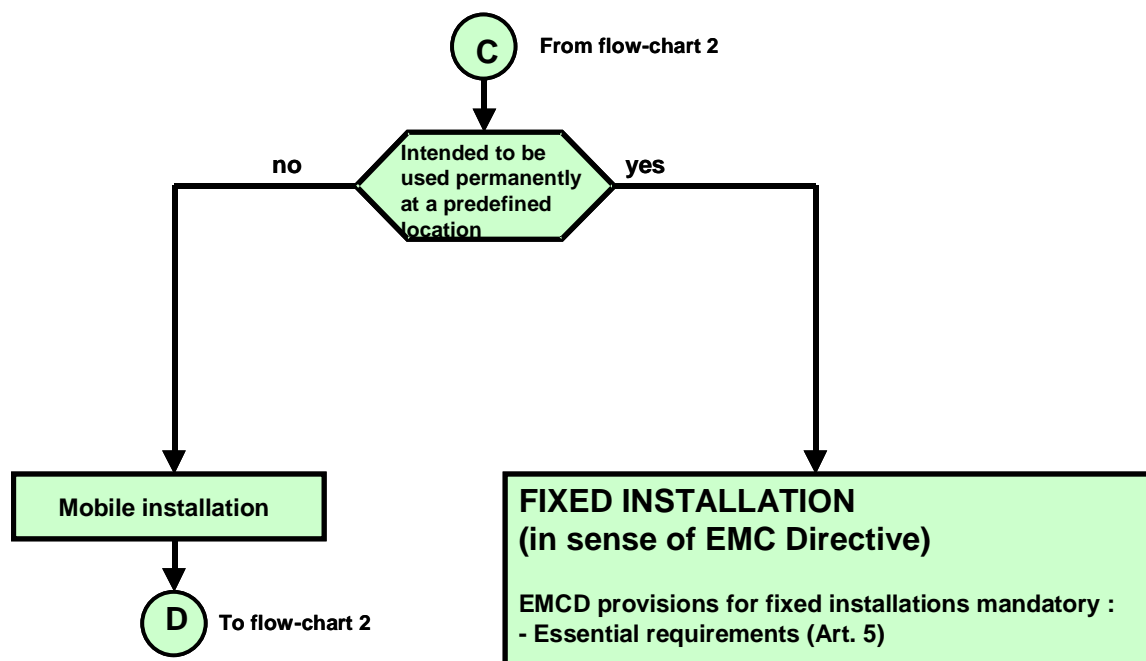
The EMC Directive provides however the possibility to exclude "inherently benign" installations. The application of this criterion of exclusion seems problematic to exclude a priori any type of fixed installation. Such exclusions could only be done on a case by case basis.

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

Examples of fixed installations:

Industrial plant, power plant, power supply networks, telecommunication networks, cable TV network, computer network, airport luggage handling installation, , airport runway lighting installation, automatic warehouse, skating hall ice rink machinery installation , storm surge barrier installation (with the control room etc), , ship elevator, wind turbines stations, , car assembly plant , water pumping stations, water treatment plants, railway infrastructures

Fixed installations must comply with the essential requirements of the EMC Directive as defined in Article 5 and Annex I of the EMC Directive



Flowchart 4 Installations

1.3.2 *Specific apparatus for fixed installations*

The general rule is that all apparatus, as defined in the EMC Directive, are subject to all the relevant provisions of the EMC Directive for apparatus. This applies also fully to apparatus that will be incorporated into fixed installations. However the EMC Directive provides an exception for apparatus intended for incorporation in a given fixed installation which are otherwise not commercially available.

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

1.4 **Used and second-hand equipment**

Link to Blue Guide

This section to be completed following the EMC WP on 20th Sept.

2 ESSENTIAL REQUIREMENTS

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

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

Complying with the essential requirements is mandatory. These are legally-binding requirements for all equipment in the scope of the EMC Directive. Only equipment complying may be placed on the market or put in service in the EEA and the law does not distinguish between EEA manufacturers and manufacturers from other countries.

The EMC Directive does not require any additional requirements (for instance requirements on product quality). Sometimes commercial contracts specify additional EMC requirements, which are outside the legislation and are only business agreements negotiable between partners.

The objective of the EMC Directive is to minimise the occurrence of EMC problems for the user. Completely eliminating all problems, would not be proportional to the objectives pursued.

The essential requirements are split into 2 parts:

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

“Specific requirements” for fixed installations.

3 CONFORMITY ASSESSMENT PROCEDURE FOR APPARATUS

3.1 Introduction

Apparatus is required to comply with the protection requirements referenced in Article 5 and detailed in Annex I of the EMC Directive. Compliance with these protection requirements is demonstrated by applying the conformity assessment procedure detailed in Article 7 and Annex II (and optionally Annex III) of the EMC Directive.

