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**GUIDELINES ON THE APPLICATION OF COUNCIL
DIRECTIVE 2004/108/EE ON THE APPROXIMATION OF THE
LAWS OF THE MEMBER STATES RELATING TO
ELECTROMAGNETIC COMPATIBILITY**

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INTRODUCTION

1. SCOPE

1.1. General

The EMC Directive applies to a vast range of equipment encompassing as broadly as possible all electrical and electronic appliances, systems and installations whether or not they are connected to the mains. The Directive does not impose any lower or upper limits on the apparatus as regards power output or selection of transmission frequencies. The Directive, therefore directly covers several sectors of electrical and electronic engineering, such as e.g. household appliances, consumer electronics, industrial manufacturing, information technology and telecommunications apparatus.

The decision flow-charts [1](#), [2](#), [3](#) and [4](#) are a practical tool in the analysis whether types of equipment are within or outside the scope of the EMC Directive and whether they should be considered as apparatus or fixed installations.

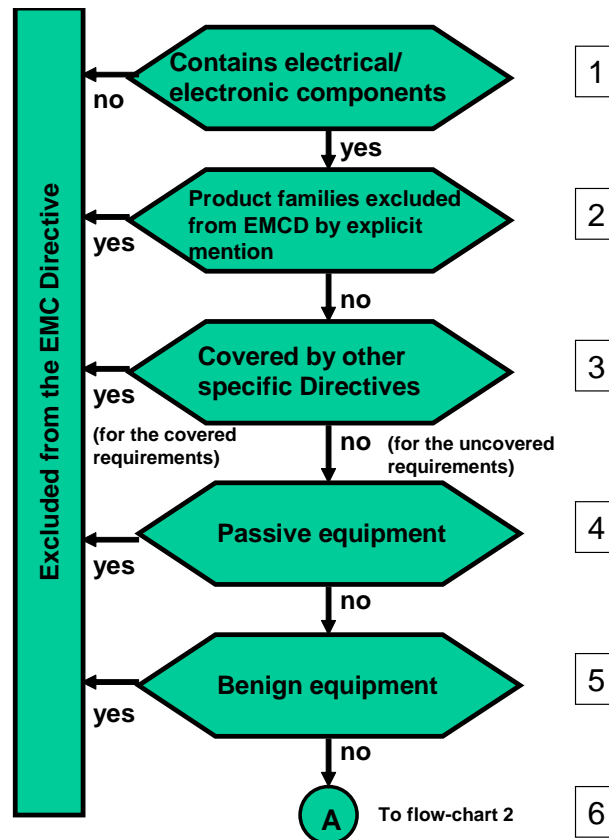


Figure 1: Flow chart 1 (i.e. Dealing with exclusions for equipment)

The successive steps and criteria of the decision [flow-chart 1](#) presented in Figure 1 are described hereafter, with references to the relevant chapters where more precise criteria and provisions are developed:

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

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- (2) To examine whether the product belongs to the product families which are explicitly quoted as exclusions in the EMC Directive in 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 passive equipment (section 1.1.4)
- (5) To apply article 1.3 whether the equipment may be considered as inherently benign in terms of electromagnetic compatibility. (section 1.1.5)

The manufacturer has to determine the classification of his equipment as apparatus or fixed installation. (Section 1.1.6) (Note: addressed in [flow chart 2](#))

The successive steps and criteria of the decision flow-chart link directly to the relevant chapters where more precise criteria and provisions are developed

1.1.1. Equipment without electrical and/or electronic parts

Equipment, which does not contain electrical and/or electronic parts or components, is not liable to generate electromagnetic disturbances and its normal operation is not affected by such disturbances. Hence, equipment without electrical and/or electronic parts or components is excluded from the scope of the EMC Directive.



1.1.2. Explicit exclusions from EMC Directive

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

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

1.1.2.1. Radio and Telecommunication Terminal equipment

Equipment covered by [Directive 1999/5/EC](#) of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity (i.e. so called "R&TTE Directive") is excluded from the EMC Directive (Article 1.2.(a) of the EMC Directive). The R&TTE Directive covers almost all radio and telecommunication terminal equipment, except broadcast receivers. Radio and telecommunication terminal equipment not covered by [Directive 1999/5/EC](#) are subject to the provisions of the EMC Directive. Typical examples of equipment not covered by the R&TTE Directive are transmitters operating below 9 kHz, transmitters intended for use in air-traffic-management systems within the meaning of article 1 of Council Directive 93/65/EEC.

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All Radio equipment that transmits measurement or test data is covered by the R&TTE Directive (1999/5/EC). However measurement equipment, which uses radio signals to measure the performance of an other equipment may only be used in specific circumstances and hence the effective use of the spectrum is normally not an issue for regulation. As a consequence, that measurement equipment should not be considered radio communication equipment and thus should not be covered by the R&TTE Directive. The provisions of the EMC Directive clearly stay applicable. Where measurement equipment is used in a set-up, which has the effect of transmitting radio signals, such use may require a national authorization from the spectrum regulator or may be forbidden without adequate spectrum protection measures.

An example of such measurement equipment (when used in a shielded enclosure) 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.

Note:

- 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 generates RF energy freely (not being ISM equipment operating on ISM designated frequency bands) licenses may be required in some countries or use may be totally forbidden outside shielded enclosures.*

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 Agency 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 as robust as 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 apparatus is available commercially (Article 1.2. (c) of the EMC Directive). This exclusion has been stipulated because of the specific nature of the activities of radio amateurs, which do not constitute any kind of commercial transaction. 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 Directive.

Kits of components to be assembled by radio amateurs and commercial equipment modified by and for the use of radio amateurs are not regarded as commercially available equipment.

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1.1.3. Equipment covered by other specific Community Directives

If the EMC requirements for equipment are wholly or partly laid down more specifically by other Community 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 directives according to article 1.4 of the EMC Directive.

Non-restrictive list of equipment totally excluded (emission and immunity) from the EMC Directive:

- Motor vehicles: covered by specific Directive 72/245/EEC¹

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 electromagnetic compatibility of vehicles. New (vehicle or component) type approvals for EMC must comply with [2004/104/EC](#) from 1st July 2006.

Components sold as aftermarket equipment and intended for the installation in motor vehicles need no type approval under the automotive 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, a 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. 3 December 2004) of the automotive 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.

- Active implantable medical devices: covered by specific [Directive 90/385/EEC](#)²
- Medical devices: covered by specific Directive 93/42/EEC³
- In vitro Diagnostic Medical Devices: covered by specific Directive 98/79/EC⁴
- Marine equipment: if covered by the specific Directive 96/98/EC⁵
- Agricultural and forestry tractors covered by Directive 75/322/EEC, as latest amended by Directive 2000/2/EC⁶

¹ OJ No L 152, 6.7.1972, as last amended by Directive 2004/104/EC, OJ No L 337, 13.11.2004

² 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.

³ OJ No L 169, 12.7.1993, amended by Directive 93/68/EEC, OJ No L 220, 30.8.1993.

⁴ OJ N° L 331, 07.12.1998.

⁵ OJ N° L 46, 20.12.96

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- Two or three-wheel motor vehicles, covered by Directive 97/24/EC⁷

Non-restrictive list of equipment excluded for immunity only from the EMC Directive
(For this equipment the EMC Directive covers the emission requirements):

- Measuring instruments : immunity covered by specific Directive 2004/22/EC⁸
- Non-automatic weighing instruments: immunity covered by Annex I-8(2) of Directive 90/384/EEC⁹.

1.1.4. *Passive equipment*

Electromagnetically passive (passive-EM) equipment considered in isolation is excluded from the scope of the EMC Directive, since it is considered not liable to cause or be susceptible to disturbances.

Equipment is considered to be passive-EM equipment if, when used as intended (without internal protection measures such as filtering or shielding) and without any user intervention, it does not create or produce any switching or oscillation of current or voltage and is not affected by electromagnetic disturbances.

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

- Cables and cabling systems¹⁰, cables accessories, considered separately
- Equipment containing only resistive loads without any automatic switching device; e.g. simple domestic heaters with no controls, thermostat, or fan.
- Batteries and accumulators.
- Headphones, loudspeakers without amplification system.

1.1.5. *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.

⁶ OJ N° L 147, 9.6.1975, amended by Directive 82/890/EEC, OJ No L 378, 31.12.1982, and by Directive 2000/2/EC, OJ L 021, 26.01.2000

⁷ OJ N° L226, 18.8.1997

⁸ OJ No L 135, 30.4.2004.

⁹ OJ No L 189, 20.7.1990, amended by Directive 93/68/EEC, OJ No L 220, 30.8.1993.

¹⁰ Manufacturers should be aware that the characteristics and installation of such equipment can have a very significant impact upon the EMC performance of the systems into which they are installed.

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Equipment is considered benign in terms of electromagnetic compatibility if its physical characteristics are such that it is incapable of generating or contributing to electromagnetic emissions which exceed a level allowing radio and telecommunications equipment and other equipment to operate as intended, and, it will operate without unacceptable degradation in the presence of the electromagnetic disturbance normally consequent upon its intended use. Hence, both conditions shall be met to classify the equipment as being benign.

The following equipment can be considered as benign equipment, based upon both of the following criteria, which have also been taken in account into the development of EMC standards:

- The emission level is by the inherent nature of the physical characteristics and mode of operation (without internal protection measures such as filtering or shielding) far below the most stringent limits of the relevant EMC standards.
- With regard to immunity, practice shows that such apparatus does function satisfactorily by the inherent nature of its physical characteristics without additional measures when used as instructed by the manufacturer in the intended electromagnetic environment.