The [EMC assessment](#) is an essential part of the conformity assessment procedure and is the fundamental basis for verifying that an apparatus meets the protection requirements. It may be performed in practice by one of the following three ways:

[Use of EMC harmonised standards](#)

[Detailed technical EMC assessment](#)

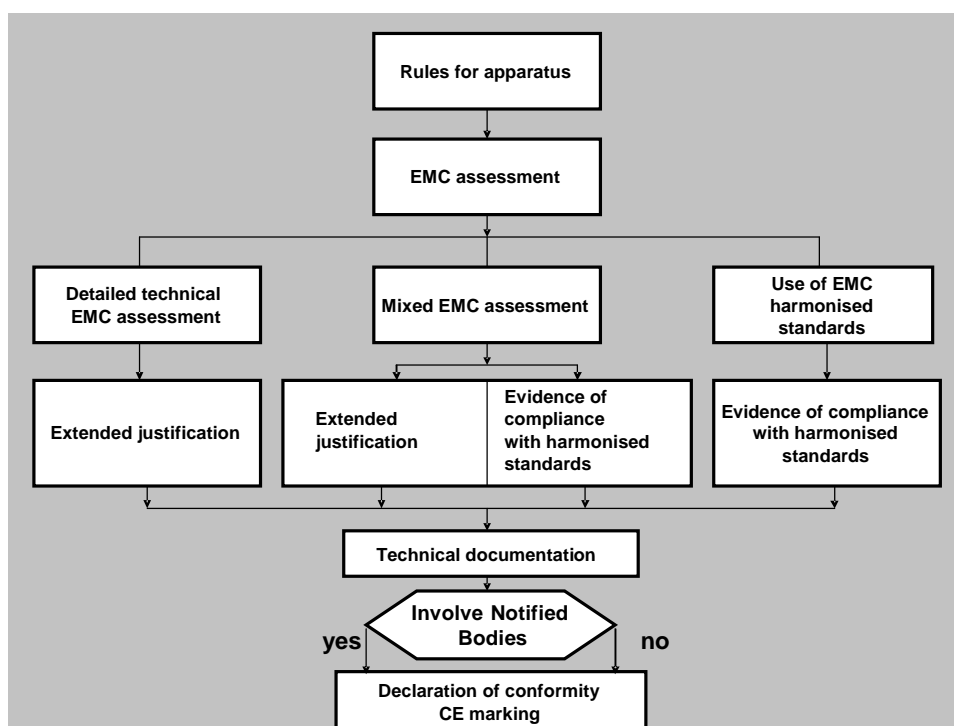
Mixed EMC assessment (combining the two previous ones)

Technical documentation has to be prepared by the manufacturer to demonstrate evidence of compliance with the protection requirements. This includes evidence that the apparatus complies with the relevant harmonised standards or, if harmonised standards are not used or only used in part, a much more detailed technical justification. The manufacturer must take all measures necessary to ensure that the apparatus are manufactured in accordance with the technical documentation. (Annex II 8 of the EMCD).

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

The manufacturer may opt to involve a [Notified Body](#) during the conformity assessment procedure.

The following flowchart illustrates the successive steps of the conformity assessment procedure.



Flowchart 5 - Complete conformity assessment procedure for apparatus

3.2 EMC Assessment

3.2.1 General Concept

According to Article 7 and Annex II of the EMC Directive the manufacturer shall perform an electromagnetic compatibility (EMC) assessment of the apparatus, based on the relevant phenomena, in order to meet the protection requirements. The EMC Directive does not require any mandatory intervention from a third party, when carrying out the assessment.

The manufacturer of apparatus is fully responsible for the appropriate choice of the assessment carried out. Recommendations are given in this Guide to help the manufacturers.

Note: Where the EMC assessment establishes that the apparatus concerned is inherently benign (as stated in recital 9) in terms of electromagnetic compatibility (both for emission and immunity) according to Article 1(3), the apparatus is excluded from the scope of EMC Directive and no further actions are necessary. It may however be wise to document the results of the assessment and its conclusion in case of questions regarding the application of Article 1(3) for the apparatus.

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

In cases where the apparatus can take different configurations, the electromagnetic compatibility assessment shall confirm that the apparatus meets the protection requirements, according to Annex II.2 of the EMC Directive “in all possible configurations identified by the manufacturer as representative of its intended use”.

In practice, this EMC assessment has to be performed following a defined methodology. Three methods are possible for the EMC assessment:

- a) Use of EMC harmonised standards developed by the European Standardisation Organisations and referenced in the list of harmonised standards for the EMC Directive published in the Official Journal of the European Union (OJEU).
- b) Detailed technical EMC assessment, when the manufacturer applies his own methodology.
- c) Mixed assessment, combining the two previous methods. The EMC Directive allows a mixture of detailed technical EMC assessment and application of harmonised standards, for example one could use the harmonised standards to cover emission phenomena and detailed technical EMC assessment for immunity aspects.

The harmonised standards provide a recognised methodology to demonstrate compliance to the protection requirements. Use of the relevant EMC harmonised standards (method a) is equivalent to performing an

EMC assessment. If a manufacturer applies his own methodology completely (method b) or partially (method c), he will have to substantiate that the steps taken are adequate to ensure compliance with the EMC Directive.

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

The EMC assessment is solely the responsibility of the manufacturer; it is never the responsibility of a third party such as a Notified Body or an EMC test laboratory.

Note: The specific services and operation of [Notified Bodies](#) are described in the chapter 6

Where a manufacturer assembles a final apparatus using components from other manufacturers, the manufacturer must retain overall control. The manufacturer is responsible for the compliance of the final apparatus therefore if he purchases components from other manufacturers then receipt of all the relevant information should be made a contractual requirement as there is no such requirement written into the EMCD.

3.2.1.1 The “Worst Case” approach

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

In such cases it is considered sufficient to perform the testing and/or evaluation on the basis of the configuration most likely to cause maximum disturbances and the configuration most likely to be susceptible to disturbances.