The Following equipment is considered as benign:

- (1) Protection equipment which only produce transitory disturbances of very short duration (e.g. $\ll 1$ s) during the clearing of a short-circuit fault or an abnormal situation in a circuit and which do not include electronic components which are EM active. Illustrative examples:
 - fuses.
 - circuit breakers without electronic parts or components which are EM active
- (2) Manual switches: appliances switches, home and building switches, etc. which do not contain any components which are EM active.
- (3) High voltage equipment in which possible sources of disturbances are due only to localised insulation defects 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 (e.g. partial discharge tests), and which do not include electronic components which are EM active.
Illustrative examples:
 - High voltage inductors.
 - High voltage transformers.
- (4) Other illustrative examples:
 - Capacitors (e.g. power factor correction capacitors).
 - Induction motors.
 - Quartz wrist watches (without additional functions, e.g. radio receivers).

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- Filament lamps (bulbs).
- Passive antennas used for TV and Radio broadcast reception

1.1.6. 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 manufacturer determines the correct category of his equipment.

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

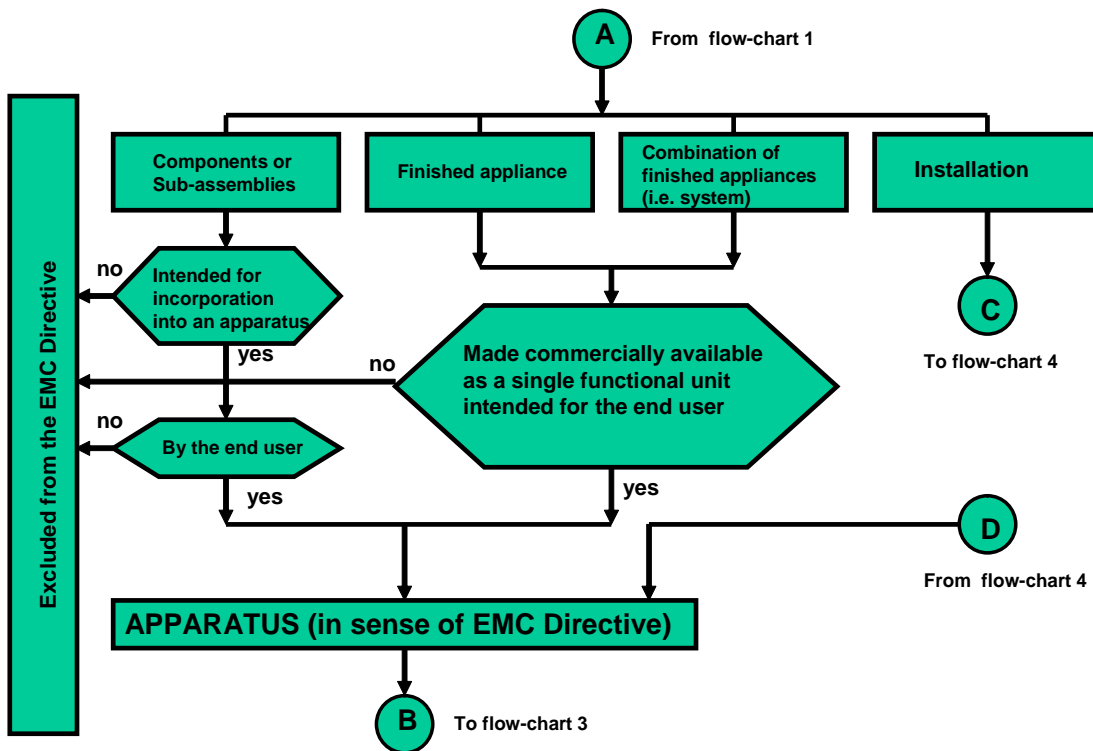


Figure 2: Flow chart 2 (i.e. dealing with the scope for apparatus)

For guidance on the applicability of the EMC Directive for components, sub-assemblies, finished appliances and systems the reader is referred to section 1.2 which defines the scope for apparatus. Also mobile installations, which are defined as a combination of apparatus (and where applicable other devices) intended to be moved and operated in a range of locations (e.g. the outside broadcast vehicle of a TV or radio station), are deemed to be apparatus.

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For guidance on the applicability of the EMC Directive for fixed installations and apparatus intended for incorporation into fixed installation the reader is referred to section 2.3 which defines the scope for fixed installations. Networks and large machines may be treated in the same way as fixed installations with respect to the application of the EMC Directive. As large machines may often also be considered as apparatus (unless they are not commercially available) the manufacturer of such large machines has the freedom to treat them as apparatus or as fixed installations with regard to the application of the directive.

1.2. Defining the scope for apparatus

Article 1 (b) of the EMC Directive defines "Apparatus" ("Apparatus" means any [finished appliance](#), or [combination thereof](#) made commercially available 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 certain conditions.

Note: IEC's International Electro technical Vocabulary - IEV 702-09-03 or 714-01-30 - defines "functional unit" as follows: "An entity of hardware or software, or both together, capable of accomplishing a specified purpose"

One of the conditions to be considered as an apparatus in the sense of the EMC Directive is that it is liable to cause electromagnetic disturbances, or its normal operation may be affected by such disturbances. If this condition is not fulfilled the apparatus may be considered as being [benign in terms of electromagnetic compatibility](#), and hence, the EMC Directive does not apply. As benign equipment has been addressed in section 1.1.5 it will not be further explored in the section on apparatus.

Flow-chart 3 summarizes the provisions applicable to apparatus.

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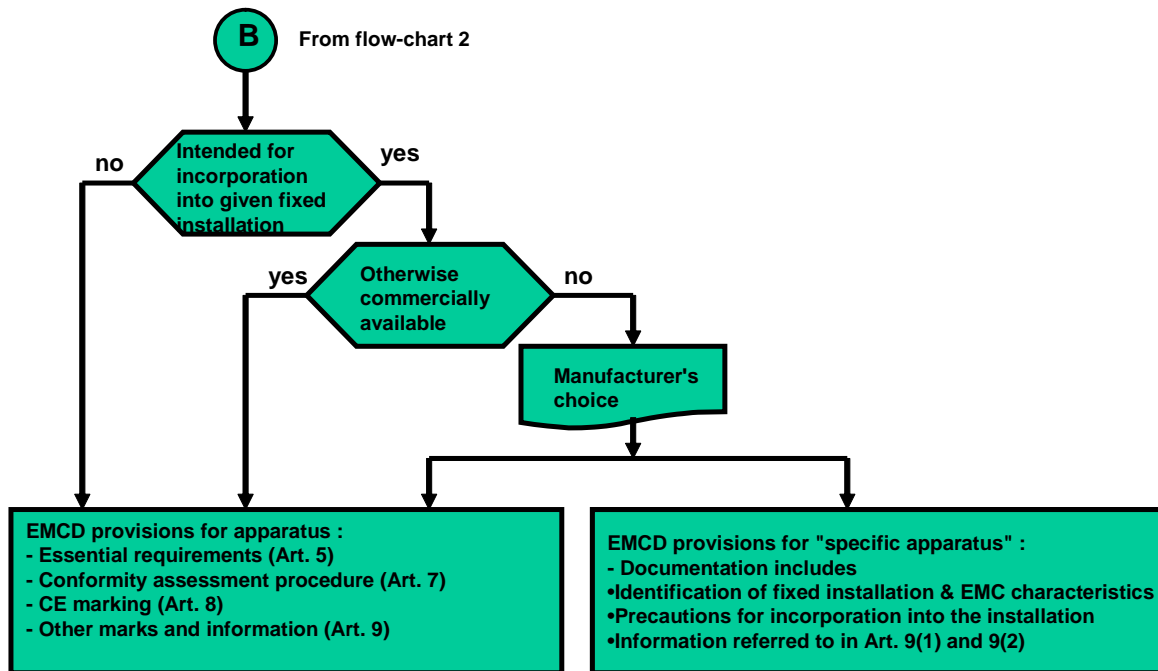


Figure 3: Flow chart 3 (i.e. dealing with provisions applicable to apparatus):

1.2.1. Finished appliances

A finished appliance is any device or unit that delivers a function and has its own enclosure, intended for final use, and - if applicable - ports and connections intended for the end users.

The manufacturer has to determine whether the finished appliance is made **commercially available as a single functional unit intended for the end user** or whether the finished appliance is intended exclusively for an industrial assembly operation for incorporation into other apparatus.

Placing on the market, with a view to distribution and/or use is further explained in the ["Guide to the implementation of directives based on the New Approach and Global Approach", section 2.3](#). All provisions of the EMC Directive, as defined for apparatus, apply. Generally this implies that the finished appliance is available for wide application (i.e. several countries, clients).

Finished appliances which are designed, manufactured and intended for incorporation in apparatus only by manufacturers are not considered placed on the market for distribution and/or final use. Consequently the EMC directive is not applicable to them. The manufacturer should however provide with such finished appliances 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 indicate EMC aspects to be considered by the manufacturer

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of the final apparatus to help him to solve foreseeable EMC problems within the final apparatus. None of the other provisions of the EMC apply. The manufacturer can nevertheless choose to consider this product as an apparatus. If he decides so, he will have to apply all provisions of the EMCD Directive related to apparatus.

1.2.2. *Combination of finished appliances (systems)*

According the definition in article 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, 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 systems described above should be aware that combining two or more CE marked finished appliances may not automatically produce a system which meets the requirements of the relevant standard. e.g.: a combination of CE marked PLC's (Programmable Logic Controllers) and motor drives within a machine tool put together to be placed on the market as a system may fail the requirements, whereas a audio system composed of a separately CE marked amplifier, tuner, DVD player, wired up correctly is quite likely to maintain its compliance.

In normal usage, the word "system" is sometimes used with a different meaning 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", and where the finished appliances were not intended to be placed together on the market as a single functional unit. The manufacturer of each constituent finished appliance within the system has already fully applied the Directive, and particularly taken into account the expected electromagnetic environment and the intended use. Hence, for such a so-called "system", the EMC Directive has already its effect and does not further apply.

1.2.3. *Components/Sub-assemblies*

By opposition to finished appliances, components /sub-assemblies do not in general have a proper enclosure intended for their final use.

1.2.3.1. *Included components/sub-assemblies*

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

Illustrative examples:

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- (1) plug-in cards for computer systems, micro-processor cards, central processing unit cards/mother boards, electronic mail cards, telecommunication cards, etc.;
- (2) programmable logic controllers;
- (3) lift controls;
- (4) electric motors (except for induction motors, see chapter 5.4);
- (5) computer disk drives;
- (6) power supply units (PSU), where they take the form of autonomous equipment;
- (7) electronic temperature controls;

Components or sub-assemblies of this type are considered equivalent to apparatus and have to comply with the provisions of the EMC Directive applicable to apparatus.

1.2.3.2. Excluded components/sub-assemblies

Components intended for incorporation by manufacturers or assemblers are not considered to be "apparatus". The latter has to optimize the EMC performance in order to comply with the EMC requirements (for example by tuning, by introducing shielding, by appropriate routing of cables, i.e. by exercising any EMC competencies).

The manufacturer should provide 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 foreseeable EMC problems within the final apparatus.

Although components and sub-assemblies always fulfil a function within the apparatus in which they are incorporated, they are not always in themselves a functional unit intended for the end user. For example, a transistor, mounted on a printed circuit board with the function of amplification fulfils a function but it is only the complete card which accomplishes the purpose as specified by the manufacturer (e.g. the amplification of a given signal) and which fulfils the expectations of the end-user.

Another example is a cathode-ray tube which performs a function within the visual display unit in which it is installed, but only the complete monitor supplies the user with the function sought, i.e. that of the visual display screen. The transistor and the cathode-ray tube are not functional units and cannot, therefore, be regarded as "apparatus" but are components, whereas the printed circuit-board, and the monitor are apparatus.

Similar examples of components which themselves are not functional units:

- (a) electrical or electronic components forming part of electrical or electronic circuits;
 - resistors, capacitors, coils;

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- diodes, transistors, thyristors, triacs, etc.;
- integrated circuits;
- (b) All or nothing relays
- (c) Plugs, sockets, terminal blocks, etc.;
- (d) LEDs,
- (e) Simple mechanical thermostats

These types of components are not considered as apparatus within the meaning of the EMC Directive.

1.2.4. *Mobile installations*

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

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



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." Networks and large machines may be treated in the same way as fixed installations with respect to the application of the EMC Directive.

Examples of fixed installations:

airport luggage transport system, traffic light installation, airport runway lighting installation, automatic warehouse transport system, skating hall ice rink machinery installation , storm surge barrier installation (with the control room etc), flower auction installation, ship elevator, process control room, large automatic water pump installation, fire detection and prevention system, radio telescope installation, telecommunication networks ,high voltage substations, wind turbines stations, air conditioning installations, water pumping stations...

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

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General information on good engineering practices within the context of installations is available in several EMC handbooks, EMC courses and technical reports. For example the IEC technical reports published in the IEC 61000-5-x series deal with installation and mitigation guidelines for EMC (e.g. [IEC TR61000-5-1](#) provides general considerations, [IEC TR61000-5-2](#) deals with earthing and cabling ...)

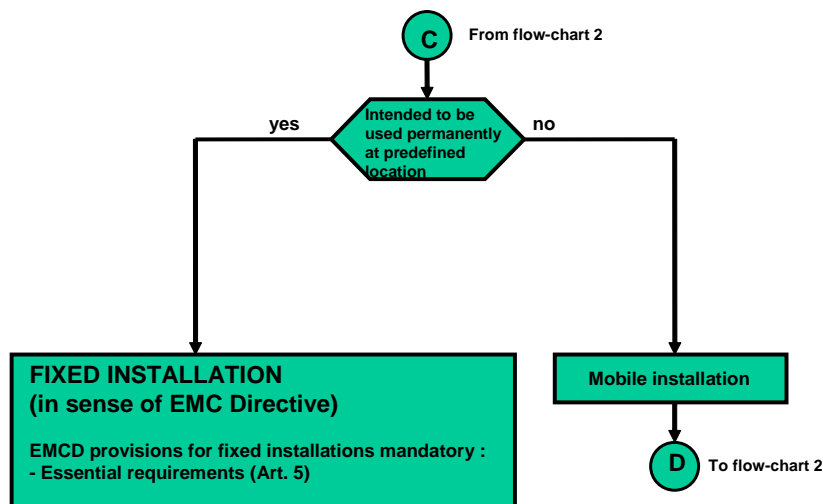


Figure 4: Flow chart 4 (i.e. dealing with installations)

1.3.2. Specific apparatus

The general rule is that all apparatus, as defined in the EMC directive, are subject to all the relevant provisions of this directive for apparatus. This applies also fully to apparatus that will be incorporated into fixed installations.

However the EMC directive has foreseen a possibility of exception for some [apparatus intended for incorporation in a given fixed installation](#) and which are otherwise not commercially available.

Generally these apparatus fully comply EMC requirement only if they are well installed, and their EMC performances depend upon the complete environment of the installation (e.g. other apparatuses to which they are connected through cables and overhead lines, disposition of the cables and overhead lines, etc.). These specific products are not “EMC finished products” until their final installation and should not bear CE marking under EMC directive. In this context, the concept of “single functional unit” is achieved when the EMC characteristics of the product in its environment, are known.

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1.4. Application of the Directive to Used, Second-hand and repaired apparatus and to spare parts

1.4.1. Used & Second-hand Apparatus

- **Used Apparatus:** an apparatus, which has previously been placed on the EU market, and at the time of placing on the market, met the requirements of the EMC Directive or of the national legislation in force. These products circulate freely on the EU market, based on the Articles 28 to 30 of the EC treaty.
- If used apparatus is transferred from the original user to another end-user without modification and is not placed on the EU market then it is termed **second-hand** and is not subject to the provisions of the Directive.
- If used apparatus, which has been modified during its operational life, is placed on the EU market then the procedure will depend on the extent to which those modifications affect the EMC performance of the apparatus. The correct choice of this procedure is under the full responsibility of the person placing the modified apparatus on the market.
- If the apparatus has been maintained and also modified, but not to any significant degree in terms of EMC, then it is termed **reconditioned** and is not subject to the provisions of the directive.
- If the apparatus has been modified more substantially then it will be referred to as **Upgraded** Apparatus and the provisions of the EMC directive apply. The manufacturer may either make a completely new assessment or assess to what extent these modifications affect the EMC performance of the originally compliant apparatus. Reference may be made to the chapter in the guide on [EMC Assessment](#); consideration must be given where components that this guide has defined as active have been substituted or upgraded whereas the substitution of components defined as [Passive](#) is generally unlikely to affect the EMC performance.
- If the manufacturer has carried out an EMC Assessment that shows the Upgraded Apparatus has not changed its compliant EMC performance from when it was originally placed on the market then the requirement of the EMC Directive have been satisfied.

Note: To meet this condition the manufacturer will need to start the EMC Assessment with the knowledge of how the apparatus was originally placed on the market. The fact that the apparatus carries a CE Mark does not necessarily imply that it was originally declared as meeting the requirements of the EMC Directive. There is no requirement for a manufacturer to provide a copy of the original Declaration of Conformity to a third party other than to a national enforcement agency.

1.4.2. Repairs and Spare Parts

Repaired apparatus are apparatus whose functionality has been restored following a defect without adding new features or any other modification. This operation does normally not affect the EMC characteristics of the original apparatus. Hence, from the EMC point of view, the repaired apparatus is not different from the original product. The EMC Directive does not apply.

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A spare part: This is any item intended to replace a defective or worn out item of apparatus previously placed and put into service on the EEA market. A typical repair operation would be replacement by a spare part. If the manufacturer of the original spare part offers a new, different one in its place (due to technical progress, discontinued production of the old part, etc.), and it is used for the repair, the repaired apparatus does not need to be brought into conformity again with the EMC Directive, if such parts do not produce an apparatus with worse EMC performance apparatus as compared with the “original”. Whenever possible manufacturers of such parts should indicate their general intended use and warn of potential EMC behaviour, to allow corrective EMC action if required.

As spare parts generally are 'components' or 'sub-assemblies', the provisions of the EMC Directive with regard to 'components' or 'sub-assemblies' are applicable. Information on the application of the EMC Directive for components/sub-assemblies is given in chapter 1.2.3

2. ESSENTIAL REQUIREMENTS

2.1.General concept

The Directive sets out mandatory “essential requirements” for all equipment within the scope of the Directive, formulated in a general manner. Those essential requirements define the results to be attained, but do not specify the detailed technical requirements. It allows also that, for instance, the materials and product design may be adapted to technological progress. The manufacturer has the freedom to choose the appropriate technical solutions to meet the requirements, as long as the final product meets the result as defined in the essential requirements.

Essential requirements lay down the necessary elements for protecting public interest.

Note: Essential requirements need to be complied with in all cases whether the manufacturer has decided to carry out a detailed [EMC assessment](#) on his apparatus or to [apply the harmonised standards](#)

Complying with the essential requirements is mandatory. All manufacturers are obliged to meet these legally-binding requirements for each product. Only products complying may be placed on the EU market and the law does not distinguish between EU manufacturers and manufacturers from other countries.

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

The objective of the EMC Directive is to minimize the EMC risks of the equipment for the user and its environment, but not to completely out rule all risks, which would be unproportional to the objectives pursued.

Having presumption of conformity does not necessarily imply an interference probability of ‘zero’ at all locations close to the intended environment of a product.

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Accepting a (very small but) non-zero probability of interference problems to occur implies that the number of these problems will be limited so that they can be handled by the national enforcement authorities. For these interference cases, [interference complaints procedures](#) can be used to deal with them in an transparent and ‘harmonised’ way, without hindering the marketing of products.

The essential requirements are split into 2 parts:

- (1) “[Protection requirements](#)” for all equipment, and in addition,
- (2) “[Specific requirements](#)” for fixed installations.

Furthermore the protection requirements for equipment cover different EMC phenomena for both emission and immunity aspects.

2.2. Application of the essential protection requirements for equipment.

EMC PROTECTION REQUIREMENTS FOR ALL EQUIPMENT

Equipment shall be so designed and manufactured, having regard to the state of the art, as to ensure that:

- (1) the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended (“Emission”);
- (2) it has a level of immunity to the electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use. (“Immunity”).