This method is often referred to as “worst case” selection and aims at decreasing the costs of the assessment mainly where testing is necessary.

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 cases. The use of the worst case approach shall be documented in the technical documentation.

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

3.2.2 Use of EMC harmonised standards

The correct application of the relevant harmonised standards, whose references have been published in the relevant section of the Official Journal of the European Union (OJEU), covering all the essential requirements of the EMC Directive shall be equivalent to the carrying out of the detailed technical EMC assessment. It is the most frequently used way to demonstrate EMC assessment.

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

The EMC Directive refers to the moment of placing on the market for each individual apparatus. This means that for an apparatus, which is continuously produced over a long period, the applicable standards may change in the course of time. The provisions explained in 3.2.2.3 concerning the date of cessation of Presumption of Conformity should be taken into account. This ensures that a transition period (usually 3 years) is foreseen during which the old and new standards are both valid. After this time a new Declaration of Conformity will be needed to be written which may require the apparatus to be retested

Alternative test and measurement methods, when introduced in a harmonised standard for the same purpose, are considered together with their associated limits, as equivalent regarding Presumption of Conformity with the covered essential requirements

Harmonised standards for EMC application are published by the three following European standardisation Bodies:

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

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

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

<http://www.newapproach.org>

3.2.2.1 List of harmonised standards

The list of harmonised standards published in the OJEU is regularly updated and is available on the following European Commission web-site:
<http://europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/reflist/emc.html>

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

www.cenelec.org

www.etsi.org

www.cenorm.be

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

For CENELEC members via whom harmonised standards can be obtained, go to:

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

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

Further guidance for the application of harmonised standards is given in Annex 3.

3.2.2.2 Relevant harmonised standards

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

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

Generally the three main aspects to be covered are:

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

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

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

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

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

The presentation adopted in the OJEU presents 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.

Although both dates are generally identical, 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. The "dow" has no meaning within the concept of the EMC Directive.

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

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

3.2.3 Detailed technical EMC assessment.

A manufacturer may wish to declare the conformity of his apparatus directly to the protection requirements, without reference to harmonised standards, by making his own EMC assessment. The EMC assessment to be performed in this case has been called 'Detailed technical EMC assessment' for the purpose of this Guide, in order to identify this procedure clearly. This detailed technical EMC assessment shall follow a technical methodology to ensure that the requirements of the EMC Directive are met.

The manufacturer will have to provide clear evidence of compliance.

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

The areas of application of the detailed technical EMC assessment, or a mixture of it with the use of harmonised standards (mixed assessment), will probably encompass:

- Where there are no harmonised standards or all the essential requirements applicable to the apparatus are not covered, generic harmonised standards may be applicable in the large majority of cases;
- Where the apparatus uses technologies, incompatible with or not yet taken into account by harmonised standards, and generic standards are not applicable;
- Where the manufacturer uses test facilities not yet covered by the harmonised standards;
- Where the manufacturer may want to apply any other standards or specifications not harmonised in the context of the EMC Directive;
- Where 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 detailed technical EMC assessment required for a particular apparatus will depend on several factors, such as:

- Nature of the apparatus (apparatus characteristics);
- Intended use;
- Location of use; EMC environment
- Types of disturbances created by or affecting the apparatus;
- Environmental conditions;

- Performance criteria for immunity.

The EMC Directive requires the manufacturer to document all steps taken and decisions made to check the conformity of the apparatus for those aspects for which the manufacturer has chosen the route of the detailed technical EMC assessment. The detailed technical EMC assessment may encompass but is not limited to items such as:

- 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 movable apparatus which must have emission and immunity characteristics appropriate for several environments. This selection is the responsibility of the manufacturer concerned. 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;
- If testing is performed it shall be done against the relevant phenomena of the apparatus and should be based on an appropriate test plan, which may include: measurement techniques and their applicability (where applicable including uncertainties), test conditions, frequency range covered, instrumentation used (where applicable including calibration information). Testing may not be necessary in all cases if other means such as simulation, design characteristics, etc. are sufficient to ensure the conformity of the apparatus with the protection requirements;
- 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 protection requirements;
- Any specification of general or specific requirements taken to limit emission of disturbances;
- Assessment of whether compliance with the protection requirements is ensured in residential areas or not. If this is not the case the restriction of use shall be clearly established;
- Assessment of whether any specific precautions have to be taken when the apparatus is assembled, installed, maintained or used, in order to ensure that, when put into service, the apparatus is in conformity with the protection requirements;
- Worst case selection criteria for series of apparatus with similarities.

Detailed guidance on the selection of electromagnetic phenomena to be assessed in the detailed technical EMC assessment is given in Annex 4 to this Guide.

Notes:

1) As a detailed technical EMC assessment will most likely include testing, it is evident that the harmonised standards are a good source for understanding any background on testing aspects that the manufacturer wishes to use.

2) Draft Harmonised standards may also provide information. These standards are either at the stage of public enquiry or, if having passed this stage, still have to be formally adopted as EN standards and then have their references published in the OJEU before they can be considered giving Presumption of Conformity. Attention is drawn to the fact that the draft standards can be subject to substantial modifications before their adoption. Manufacturers may consider them as general guidelines, bearing in mind that the solutions proposed by these draft standards may be abandoned or refused at a later stage of the adoption procedure. The recourse to the draft standards should therefore be carried out with great caution.