Notes:

1. *Several Directives may be applicable to a given product at the same time, since essential requirements of different Directives need to be applied simultaneously in order to cover all relevant public interests.*
2. *Ad 1. “State of the art” is generally recognised by the public authority as the accepted status at a given point of time. It is not a legal definition; but a notion. This is an important concept and requires certain explanations. The concept takes account of all the material circumstances affecting a product, whether technical, economic, social or environmental. « developed state of technical possibilities, at a given time, relating to products, processes and services, as based on scientific knowledge, technology and experience». Good engineering practice comprises suitable technical behaviour, available to the respective professional body and corresponding to the state of the art at that particular time. Good engineering practice is generally the expression of a technical custom. It is therefore attached to this source of the law. Only proven uses form part of good engineering practice. This assumes «long-standing, constant, well-known and general use». The technical uses which form part of good engineering practice include all the theoretical and practical knowledge which is currently applied in industrial companies. The majority of*

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these uses are passed on to junior engineers and technicians by the technical establishments and during their apprenticeships in the company. These uses include, for example, the methods of graphic representation of apparatus parts, knowledge of EMC design solutions (enclosing of parts, assembly techniques, choices of materials, definition of the product, etc.).

3. *Ad 1. "Operate as intended" means using that equipment concerned in accordance with the manufacturer's/operator's instructions and other legal provisions and using it in the electromagnetic environment determined by the manufacturer.*
4. *Ad 2. "Unacceptable degradation" means here without degradation of quality of performance below an acceptable performance criteria level. The manufacturer's EMC assessment of the apparatus, needs to establish these performance criteria and will determine the necessary action to be taken. This is very much product dependent, For example, this means that a slight distortion of a display could be accepted whereas changing of any information could not be tolerated.*
5. *Ad 2. "In its intended use" to work so as to allow its unhindered operation, taking into account the levels of disturbance in the electromagnetic environment intended for its use.*

The Directive does not further detail the protection requirements but it is clear that the following applies:

- (1) **For Emission aspects:** The aim of the protection requirement is to ensure that the functioning of all other electrical and electronic appliances (in particular radio reception), installations (in particular power supply and telecommunication networks) or systems is not degraded by an electromagnetic phenomenon produced by a given equipment when used as intended. The maximum electromagnetic disturbance generated by the equipment shall be such as not to hinder the use of practically all other electronic and electric apparatus and fixed installations, with particular emphasis on the protection of radio communications, of electrical supply and of telecommunication networks. In certain cases a minimum distance between source and victim can be assumed.
- (2) **For Immunity aspects:** The aim of the protection requirement here, too, is the function of the electrical and electronic appliance, equipment and installation containing electrical and/or electronic components and not the quality of such apparatus.
For instance, an electronic low cost credit card calculator is not expected to be immune to all electromagnetic disturbances outside the ones for which it has been designed when used as intended in its determined electromagnetic environment. Practice indicates that, normally, users would not buy more expensive calculators simply to ensure that they will never be affected by electromagnetic disturbances.
Apparatus should have an adequate level of electromagnetic immunity in the usual electromagnetic environment where the apparatus is intended to work so as to allow its unhindered operation, taking also into account the levels of

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disturbance generated by apparatus in that environment under the conditions that these apparatus fulfil the requirements applicable to them.

3. RULES FOR APPARATUS

This chapter deals with all the rules of the EMC directive for apparatus.

The [EMC assessment](#) is the fundamental basis for verifying that an apparatus meets the essential requirements. It may be performed in practice by either:

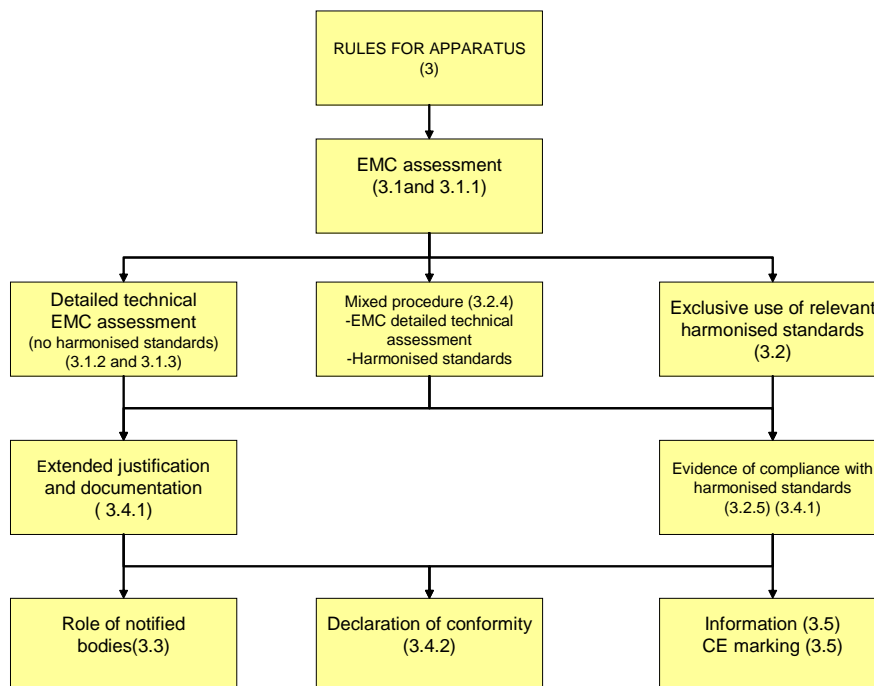
- [A detailed technical EMC assessment](#)
- [The exclusive use of relevant harmonised EMC standards](#)
- [A mixed procedure](#)

In the next step, a documentation has to be prepared by the manufacturer in a [technical documentation](#) comprising evidence of compliance with harmonised standards, when this route is chosen or/and a much more detailed documentation and complete justification, when the detailed EMC technical assessment has to be made, in the case where harmonised standards are not followed.

Finally the [declaration of conformity](#), the needed information and [CE marking](#) have to be established by the manufacturer.

When choosing to use the conformity assessment according to article 7 and annex 3 of the directive, the manufacturer involves a [Notified Body](#).

The following diagram illustrated the structure of the chapter 3.



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3.1. EMC Assessment

3.1.1. General Concept

According to Article 7 and Annex I of the Directive the manufacturer shall perform an electromagnetic compatibility (EMC) assessment of the apparatus, based on the relevant phenomena, with a view to meeting all relevant essential requirements. This assessment shall be performed before the apparatus is placed on the market. The Directive does not require any mandatory intervention from any third party, including a Notified Body, when carrying out the assessment.

The manufacturer of apparatus is fully responsible for the appropriate choice of the assessment carried out. However, the manufacturers should consider the recommendations given in this guide.

Notes:

1. *It is not necessary to carry out an EMC assessment of apparatus intended for incorporation into defined fixed installations, and otherwise not commercially available, in isolation from the fixed installation into which it is to be incorporated.*
2. *Where the EMC assessment establishes that the apparatus concerned is inherently benign in terms of electromagnetic compatibility (both for emission and immunity) according to Article 1.3, the EMC Directive will no further apply and no further actions are necessary. It may however be wise to document the results of the assessment and its conclusion should there be any questioning 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 essential requirements 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 predefined methodology. This methodology can be:

- a) a detailed technical EMC assessment, when the manufacturer applies his own methodology
- b) A methodology using exclusively harmonised standards developed by the European standardisation Organisations and published on the OJEU. As the standards are recognised as providing an adequate methodology to demonstrate compliance, application of the standards is equivalent of performing an assessment.
- c) Mixed assessment, combining the two previous methods. The Directive allows indeed a mixture of the detailed technical EMC assessment and of the application of harmonised standards, for example one could use the harmonised standards to cover emission phenomena and the assessment procedure for immunity aspects.

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The harmonised standards provide a recognised methodology to demonstrate compliance. Application of the standard is thus equivalent to performing an assessment. If a manufacturer applies his own methodology, he will have to substantiate that the steps taken are adequate to ensure compliance with the Directive, and show his methodology is valid. It is thus expected that the technical documentation will be much more detailed in such a case.

Therefore, although the detailed technical EMC assessment procedure can be used for any apparatus it is evident that for a large majority of apparatus the route of compliance according to harmonised standards will be used instead of the detailed EMC assessment procedure. The areas of application of the detailed technical EMC assessment, or a mixture of it with the use of harmonised standards, will probably encompass:

- Where there are no or no complete harmonised standards really applicable to the product, although generic harmonised standards may be applicable in most 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 or “allowed by” the harmonised standards;
- Where the manufacturer may want to apply any other standards or specifications not harmonised in the context of EMC
- 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 manufacturer may ask a third party to perform the EMC assessment for him or help him with part of it, but he is and remains fully responsible for his apparatus.

The manufacturer is, therefore, fully responsible for defining what parts of the assessment he wants to subcontract to the third party or to a Notified Body.

The conformity assessment is and stays always only the responsibility of the manufacturer, even if help is asked from a Notified Body or any other third party!

Note: The specific services and operation of Notified Bodies is described [in section.3.3](#)

Where a manufacturer assembles a final product using components from other manufacturers, the manufacturer must retain the overall control for the product and ensure that he receives all the information that is necessary to fulfil his responsibilities for components from other manufacturers.

The manufacturer must take all measures necessary in order that the manufacturing process ensures compliance of the manufactured products with the [technical documentation](#). (link to 3.4.1)

If an apparatus is modified after the initial assessment, the manufacturer shall make sure that the modification does not affect the initial assessment. If that is the case the apparatus needs to be reassessed and the documentation adapted.

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3.1.2. Detailed technical EMC assessment.

A product may be manufactured directly on the basis of the essential requirements, without direct reference to harmonised standards, but the manufacturer will have to demonstrate clearly compliance. This is very important for it guarantees the ground for technical development, crucial when manufacturers of new or innovative products for which standards do not exist, or cannot be used, want to assess their product according to essential requirements.

In selecting the most appropriate solutions, the manufacturer should apply the following principles in the following order:

- (1) eliminate or reduce EMC risks as far as possible (inherently EMC safe design and construction);
- (2) where appropriate and necessary take adequate protection measures, in relation to risks that can not be eliminated;
- (3) inform users of any residual risks due to shortcomings of the protection methods adopted.

The selection of the kind of assessment to be applied to a particular apparatus depends on several factors, such as:

- Nature of the product (product characteristics);
- Actual intended use;
- Types of disturbances created by or affecting the apparatus;
- Location of use;
- Environmental conditions;
- Required reliability and behaviour;
- Economic constraints;

It is however the intention of the Directive to clearly require from 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 EMC assessment shall follow a convincing technical methodology to ensure that the prescriptions of the directive are met.

The detailed technical EMC assessment may encompass but is not limited to items such as:

- **Description and definition of the product** operating conditions and its intended purpose. This should also cover notion of the power supply voltage and frequency aspects relevant to the product.
- **Specification, descriptions and classification of the environments** in which the apparatus will be used. This may cover also aspects of e.g. (large) movable products

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which must have emission and immunity characteristics appropriate for several environments. This selection is the responsibility of the manufacturer concerned (based on his experience). In all cases, knowledge of the electromagnetic environment and awareness of the statistical aspects involved will be helpful.

- Clear specification of relevant sources and effects of the **electromagnetic phenomena** covered and compatibility levels applied;
- Specification of **product performance criteria**. These should be set taking into account of what the users may reasonably expect;
- If **testing** is performed it shall be done against the relevant phenomena of the apparatus and should be based on a appropriate test plan, describing 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. guarantee with a high degree of certainty the conformity of the apparatus with the essential protection requirements:
- Test levels with regard to the immunity of the equipment_ Limits adopted for emission, etc.;
- Reference to available documents such as any (harmonised) standards, recommendations;
- Indication of any deviations made to available reference documents. These deviations may concern the phenomena considered, tests methods, test facilities or test levels, etc.;
- EMC Design considerations and/or calculation results;
- Statistical evaluations, theoretical studies or other examinations carried out, presenting background theory, arguments, results and conclusion. This may include information on the levels of occurrence and statistical distribution of the disturbances;
- Description on how components are selected;
- Information on shielding, cable screening and routing, filters, ferrites etc;
- Any description of the solutions adopted in order to comply with the essential requirements;
- Any specification of general or specific requirements taken to limit emission of disturbances;
- Assess 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.
- Assess 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.

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- Worst case selection criteria for series of products with similarities;

Notes:

1. *As a detailed technical EMC assessment will most likely include testing, it is evident that the harmonised standards are a good tool to provide any background on testing aspect that the manufacturer wishes to use.*
2. *Draft Harmonised standards may also provide some adequate 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 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 caution.*
3. *Standards relating to the EMC field 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 the above indicated 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.*

3.1.3. *Selecting the electromagnetic phenomena to be assessed*

This section is essentially relevant in conjunction with the use of the method of the detailed [technical assessment](#)

When the assessment uses exclusively relevant harmonised standards (link to 3.2), this selection is made in those applied standards.

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

Although the Directive does not specify a frequency range, it is general practice to take account of the range of frequency encompassed in the EMC assessment to be 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 disturbance phenomena: the frequency range to take into account is usually 9 kHz to 30 MHz) or as for some products, electromagnetic phenomena are inherently limited in frequency range by the principle of construction or the physical nature of the product.

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

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

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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 equipment in practice will experience disturbance levels the severity of which is above those specified as characteristic of the product. 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 products.

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 products 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 equipment are complex due to the different number, nature and interaction of interference sources that are active within the equipment.

It is thus important that the detailed technical EMC assessment takes account of the EM environment in which the apparatus needs to function correctly and a correct selection of the relevant phenomena to be assessed has to be performed in order to guarantee that the apparatus is in conformity with the essential protection requirements.

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 equipment 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 is obvious 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
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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 products 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 products 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, most apparatus are normally not disturbed by voltage fluctuations. However, this phenomenon may be relevant for equipment 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 equipment. If the principle of the apparatus requires or involves a particular sensitivity to such phenomena, this has to be indicated in the user documentation.</p> <p>e) voltage unbalance;</p> <p>Only applicable in special cases for three phase equipment</p> <p>f) power frequency variations of the mains supply</p> <p>This may apply to equipment intended to be installed at locations where the power frequency has large variations (for example equipment connected to an emergency power supply).</p> <p>g) induced low frequency voltages</p> <p>For sensitive low level measuring instruments;</p>

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	<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 products which are susceptible to magnetic fields (for example Hall effect devices, CRT and special products to be installed in high magnetic field environments). If equipment 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 very special applications in measurements</p>
Conducted high-frequency phenomena	
Emission	Immunity
<p>Generally relevant for most electronic and for many electrical products. Exceptions may occur for products 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> <p>– common mode (also called asymmetrical mode)</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 most electronic apparatus, except very simple ones.</p> <p>In general, fast transient aspects should be assessed for products 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 products which are connected to networks leaving the building or mains in general.</p>

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<p>– differential mode (also called symmetrical mode)</p> <p>– unsymmetrical mode</p> <p>NOTE the unsymmetrical mode voltage is primarily measured at the mains network. The common mode voltage (or current) is measured primarily for signal and control lines.</p> <p>Account should be taken of the following types of disturbance:</p> <p>a) narrowband continuous disturbance,</p> <p>b) broadband continuous disturbance; and</p> <p>c) broadband discontinuous disturbance</p>	<p>leaving the building or mains in general.</p>
<p>Radiated high-frequency field phenomena</p>	
<p>Emission</p>	<p>Immunity</p>
<p>a) magnetic fields;</p> <p>b) electric fields;</p> <p>c) electromagnetic fields</p> <p>1) continuous waves;</p> <p>2) modulated waves;</p> <p>3) transients.</p> <p>Generally relevant for most electronic and for many electrical products. Exceptions may occur for products 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 equipment with fast microprocessors.</p>	<p>a) magnetic fields;</p> <p>b) electric fields;</p> <p>c) electromagnetic fields</p> <p>1) continuous waves;</p> <p>2) modulated waves;</p> <p>3) transients.</p> <p>In general, the radiated immunity phenomenon is relevant to all products. Exclusions may include non-electronic equipment.</p> <p>Pulse magnetic fields. This test is mainly applicable to products to be installed in electrical plants (for example telecontrol centres in close proximity to switchgear).</p>

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Electrostatic discharge phenomena (ESD)	
	Immunity
	<p>In general, electrostatic discharge aspects are applicable to all equipment which is used in an environment where electrostatic discharges may occur. Direct and indirect discharges should be taken into account. Exclusions may include equipment limited for use in ESD-controlled environmental conditions and non-electronic products.</p>

Table 1: List of examples of electromagnetic phenomena

3.1.4. The “Worst Case” approach

Where apparatus (or system) can take different configurations, the 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 should be sufficient to perform an assessment on the basis of the configuration most likely to cause maximum disturbance and the configuration most susceptible to disturbance. This does not impose to the manufacturer to make a fully exhaustive research on the worst case, which would be disproportionate.

Note: The Directive obliges the manufacturer to take account of foreseeable configurations. The manufacturer is required to foresee only “reasonable” situations, i.e. based on logic, rational usage and common sense. This is more a quality judgement than a “mathematical” one.

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 originate from a series that all have similar characteristics such that it would be an overkill to have all apparatus separately assessed/tested. It also applies to apparatus that may have itself different configurations by merely adding devices or functions to it:

- Computer with external displays, CD-ROM devices, etc.
- Routing of cables between several apparatus,
- Apparatus of the same type with different power outputs where the source of interference or immunity is independent from the power output.

It is not necessary to assess/test all configurations but sufficient to perform an assessment on the basis of the configuration most likely to cause maximum disturbance (emission) and the configuration most susceptible to disturbance (immunity).

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Procedure:

- (1) Identify the worst case type(s) in respect to the EMC characteristics;
- (2) Perform an EMC assessment or test according to the harmonised standards the worst case type(s); (Cover both emission & immunity phenomena!);
- (3) Declare the type(s) representative for the whole series.
- (4) Document the selection of the worst case(s).
- (5) Indicate in instruction the means to reduce EMC problems.

The manufacturer is responsible for identifying the possible configurations and the choice of the worst cases. He may however ask help from a Notified Body or any other party in helping to make the selection!

Notes:

1. *If the worst case selection for immunity and emission aspects is different, then 2 different cases shall be assessed at least;*
2. *Within the immunity phenomena to be covered, there can also be different worst case selections (because of non-related phenomenon). That may increase the number of product cases to be investigated.*

3.2. Use of standards

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

At the moment individual apparatus are placed on the market, the compliance of apparatus with the EMC requirements of the relevant harmonised standards, as given in the latest available consolidated list of the Official Journal of the European Union (OJEU), gives 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 a product, which is continuously placed unchanged on the market for a long period, the applicable standards may change in the course of time. The provisions given by the application of 3.2.2 ensure that a transition period of at least 3 years is foreseen between successively valid editions of the same standard.

Harmonised standards for EMC application are prepared by the three following European standardisation bodies:

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

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

http://www.europa.eu.int/comm/enterprise/standards_policy/european/index.htm

3.2.1. List of harmonised standards

The list of harmonised standards of the OJEU is regularly updated and is available on the following European Commission Internet address:

<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.