3) Standards related to EMC but not harmonised under the EMC Directive may also contain valid information e.g. basic EMC standards. Attention is drawn to the fact that the use of such standards does not provide a Presumption of Conformity; however these standards may be used as guidance by manufacturers applying a detailed technical EMC assessment of apparatus.

3.3 Documentation required by the EMC Directive for the competent authorities

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

3.3.1 Technical documentation

As indicated in Annex II.3 and Annex IV of the EMC Directive, the manufacturer shall draw up technical documentation providing evidence of the conformity of the apparatus with the essential requirements of this Directive.

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

- An identification of the product covered by the technical documentation. This identification should allow unambiguously linking between the technical document and the product.
- A general description of the apparatus. The amount of information required will depend on the complexity of the apparatus, a simple apparatus may be fully defined in one line whereas a more complex apparatus may require a complete description (a picture may be included).
- If harmonised standards have been applied then evidence of compliance is required. At a minimum this will be a dated list of the harmonised standards applied and the results obtained when applying the standards.
- 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 (i.e. detailed technical assessment) - must be included. The documentation for this detailed technical EMC assessment includes test reports, design calculations made, examinations carried out etc.
- If a manufacturer is using the procedure of Annex III of the EMCD, then the Notified Body statement shall be included.

3.3.2 Declaration of Conformity

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

Notes:

1) In line with the New Approach Guide (see section 5.4), the EMC Directive uses the wording 'EC' Declaration of Conformity. In other documents it is often referred to as SDoC: "Suppliers Declaration of Conformity".

2) There is no requirement to have the CE marking on the DoC, however it is not forbidden to do so.

3) The "person empowered to bind the manufacturer or the authorised representative" does not need to be resident on EU territory.

Annex IV, 2 of the EMC Directive specifies the mandatory minimum content of the DoC.

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 including the [detailed technical EMC assessment](#) should be included and a reference to any identifiable non-harmonised standards or specifications that have been applied.

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

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

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

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

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

It is at the discretion of the manufacturer to add on to the DoC any information that could be valid in order to make the DoC applicable to areas outside the EU, in order to facilitate international usage provided that it does not conflict with the requirements of the EMCDD.

Furthermore in the case where several Directives apply simultaneously to the apparatus the manufacturer or the authorised representative is free to decide whether it is worthwhile to merge all the DoCs into a single DoC. However, this may not be possible if a Directive provides for a specific form of the DoC (such as the Directive relating to personal protective equipment) that are in practice not compatible with the DoC for the EMC Directive.

All information regarding the concept of making the DoC available for the authorities, as well as where to keep the DoC is given in section 3.3.3. The EC Declaration of Conformity should be drawn up or translated in one of the official languages of the Community but it does not have to be in the official languages of the countries where the apparatus is placed on the market/or put into service.

Annex 6 contains examples of DoC layout and content

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

The Directive requires that:

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

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

The concept of holding at the disposal of means:

1. There shall be one person in the Community responsible for making available the EC Declaration of Conformity and the technical documentation
2. This person must present the EC Declaration of Conformity and the technical documentation upon request from the competent authorities, within a reasonable time. He has to take positive actions to make it actually available to those authorities (send a copy of the file, email, etc.).
3. A failure to present the information within a reasonable period, in response to a request by the authorities, constitutes an infringement of one of the administrative requirements of the EMC Directive.

4. This person needs not be in possession of the documents. The documents can be kept on the manufacturer's premises, even if the manufacturer is outside the Community. However the authorities, who have limited geographical jurisdiction, cannot be expected to go beyond their frontiers to examine the technical documentation at the manufacturer's premises. The manufacturer or his authorised representative in the Community is obliged to hold the required documents in such a way that they can be presented to the authorities upon first request and within a reasonable timeframe. In any case the effort required to present the documentation should always be produced by the manufacturer or his authorised representative in the Community.
5. The information to be made available on request needs not to be an original but can be a copy of it. Further, the technical documentation can be kept in any format (for example as a hard copy or CD-ROM or any other electronic storage method), which allows it to be made available within a reasonable period of time. When a manufacturer responds to a request by the authorities for (part of) the file, it should be in one of the languages of the Community.

Neither the technical documentation nor the Declaration of Conformity has to accompany the apparatus.

Manufacturers are not obliged to accept requests for the technical documentation from their customers.

3.4 CE Marking and information

3.4.1 CE marking

The EMC Directive requires that the apparatus bears the CE marking as an attestation of compliance with the EMC Directive. The details are given in Article 8 and Annex V of the EMC Directive.

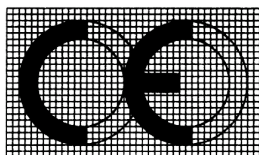
When use is made of the exemption provided by Article 13(1) for apparatus, intended for incorporation into a given fixed installation and otherwise not commercially available (see section 3.4.4), it is not allowed to affix the CE marking to such apparatus to attest compliance with the EMC Directive.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

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

The EMC Directive also forbids affixing of marks that look like the CE marking, and also marks that are likely to mislead third parties in relation

to the meaning of the CE marking, e.g. by giving the impression that they are needed in order to have free access to a Member State's market.

However, for apparatus under the EMC Directive, the CE marking is the only mark having regulatory meaning regarding EMC within the European Community.



As a general rule, the CE marking must be affixed to the apparatus or to its data plate. For most apparatus this poses no difficulties to achieve while observing the requirement on minimum height of 5 mm.

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

The [Guide](#) to the implementation of directives based on the New Approach and the Global Approach (Chapter 7.3) gives more information as to under what circumstances this exemption is allowed.

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

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

3.4.2 *Other identifying marks*

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

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

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

3.4.3 Information for traceability

In order to facilitate traceability, the EMC Directive requires that the actual manufacturer be identified with name and address. In case the manufacturer is located outside of the European Community, also the name and address of the authorised representative or the person responsible for placing the apparatus on the Community market needs to be given.

This identification information has to “accompany” the apparatus. It can thus be given in the documentation accompanying the apparatus, complementing the information usually found on the apparatus itself (see section 3.4.2)).

3.4.4 Information regarding installation, use and maintenance

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

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

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

Furthermore any precaution that needs to be observed for the apparatus to maintain its compliance with the protection requirements regarding use and maintenance shall also be indicated. Finally information on use of the apparatus in accordance with its intended purpose needs to be provided in the user’s instructions.

Provision of information regarding installation, use and maintenance use shall be adapted to the target audience. Depending on the type of product, it can be supplied in paper format or in an electronic format that is commonly available (such as document on a computer disc or accessible via the Internet). If so it is expected that a minimum set of information in paper form be provided with the apparatus to inform the user of how to access this electronic information.

3.4.5 *Information when compliance is not ensured with the limits of the protection requirements in residential areas*

The EMC Directive recognises that the electromagnetic environment of residential areas requires a particular protection. The EMC Directive requires that apparatus for which compliance with the protection requirements in residential areas is not ensured by the manufacturer (for example when limits for the residential environment in standards are exceeded) has to be accompanied by a clear indication of this restriction of use, where appropriate also on the packaging". There are many ways of meeting this obligation.

Note: One example can be found in EN 55022, the emission standard for information technology equipment, which in the case of apparatus designed for non-domestic areas (called 'class A' in the standard) requires that a warning text be provided in the user's instructions.

A suitable indication in the users' instructions would be that use in residential areas may cause interference, and that in such case special measures may have to be taken by the user regarding emissions.

4 PROCEDURES FOR FIXED INSTALLATIONS

4.1 Essential requirements

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

Owing to their characteristics fixed installations will not be subject to the need for free movement within the EEA. Therefore they are not subject to the requirements for a CE marking nor to the need for a DoC or for a formal EMC assessment before putting into service. Fixed installations have however to comply with the protection requirements and other specific requirements (Annex I of the EMCD) are applicable to them. Measures are proscribed in the EMC Directive to enable the Competent Authorities to handle complaints generated by fixed installations (Article 13 (2))

A fixed installation may be assembled by the incorporation of several apparatus including specific apparatus as described in Article 13(1) and

other devices outside the scope of the EMC Directive. In order to fulfil the protection and documentation requirements it may be advisable to specify in the technical documentation the EMC characteristics of all these devices.

Apparatus making part of a fixed installation should have been submitted to all the rules applicable to apparatus under this EMC Directive. There is however a possibility of conditional exemption detailed in Article 13 of the EMC Directive. Sections 1.3.2 and 4.4 provide further information on this matter. To invoke this exemption the apparatus must be used in the installation for which it is intended.

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

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

Intended use of components

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

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

These instructions may concern for example:

- 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 practices

Good engineering practice comprises suitable technical behaviour taking account of relevant 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

Note 1: ISO/IEC guide 2 defines "Good engineering practice" as follows :

Good engineering practice represents the state of the art, the recognised definition of which is: developed stage of a technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience. The basis of good engineering practice is mainly formed by legal requirements and recognised standards / codes of practice.

Note 2: General information on good engineering practices within the context of installations is available in several EMC handbooks, EMC courses and technical reports. For example some technical reports published by standardisation bodies deal with installation and mitigation guidelines for EMC.

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

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

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

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

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

- The coupling mechanism with the external environment
- The radiation towards or from the external environment

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

4.2 Documentation

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

4.3 Responsible person for fixed installations

Member States are responsible for establishing provisions to identify such persons.

4.4 Requirements for specific apparatus for given fixed installations

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

The wording in the EMC Directive defines the conditions under which this possible exemption is allowed. It means in particular that this exemption cannot be used for apparatus placed on the market and thus may become available to the general public. An apparatus can only benefit of 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 installations for which that specific apparatus is intended. A relation provider-customer is required.

For the specific apparatus which may benefit from this exemption, the protection requirements for those apparatus considered in isolation, the conformity assessment procedure for apparatus, the subsequent EC Declaration of Conformity and the specific marks and information for apparatus are not compulsory. However other requirements apply (see 4.4.1), if use is made of this exemption clause.

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

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

The accompanying documentation shall identify the fixed installations for which the specific apparatus is intended and the electromagnetic compatibility characteristics of those fixed installations

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, shall be indicated in the accompanying documentation. This may include precautions and requirements for cabling, for the choice of cables, for distances to be respected, for earthing, for screening, for equipotential bonding, for environmental restrictions etc.