CENELEC members via which harmonised standards can be obtained

		Hungary-MSZT	http://www.mszt.hu
Austria-OVE	http://www.ove.at	Iceland-IST	http://www.stadiar.is
Belgium CEB-BEC	http://www.bec-ceb..be	Ireland-ETCI	http://www.etcie.ie
Cyprus-CYS	http://www2.cytanet.com.cy/cys	Italy- CEI	http://www.ceiuni.it
Czech Republic- CSNI	http://www.csni.cz	Latvia-LST	http://www.lvs.lv
Denmark-DS	http://www.ds.dk	Lithuania- LST	http://www.lst.lt
Estonia-EVS	http://www.evs.ee	Luxembourg- SEE	http://www.see.lu
Finland- SESKO	http://www.sesko.fi	Malta-MSA	http://www.msa.org.mt
France- UTE	http://www.ute-fr.com	Nederland- NEC	http://www.nen.nl
Germany- DKE	http://www.dke.de	Norway- NEK	http://www.nek.no
Greece- ELOT	http://www.elot.gr	Poland-PKN	http://www.pkn.pl

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Portugal-IPQ	http://www.ipq.pt	Sweden-SEK	http://www.sekom.se
Spain-AENOR	http://www.aenor.es	Switzerland-CES	http://www.electrosuisse.ch
Slovakia-SEV	http://www.sutn.gov.sk	United Kingdom-BEC	http://bsi-global.com
Slovenia-SIST	http://www.sist.si		

ETSI harmonised standards can be freely downloaded from <http://www.etsi.org>

3.2.2. Relevant harmonised standards

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

In many cases it may be necessary to apply several 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) for apparatus intended to be connected directly to low-voltage public power distribution systems
- immunity to various permanent and transient 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 alarms function.

Very 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 sites explains the general structure of the EMC standardisation and the respective roles of EMC standards, e.g. basic standards, generic and product 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.

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

3.2.3. Date of cessation of conformity of the superseded standard

The presentation adopted on OJEU gives, next to each harmonised standard, the reference and title of which are given in column 2, the reference of the superseded standard in column 3 and the date of cessation of conformity of the superseded standard in column 4

Either the most recent published harmonised standard or the corresponding superseded standard may be used for presumption of conformity until the date of cessation of conformity of this superseded standard. After the date of cessation of conformity is expired, only the most recent standard may be applied.

Following example is extracted from the explanatory note regularly updated in OJEU.

CENELEC	EN 55013:1990		
	Limits and methods of measurement of radio disturbance characteristics of broadcast receivers and associated equipment <i>[The referenced standard is EN 55013:1990]</i>	None <i>[There is no superseded standard]</i>	-
	Amendment A12:1994 to EN 55013:1990 <i>[The referenced standard is EN 55013:1990 +A12:1994 to EN 55013:1990]</i>	Note 3 <i>[The superseded standard is EN 55013:1990]</i>	Date expired (31.12.1998)
	Amendment A13:1996 to EN 55013:1990 <i>[The referenced standard is EN 55013:1990 +A12:1994 to EN 55013:1990 +A13:1996 to EN 55013:1990]</i>	Note 3 <i>[The superseded standard is EN 55013:1990 +A12:1994 to EN 55013:1990]</i>	Date expired (01.06.1999)
Amendment A14:1999 to EN 55013:1990 <i>[The referenced standard is EN 55013:1990 +A12:1994 to EN 55013:1990 +A13:1996 to EN 55013:1990 +A14:1999 to EN 55013:1990]</i>	Note 3 <i>[The superseded standard is EN 55013:1990 +A12:1994 to EN 55013:1990 +A13:1996 to EN 55013:1990]</i>	Date expired (01.08.2001)	

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3.2.4. *Partial application of harmonised standards*

The manufacturer may decide for particular reason not to apply fully harmonised standards, but to refer directly to Essential Requirements of the directive. This mixed procedure, allowed by the directive, is not recommended for manufacturers having not a real expertise in EMC.

However, it may be justified in some cases, as explained in [clause 3.1.1](#), that the manufacturer applies the harmonised standards only partially or does not use all the harmonised standards needed to cover all the essential requirements.

In that case, the manufacturer needs to indicate very clearly in the declaration of conformity which respective requirements are covered by harmonised standards and which are not. He needs to make a detailed technical [EMC assessment](#) (see 3.1.2) with all the documentation needed for the part of the essential requirements not covered by the application of harmonised standards.

3.2.5. *Full application of harmonised standards*

3.2.5.1. Principle

Full application of a given harmonised standard indicates that the manufacturer guarantees that all the requirements of the standard are fully respected, when applying all the provisions, test and measurements methods described in the standard without deviations.

He takes thus responsibility that its product complies fully with all the detailed methods and requirements of the standard.

Consequently the manufacturer has no excuse if the market surveillance finds after performing the tests that it is not in conformity to the standard.

Note. The manufacturer may also as explained in [clause 3.2.4.](#), in some circumstances declare conformity to a part of a standard. This part has to be clearly identified

3.2.5.2. How to implement that principle in practice

The most secure way for the manufacturer is indeed to apply strictly all the prescriptions, methods, etc. of the declared standard to its product without any deviation. As most EMC standards include a series of tests with associated measurement methods, it means in particular that all normative tests indicated should always be done and exactly as required by the standard with regard to test and measurement methods.

Note: it should be noted that this concept is not applied in practice for each individual appliance placed on the market. It is only being applied as type tests to apparatus.

There are numerous circumstances where the manufacturer may wish for economical or practical reasons to deviate, under his full responsibility, from the ideal way described above. The following examples are given:

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- (1) The manufacturer may in some cases not perform some tests if he can guarantee by other means (e.g. design precautions, comparison with almost similar product) with sufficient certitude that the requirements will be met, if the tests were executed. He may also be justified not to perform some tests if the inherent physical characteristics of the product are such that for example negligible disturbances will occur in a given frequency band
- (2) The manufacture may also not have at disposal test installations respecting all the prescriptions of the standard or use simplified methods (sometimes called precompliance methods). He then takes a risk in declaring conformity to the standard but the risk may be minimised by taking more important margins of safety with regard to the limits or by having performed comparison tests between his simplified method and the full compliant method.
- (3) A prescan 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 necessary. More information may for example be found in EN 55016-2 (CISPR 16-2) on this particular subject.

All the deviations described above imply a risk for the manufacturer. He has to evaluate this risk when he declares conformity to a standard by making use of these deviations

The test and evaluation report should indicate exactly what has been done or not, should record the test methods used and give all the justifications on which the manufacturer bases his declaration of conformity to the standard.

3.3.Role of notified bodies

3.3.1. General concept.

Information on the operation of Notified Bodies can be found in Chapter 6 of the [Blue Guide](#).

In most Directives Notified Bodies play a specific mandatory role in the conformity process, e.g. as an independent test house or certification body carrying out the conformity assessment procedures specified in those Directives. The EMC Directive is different in the sense that the involvement of the NB in the process is totally voluntary and the service required of the NB is assist the manufacturer, or his authorised representative within the Community in the conformity assessment process for his apparatus. The Directive actually applies module A (Internal control of production), see [modules](#) in the Blue Guide, which does not require the mandatory involvement of a NB.

3.3.2. The Role of the Notified Body.

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

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The Notified Body shall:

- (1) Initially be contacted by a manufacturer (either within or external to the EU) or the manufacturer's representative in the Community; He should only accept a request for help from one of those persons
- (2) Review the technical documentation and assess whether the technical documentation properly demonstrates that the requirements of the Directive have been met; Note that the manufacturer may define those elements of the essential requirements that the NB is to review but the NB will have the freedom to reject the offer if this request is not technically coherent.
- (3) If the compliance of the apparatus is confirmed, issue a Notified Body statement to the manufacturer or his authorised representative established within the Community. The Notified Body should only give a statement on those aspects of the essential requirements of the apparatus that have been assessed by the Notified Body;
- (4) The activities of an EMC Directive NB are only related to apparatus, not to Fixed Installations (including Large machines and Networks).

This NB assessment will consist solely of reviewing the technical documentation of the apparatus provided by the manufacturer, or his authorised representative within the Community and assess whether that technical documentation properly demonstrates that the requirements of the Directive have been met. If the compliance of the apparatus is confirmed, the NB shall issue a statement confirming the compliance of the apparatus. The manufacturer shall add the statement of the NB to the technical documentation.

Notes:

- 1. If the compliance of the apparatus is not confirmed, it seems logical that the NB provides the manufacturer with a negative response clearly describing on what grounds the technical documentation of the apparatus fails to demonstrate that the requirements of the Directive have been met.*
- 2. Although the Directive does not require this at all, some manufacturers mention the name and address details of the NB used in the conformity process on the Declaration of Conformity for the apparatus.*

3.4.Documentation for national authorities

The documentation for national authorities is made of the [Declaration of conformity](#) and the [Technical Documentation](#)

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3.4.1. [R.D.4] Technical documentation

As indicated in Annex IV of the EMC Directive, the manufacturer shall also 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 then all necessary practical (technical) details:

- An identification of the product covered by the technical documentation. This identification should allow to unambiguously link the technical document and the product. A suggestion is to copy the information requested in Article 9(1) of the Directive.
- 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 (possibly with a picture).<<<new wording to be provided within a week >>>
- 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 must be included. In addition to the detailed technical [EMC Assessment](#), which must be included, the manufacturer may include test reports, design calculations and other documentation. It is up to the manufacturer to decide whether there is sufficient expertise in-house to assess this information and determine whether it does demonstrate that the apparatus meets the essential requirements. Alternatively a manufacturer may consult a Notified Body to assess the documentation.
- If a manufacturer has consulted a Notified Body then the Notified Body statement will be included.

3.4.2. Declaration of conformity

The compliance of apparatus with all relevant essential requirements shall be attested by an EC Declaration of Conformity issued by the manufacturer 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

Note 1: A fixed installation does not require a DoC.

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Note 2: In line with the [Blue 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".

Note 3: There is no requirement to have the CE marking on the DoC, however it is not forbidden to do so.

Note 4: The "person empowered to bind the manufacturer or the authorised representative" does not need to be resident on the EEA territory.

Annex IV of the EMC directive specifies the mandatory minimum content of the DoC, containing at least:

- reference to the EMC Directive,
- identification of the apparatus,
- name and address of the manufacturer and, where applicable, the name and address of his authorised representative in the Community,
- dated reference to the specifications under which conformity is declared,
- date of the declaration,
- identity and signature of the person empowered to bind the manufacturer or his authorised representative.