4.4.2 .Examples of conditions under which the exemption for specific apparatus intended for fixed installations may be used

- Specific apparatus may fulfil this condition if they are made according to particular specifications intended for a fixed installation or fixed installations that have been assessed as equivalent by the manufacturer.
- Apparatus designed according to a specific specification given by a customer, intended for a given fixed installation.
- Apparatus derived from a generic apparatus adapted to the specific need of the customer or to the specificity of any particular location, in a fixed installation.
- Apparatus made in small series and delivered for incorporation into a well defined type of fixed installations each of them necessitating appropriate EMC adjustments at the final location using the manufacturer's instructions accompanying the specific apparatus.

5 ENFORCEMENT OF THE EMC DIRECTIVE

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

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

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

It requires thus that Member States, where applicable:

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

The EMCD does not contain special provisions on how surveillance should be organised and carried out in the Member States. The legal and administrative surveillance infrastructures can thus differ from one Member State to another.

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

The EMC Directive enables surveillance authorities to get access to information on the equipment, the EC Declaration of Conformity and the technical documentation. These must be made available by the manufacturer, the authorised representative established within the Community, or under certain circumstances by the importer or person responsible for placing on the market, or by the responsible person for a fixed installation.

Note: Where the conformity of apparatus is based on applying the detailed EMC assessment instead of harmonised standards, the technical documentation becomes more important for the surveillance authorities for checking if and how conformity with the protection requirements was achieved.

5.1 Special measures regarding equipment at trade fairs, etc.

An exception to the principle that market surveillance can only take place after the manufacturer has taken formal responsibility for the equipment, is the case of equipment being displayed and/or demonstrated at trade fairs, exhibitions and demonstrations (Article 4(3)).

According to 4(3), the EMC Directive allows the display and/or demonstration of not yet compliant equipment under specific

circumstances, i.e. provided that a visible sign clearly indicates that the equipment may not be marketed or put into service until it has been made to comply, and that adequate measures are taken during demonstrations, where appropriate, to ensure that radio-communications, electrical supply and telecommunications networks, as well as equipment connected thereto, are protected against electromagnetic disturbances.

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

6 NOTIFIED BODIES

6.1 General concept

In the EMC Directive the involvement of the NB is **voluntary** and the purpose of the NB is to help the manufacturer (or his authorised representative within the Community) by reviewing the technical documentation for apparatus drawn up by the manufacturer. It is an important and valuable service.

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

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

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

Note: 6 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](#), [1/01/2002 with Japan](#), [1/06/2002 with Switzerland](#)

6.2 Role of Notified Bodies

The role of the NB derives from Article 7 and Annex III of the EMC Directive, their appointment is defined in Article 12.

The NB shall:

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

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

6.3 Selection of a Notified Body.

The EU Commission maintains a website list of all NBs including CABs. (** Insert a link to the web site list when ready*) The list includes the address of each organisation as well as the scope of the designation.

When selecting a NB, manufacturers should consider the following:

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

The NB is free to offer its services, to any manufacturer established either inside or outside the Community. Although the NB 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 NB. There is no need to choose an NB located in the country where the apparatus is manufactured, nor in the country to which the apparatus will be shipped or where the apparatus is brought on the market or taking into service.

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

A manufacturer may consult more than one NB in respect of any apparatus and their opinion is not binding.

6.4 Coordination between Notified Bodies.

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

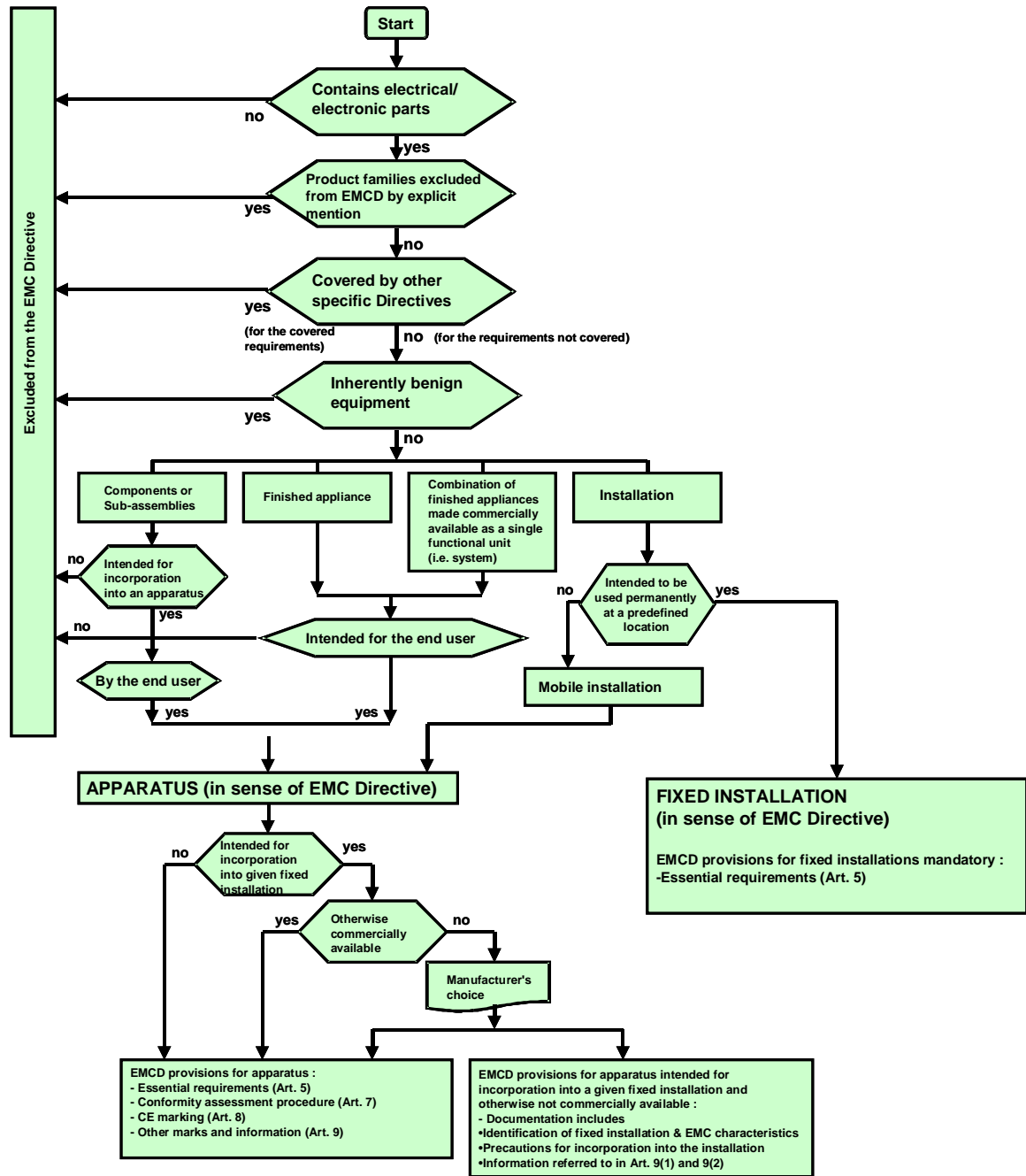
The relevant ECANB working documents, meeting reports, recommendations and guidelines are available to all NBs. The ECANB issues information sheets, called technical guidance notes (TGNs) which have been established in order to assist the NBs in their task. These TGNs may also contain valuable background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

6.5 Complaints regarding the service of the NB

Where a manufacturer has a complaint regarding the service performed by a NB, he should preferably first file a complaint with the NB in question. However, the options exist, as with any other complaint, to contact the competent authority of the Member State.

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

ANNEX 1 - Overall Flowchart



Flowchart 6 - Overall Flowchart, grouping flowcharts 1, 2, 3 and 4

ANNEX 2 - Special radio measurement equipment for measurements and testing

All measurement equipment that transmits measurement or test data by radio waves is covered by the R&TTE Directive (1999/5/EC). Where measurement equipment is used in a set-up which transmits radio signals, such use may require a national authorization from the spectrum regulator or may be forbidden without adequate spectrum protection measures.

However measurement equipment, which uses radio signals to measure the performance of another equipment and which may only be used in specific circumstances should not be considered radio communication equipment and thus should not be covered by the R&TTE Directive. The provisions of the EMC Directive remain applicable.

See <http://europa.eu.int/comm/enterprise/rtte/tcam14.htm#Test%20equipment>.

An example of such measurement equipment is a signal generator combined with a power amplifier and antenna meant to create an RF electromagnetic field to measure the immunity aspect of a product within the field.

Notes:

1) The EMC Directive requires that adequate measures are taken during operation of the measurement equipment to ensure that radio-communications, electrical supply and telecommunications networks, as well as equipment connected thereto, are protected against any electromagnetic disturbance.

2) For equipment that intentionally transmits RF energy licenses may be required or use may be totally forbidden outside shielded enclosures. The provision does not apply to Industrial, Scientific or Medical (ISM) equipment transmitting on frequencies approved by the ITU or local country.

ANNEX 3 - Guidance on using a (harmonised) standard

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

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

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

Notes on some practices

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

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

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

c) A pre-scan measurement is made to quickly obtain information on the unknown emission spectrum of the apparatus in order to decide whether a full complete measurement is considered necessary. More information may for example be found in EN 55016-2 (CISPR 16-2) on this particular subject.

d) When new editions or amendments of harmonised standards have to be applied (and declared in the DoC) for a given apparatus already in production, it does not mean that the whole assessment of this apparatus has to be repeated. The reassessment may in practice be limited to the modifications of the standard, if any, directly affecting the apparatus concerned. Modifications or revisions in standards often concern only a small range of the apparatus in the scope (and do not affect the others) or concern only one particular clause or phenomenon

ANNEX 4 - Detailed technical EMC assessment

Guidance for selecting the electromagnetic phenomena to be assessed

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

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

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

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

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

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

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

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

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

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

For the detailed technical EMC assessment the phenomena in the list need to be considered, unless it can be justified that a phenomenon is not relevant for the apparatus to be assessed. It may 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
<p>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.</p>	<p>a) harmonics, interharmonics on the mains supply</p> <p>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.</p> <p>b) signals superimposed on power lines;</p> <p>May be relevant for apparatus operating at low level of sensitivity such as residual current operated protection devices.</p> <p>c) voltage fluctuations on the mains supply</p> <p>In general, voltage fluctuations have an amplitude not exceeding 10 %; therefore,</p>

	<p>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.</p> <p>d) voltage dips and interruptions on the mains supply</p> <p>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.</p> <p>e) voltage unbalance;</p> <p>Only applicable in special cases for three phase apparatus</p> <p>f) power frequency variations of the mains supply</p> <p>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).</p> <p>g) induced low frequency voltages</p> <p>For sensitive low level measuring instruments;</p> <p>h) d.c. component in a.c. networks.</p> <p>For special cases as residual current circuit breakers</p>
Radiated low-frequency field phenomena	
Emission	Immunity
Generally not relevant	<p>a) magnetic fields</p> <p>1) continuous;</p> <p>2) transient;</p>