In most case the dated reference to the specifications under which conformity is declared, will be the harmonised standards that are applicable to the apparatus in question as listed in the *Official Journal*. If harmonised standards have not been used or only partially, a reference to the manufacturer's technical documentation where the [detailed technical EMC assessment](#) is given should be included and a reference to any identifiable non harmonised standards or specifications that have been applied

When harmonised standards are only used partially, the reference to the standard should be followed by the indication (partial) in brackets or the relevant sections of the standards should be indicated. When such an indication is not given, it is assumed that complete compliance with the quoted standard is guaranteed.

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 Law Enforcement Authority of the Member State.

The standard EN 45014:1998 "General criteria for suppliers Declaration of Conformity" has been drawn up with the objective of providing the general criteria for the declaration of conformity, and it can also be used as a guidance document in view of New Approach directives.

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It is at the discretion of the manufacturer to add on the DoC any information he finds useful. There is no limitation for this. This could be valid in order to make the DoC also applicable for areas outside the EU, in order to facilitate international trade.

Such useful information to be included in the DoC could be for example:

- the name, address and identification number of the notified body when it has been involved in the conformity assessment procedure;
- the name and address of the person who keeps the technical documentation;
- any restriction in use of the apparatus;
- the logo of the company and the CE marking;
- a document number.

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 DoC 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 3.4.4

The EC declaration of conformity must be drawn up in one of the official languages of the Community. As the EMC Directive does not require the apparatus to be accompanied by the DoC, (the DoC in principle is not aimed at providing information to the user), it does not have to be in the official language of the country of use.

3.4.3. Examples of DoC layout and content.

There are many different situations and for some situations examples of a DoC are provided for guidance.

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;
- The apparatus has some restrictive use;

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- 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.*

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	<i>TAL Japan Ltd</i>
---	----------------------

EC Declaration of Conformity

We, the undersigned,

Manufacturer	Tokyo Apparatus Ltd. (TAL)
Address, City	Nagata-cho 1-11-35, Chiyoda-ku, Tokyo
Country	Japan
<i>Phone number</i>	+ 81 123456
<i>Fax number</i>	+ 81 1234566
Authorised representative in Europe	Mr. E. Veen, Director TAL Europe B.V.
Address, City	Zoutstraat 2, 9700 AB Groningen
Country	The Netherlands

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 01
<i>Restrictive use</i>	For Residential and Office environment only

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

Standards
EN 55022:1994+A1:1995+A2:1997
EN 55024:1998+A1:2000
EN 61000-3-2
EN 61000-3-3:1995+A1:2001

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


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

Notified Body reference	Identification of NB letter of Opinion	Name and address of NB
NB Nr: 0999	281148/001	NB Services B.V Maarsdijk 2 9822 TJ Faan, The Netherlands

The Technical documentation is kept at the following address:

Company	TAL Europe B.V.
Address, City	Zoutstraat 2, 9700 AB, Groningen
Country	The Netherlands
<i>Phone number</i>	+ 31 50 5877136
<i>Fax number</i>	+ 31 50 5877400



Name and position of person binding the manufacturer or his authorised representative	Mr. T. Weltevrete Sales Manager TAL Europe B.V.
Signature 	Date 25 July 2007

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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;
- The apparatus has no restrictive use;

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Suppliers Declaration of Conformity (conform ISO 17050)

1. **Number of SdoC:** 23456
2. **Issuer's name:** VEEN Electronic Cleaning B.V. (manufacturer)
Maarsdijk 2, 9822 TJ Niekerk
The Netherlands
3. **Object of declaration:** Seminar presentation machine
Model A, type 01
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)
EN 61000-3-2:2000	Electromagnetic compatibility (EMC) -- Part 3-2: Limits - Limits for harmonic current emissions (equipment input current up to and including 16 A per phase)
EN 61000-3-3:1995 + A1:2001	Electromagnetic compatibility (EMC) -- Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current \leq 16 A per phase and not subject to conditional connection
EN 55022:1994: +A1:1995 + A2:1997	Limits and methods of measurement of radio disturbance characteristics of information technology equipment (Class B)
EN 55024:1998 + A1:2001	Information technology equipment - Immunity characteristics - Limits and methods of measurement (excluding radiated electromagnetic test)
VEEN Imm 2::2004	Radiated electromagnetic test
5. **Additional information** A technical documentation nr. 546887 is available
6. **Signed for and on behalf of:** VEEN Electronic Cleaning B.V.
7. **Date:** 20 July 2007
8. **Name and Function:** 
Mr. E. Veen
Managing Director

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Note: These Doc's are only given as examples as the quoted required standards may change. Users should always refer to the latest consolidated list of harmonised standards in OJEU

3.4.4. The Concept of “making available”

“Making available” covers the handover of documentation to the relevant Authority.

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 competent 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

The competent authorities in this case are the [public authorities](#) , involved in surveillance activities.

The Concept of making available means:

- (1) There shall be one responsible person in the Community responsible for making available EC Declaration of Conformity and the technical documentation
- (2) The responsible person must present the EC Declaration of Conformity and the technical documentation upon request from the national authority, 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 EC Declaration of Conformity or the technical documentation within a reasonable period, in response to a duly substantiated request by the surveillance authority, constitutes sufficient grounds for doubting the presumption of conformity of the product with the requirements of the EMC Directive.
- (4) The technical documentation or the EC Declaration of Conformity to be made available to the authorities on request need not to be an original but can be a copy of it.
- (5) The responsible person must not be in possession of the documents, as long as he can fulfil requirement (2). 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

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beyond their frontiers to examine the technical documentation at the manufacturer's premises. Submission of the files to the authorities has to be direct, not through any diplomatic channels.

- (6) 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, as long as it can be exploited easily by the Authority.
- (7) Surveillance authority will keep in mind the principle of proportionality when requesting the documentation, taking into account the need to ensure the public interests foreseen in the directives, as well as to protect the economic operators from unnecessary burden.
- (8) When a manufacturer responds to a request by the authorities for (part of) the file should be one of the languages of the Community.
- (9) According to the [blue guide](#), a national authority may request a translation of the technical documentation and the EC declaration of conformity into its official language. However, it should avoid doing so if they, especially the detailed technical information of the documentation, are available in a language that can be understood by the national authority in question. If the authority considers a translation necessary, it must clearly define the part of the documentation to be translated and allow reasonable time for this to take place. No further conditions may be imposed on the translation, such as a requirement of a translator accredited or recognised by the public authorities. The request for a translation must be done on a case by case basis, taking into consideration the proportionality of the demands.

Notes:

1. *The Technical documentation does not have to accompany the apparatus.*
2. *Manufacturers are not obliged to accept requests for the technical documentation from their customers.*

3.5. Marking and information

3.5.1. CE-marking

The EMC directive requires that the apparatus bears the CE marking as an attestation of compliance with the directive. The details of the marking are given in article 8 and annex V of the directive.

However, CE-marking it is in some cases not mandatory for [apparatus intended to be incorporated into fixed installations](#)

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Following the “CE-Marking directive” (93/68/EEC) the CE-marking regime is largely harmonised between the EC directives applicable to the products subject to the EMC directive. The procedures specified in article 8 and annex V of the EMC directive follow these well-established principles, i.e. there is no change compared to the old EMC directive.

The directive also forbids affixing of markings that look like the CE-marking, and also markings 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 or to fully meet the public interest objectives covered by the EMC directive. However, for equipment under the EMC Directive, the CE-marking is the only marking having regulatory meaning 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 exist and in addition to the accompanying documents. Note that although the word “documents” is in plural, the intention is that the CE-marking is in the “primary” documentation, such as the user manual.

The [New Approach Guide](#) gives more information as to under what circumstances this exemption is allowed: where it would not be possible “under reasonable technical or economic conditions, or where the minimum dimensions could not be respected, or it could not be ensured that the CE marking was visibly, legibly and indelibly affixed”. This is usually the case of very small apparatus or apparatus where no space is available for marks.

The 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 requiring CE-marking, unless one or more of those directives allow for a transitional arrangement that does not use the CE-marking and the manufacturer has chosen to use that possibility. In such case the CE-marking on the apparatus only denotes compliance to those directives that the manufacturer has applied,

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and he must indicate the particulars of the other directives in the accompanying documentation.

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 can not be CE marked.

3.5.2. *Other identifying marks*

The 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. It shall allow to unambiguously correlating the apparatus 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 for incorporated into given fixed installations and otherwise not commercially available shall have this identification information in the accompanying documentation, and need not have it on the apparatus.

3.5.3. *Information for traceability*

In order to facilitate traceability in the course of market surveillance, 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.

The 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 previous sub clause).

3.5.4. *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 (where this is to be done by the user) 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:

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- 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 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 “pdf”-file 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.

3.5.5. *Information when compliance is not ensured in residential areas*

The directive recognises that the electromagnetic environment differs between residential areas and non-residential areas. It is also recognised that products may end up in areas for which they are not intended (as specified by the manufacturer).

The directive requires that apparatus for which compliance with the protection requirements (emission and immunity) is not ensured by the manufacturer in residential areas be “accompanied by a clear indication of this restriction of use”. There are many ways of meeting this obligation. One example can be found in EN 55022, the emission standard for information technology equipment, which in the case of equipment designed for non-domestic areas (called “class A” in the standard) requires that a warning text be provided in the user instructions. Another example allowed under the EMC Directive would be to include an explicit sign or symbol.

The directive requires that the indication of restriction of use also be provided on the packaging “where appropriate”. In general this would be where small professional apparatus, intended for non-residential use, is likely to be bought also by consumers for use in the residential area, and the apparatus has not been designed to meet the protection requirements applicable to the residential area.

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4. RULES FOR FIXED INSTALLATIONS

4.1. Essential requirements

4.1.1. General concept

"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

By their nature fixed installations will not be subject to the need for free movement within the European Community. Therefore they are not subject to the requirements for CE marking or the need for a declaration of conformity or for a formal EMC assessment before installation.