	<p>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.</p> <p>b) electric fields.</p> <p>Relevant only for special applications in measurements</p>
Conducted high-frequency phenomena	
Emission	Immunity
<p>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.</p> <p>a) induced voltages or currents</p> <p>1) continuous waves;</p> <p>2) modulated waves;</p> <p>3) discontinuous waves</p> <p>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.:</p> <ul style="list-style-type: none"> – common mode (also called asymmetrical mode) – differential mode (also called symmetrical mode) – unsymmetrical mode (combines both modes by using specific artificial test networks) <p><i>NOTE the unsymmetrical mode voltage is primarily measured at the mains network.</i></p>	<p>a) induced voltages or currents</p> <p>1) continuous waves;</p> <p>2) modulated waves;</p> <p>b) unidirectional transients ;</p> <p>c) oscillatory transients.</p> <p>Induced high frequency voltages or currents are generally relevant for electronic apparatus, except the simplest ones.</p> <p>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.</p> <p>The surge aspects should be assessed for apparatus which are connected to networks leaving the building or mains in general.</p>

<p><i>The common mode voltage (or current) is measured primarily for signal and control lines.</i></p> <p>Account should be taken of the following types of disturbance:</p> <p>a) narrowband continuous disturbance, b) broadband continuous disturbance; and c) broadband discontinuous disturbance</p>	
Radiated high-frequency field phenomena	
Emission	Immunity
<p>a) magnetic fields; b) electric fields; c) electromagnetic fields</p> <p>1) continuous waves; 2) modulated waves; 3) transients.</p> <p>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.</p> <p>Generally magnetic fields are considered up to 30MHz and electromagnetic fields above 30MHz up to 1000MHz.</p> <p>There may be a need to cover phenomena above 1000MHz for apparatus with fast microprocessors.</p>	<p>a) magnetic fields; b) electric fields; c) electromagnetic fields</p> <p>1) continuous waves; 2) modulated waves; 3) transients.</p> <p>In general, the radiated immunity to electromagnetic fields is relevant to all apparatus. Exclusions may include non-electronic apparatus.</p> <p>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).</p>
Electrostatic discharge phenomena (ESD)	
	Immunity

	<p>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.</p>
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ANNEX 5 – Transitional arrangements

Date of application (Article 14) :20 July 2007

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

**The interpretation below is provisional
and under scrutiny by the Commission's legal Service**

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

- For apparatus in the sense of the old EMC Directive 89/336 (i.e. excluding installations in the sense of this same old EMC Directive) which, before 20 July 2007, were subject to the Article 10(1) procedure of the old EMC Directive: only apparatus for which the manufacturer or his authorized representative has issued a Declaration of Conformity pursuant to the Article 10(1) procedure before 20 July 2007 can continue to be manufactured and placed on the market up to 20 July 2009.
- For apparatus in the sense of the old EMC Directive 89/336 (i.e. excluding installations the sense of this same old EMC Directive) which, before 20 July 2007, were subject to the Article 10(2) procedure of the old EMC Directive: only apparatus for which a technical report or a certificate has been obtained from a competent body pursuant to the Article 10(2) procedure before 20 July 2007 can continue to be manufactured and placed on the market up to 20 July 2009.
- Installations: installations are excluded from the scope of the transitional provisions laid down in Article 15 of 2004/108 as installations are not, as such, placed on the market and, according to its wording, Article 15 only applies to "equipment" which is "placed on the market". As a result, new installations put into service on or after 20 July 2007 will have to comply with the new EMC Directive 2004/108.

ANNEX 6 Examples of EC Declarations of Conformity

Example 1.

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



EC Declaration of Conformity

We, the undersigned,

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

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

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

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

<p>EU Harmonised Standards</p> <p>EN 55099:2009</p> <p>EN 55099:2010</p> <p>EN 55088:2008</p>

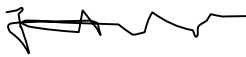
and therefore complies with the essential requirements and provisions of the EMC Directive.

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

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

The Technical documentation is kept at the following address:

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

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

Example 2.

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

Suppliers Declaration of Conformity (conform ISO 17050)

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

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



ANNEX 7 Acronyms and abbreviations

a.c.	Alternative current
CEN	European Committee for Standardisation
CENELEC	European Committee for Electrotechnical Standardization
CISPR	International Special Committee on Radio interference (Comité International Spécial des Perturbations Radioélectriques)
d.c.	Direct current
DoC	EC Declaration of Conformity
DIMM	Dual In-line Memory Module
ECANB	Association of Competent Bodies
EEA	European Economic Area
EMC	Electromagnetic Compatibility
EMCD.	Electromagnetic Compatibility Directive
ESD	Electrostatic discharge
ETSI	European Telecommunications Standards Institute
EU	European Union
IEC	International Electrotechnical Commission
IEV	International Electrotechnical Vocabulary
ISO	International Organization for Standardization
ITU	International Telecommunication Union
LED	Light emitting diode

MRA	Mutual Recognition Agreement
NB	Notified Body
OJEU	Official Journal of the European Union
R&TTE	Radio and Telecommunication Terminal Equipment
RF	Radio frequency
TGN	Technical_Guidance_Note
TR	Technical Report