Notes

"mobile installations" defined as a combination of apparatus and, where applicable, other devices, intended to be moved and operated in a range of locations are apparatus and are fully covered by the requirements applicable to apparatus.

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 clause 4.5](#)

The 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 regarding the intended use of the components making up the fixed installation. This is in view of respecting the essential protection requirements which are expressed in an identical way for fixed installations as for apparatus:

Equipment shall be so designed and manufactured, having regard to the state of the art, as to ensure that:

the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended;

it has a level of immunity to the electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use.

In the context of this phrase within the EMC Directive, the word "permanent" is taken to mean a significant part of the useful life of the apparatus and/or components that make up the fixed installation.

These two basic requirements relating to the use of components and good engineering practice can be summarised thus:

(1) Intended use of components

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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 respected. This applies to any sub-part, whether those parts are large machines, apparatus, components not submitted as such to the directive, specific apparatus for the fixed installation, etc.

These instructions may concern for example:

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

(2) Good engineering practice

Legal requirements and recognised standards / codes of practice will form the basis of any definition of good engineering practice.

Good engineering practice comprises suitable technical behaviour by the responsible person, taking account of all relevant recognised standards and codes of practice applicable to the particular fixed installation.

The responsible person should be aware that good engineering practice, particularly in the field of EMC, is in constant evolution. Therefore the responsible person will need to ensure that they employ 'state of the art' practices ie the most modern publications, when seeking to ensure that their fixed installation meets the requirements for protection specified in the EMC Directive.

Standards for installations cannot cover all particular and local conditions. Therefore it is necessary for the responsible person to be aware of some guiding principles for what should be considered when looking to demonstrate good engineering practice:

- Emissions: take appropriate actions to mitigate the source of disturbances by EMC design, 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 is protected against the various types of disturbance that might be expected.

When applying the essential requirements to a defined fixed installation, it is essential to define the borderlines/geographical limits of this fixed installation in order to distinguish

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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 EMC between equipment inside the borders of the defined fixed installation. This aspect is sometimes referred to as ‘intra-system’ EMC. Nevertheless there is a direct technical link and a good intra system EMC greatly improves in practice the chances of avoiding problems with the external environment

The [electromagnetic phenomena](#) to be considered for fixed installations are the same as for apparatus

4.1.2. Emissions

Emissions from Fixed installations can be considered in four broad groupings, depending of the origin of the emitted disturbances:

- (1) Emissions as a result of apparatus incorporated within the fixed installation;
- (2) Emissions from the other components that make up the Fixed installation;
- (3) Emissions from a fixed installation as a result of disturbances caused by equipment outside of the fixed installation.
- (4) Emission from a new fixed installation that is connected to or constitutes a sub part into a larger fixed installation

Considering each case in more detail it is possible to offer guidance on how the responsible person can take measures to reduce the risk of emissions from the fixed installation.

Note that in practice it can sometimes be difficult to assign clearly the cause of the disturbances to one single group of equipment.

4.1.2.1. Emissions as a result of apparatus incorporated within the fixed installation

Normally there should be no adverse effects as a result of incorporating apparatus that are compliant with the EMC directive particularly when they comply with harmonized standards under the EMC Directive, since the emissions allowed under these standards

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are based on a reference network / environment in which the apparatus is expected to be operated.

For large items of apparatus or apparatus that for other reasons is subject to an assessment prior to being incorporated into a fixed installation, it will be advisable for the responsible person to carry out a bespoke assessment to determine the level of emissions that will emanate from the fixed installation if the apparatus were to be incorporated. In order to carry out this assessment it will be necessary for the responsible person to consider the characteristics of the fixed installation and the apparatus. The apparatus should only be incorporated if the predicted level of emissions is within acceptable levels; if this is not possible it will be necessary for the responsible person to consider mitigation measures that might need to be applied to the apparatus and / or the fixed installation. In those cases where the possible infringement on acceptable emission levels is marginal it might be acceptable to provide a conditional connection in that the apparatus is connected on the condition that measurements will be carried when the apparatus is operational to determine if the actual emissions are acceptable to responsible person.

In the case of specific apparatus that has been specifically designed for incorporation within a fixed installation, it may be necessary to consider their effects on the emitted disturbances, noting in particular the information provided by the manufacturer

4.1.2.2. Emissions from the other components that make up the fixed installation

In order to mitigate the risk of components within an installation producing an unacceptable level of emissions it will be necessary for the responsible person to ensure that the components used within the fixed installation are appropriate regarding EMC parameters for the functions that they are to perform. For example, considering cables, these should be:

- Of correct construction for the EMC environment in which they are to operate;
- Installed and separated in a manner that will not lead to excessive couplings or radiated emissions;
- Where appropriate, fitted with the necessary screening protection
- Fitted with the correct electrical protection to avoid damage as a result of faults of overloads.

The risk of unacceptable emissions will be reduced if the fixed installation is designed, constructed and operated in accordance with the appropriate standards. For example, low voltage installations should be constructed in accordance with HD 438.

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4.1.2.3. Emissions from a fixed installation as a result of disturbances caused by equipment outside of the fixed installation

This aspect is generally more relevant for large networks which have many external ports/interfaces to which many items of equipment are connected either directly or indirectly.

Normally there should be no adverse effects as a result of connecting apparatus that are compliant with the EMC directive particularly when they comply with harmonized standards under the EMC Directive, since the emissions allowed under these standards are based on a reference network / environment in which the apparatus is expected to be operated.

4.1.2.4. Emissions from a new fixed installation that is connected to or constitutes a subpart of a fixed installation

Prior to constructing and/or operating a new fixed installation it is necessary to take account of the electromagnetic environment within which it is to be situated. In particular it is necessary to consider the effect that this new fixed installation might have on any existing equipment, including fixed installations.

For persons looking to install a new Fixed installation it will be necessary to take full recognition of existing Fixed installations to the extent that the responsible person for the former might need to carry out a detailed assessment of the interaction between the two Fixed installations and where necessary take mitigating action to avoid an unacceptable level of emissions being transferred from one installation to the other.

4.1.2.5. Particular case of emissions disturbing radio services

Where it is has been identified that a Fixed installation might generate radio frequency emissions conducted or radiated to the external environment i.e. beyond the defined borderline of the Fixed installation, where these radio frequency emissions might have a harmful affect on radio services, the particular external environment (distance to residential area, nature, presence and distance to other sensitive installations etc.) should be taken into consideration to ensure that these effects remain under control. Proportionate mitigation measures should be taken regarding filtering, cabling, shielding, and choice of equipment in order to achieve this purpose. In the case of complaints from users in the external environment, the responsible person will be required to carry out a series of measures:

- Identify if the Fixed installation is the source of the disturbance; if so
- Take the necessary measures to limit the emitted disturbances

Note: The Cenelec technical specification TS 50217 “Guide for in-situ measurements of disturbance emission”: may be a useful tool in this respect.

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4.1.3. Immunity

Fixed installations may be particularly sensitive to electromagnetic disturbances either because of the complex combination of apparatus forming the installation or because of the purpose of the equipment itself. In such cases it will be necessary for to take additional precautions to improve the immunity of the overall installation or to provide an environment within the installation in which particular sensitive apparatus can function as intended.

In assessing the mitigation measures necessary to allow sensitive equipment to operate as intended the designer of the installation should consider the electromagnetic environment required against the levels of disturbance which will be present. The designer must consider the effects of radiated and conducted disturbances and the location of possible sources of these disturbances with respect to the installation, in particular the possible influence from existing fixed installations.

Each type of disturbance may need particular types of mitigation techniques which are documented in many EMC guide books

As with considerations for mitigation and control of conducted emissions, conducted disturbances may, to a certain extent, be mitigated by appropriate selection of the design and rating of the components and apparatus incorporated within the fixed installation. Where the installation is particularly susceptible to the types of typical disturbances, which may be expected on public electricity supply networks it may be necessary to consider additional active mitigation measures to provide additional protection against these external conducted influences.

Control of disturbances caused by radiated emissions may require that the construction of the installation consider employing either as part of the apparatus within the installation or as part of the overall construction of the installation additional electromagnetic shielding, filtering and cabling precautions.

Guidance on general considerations and techniques for earthing and cabling for the mitigation of disturbances in installations can be found in IEC 61000-5-1 and IEC 61000-5-2 respectively

4.2.Documentation

With regard to the documentation for fixed installations, the EMC Directive places the following requirements on the responsible person:

- In such cases, the accompanying documentation shall identify the fixed installation and its EMC characteristics and indicate the precautions to be taken for the incorporation of the apparatus into the fixed installation in order not to compromise the conformity of the specified installation. It shall furthermore include the information referred to in Article 9.1 and 9.2!
- A fixed installation shall be installed applying good engineering practices and respecting the information on the intended use of its components, with a view to

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meeting the protection requirements set out in Point 1. These good engineering practices shall be documented and the documentation shall be held by the responsible person(s) at the disposal of the relevant national authorities for inspection purposes as long as the fixed installation is in operation.

In the case of specific apparatus (*link to 4.3*) designed for use within a specific Fixed installation, the responsible person should ensure that the documentation which accompanies the apparatus adequately describes how the apparatus is to be installed and operated in order not to cause interference with other equipment or to be subject to interference itself to such a level that there will be a degradation in performance either of the apparatus or of other equipment.

In the case of the fixed installation it will be necessary for the responsible person to ensure that the good engineering practices applied to design, installation and operation of the fixed installation are adequately documented and that this documentation is maintained and available if required for inspection by the relevant national authorities. In order to facilitate this requirement it is recommended that whenever practicable the responsible person uses recognised practices and procedures as documented in IEC or Cenelec or national standards or technical reports / specifications or codes of practice

4.3.Responsible person for fixed installations

To be consolidated

4.4.Examples related to electrical installations

4.4.1. Connection of equipment

Whilst the responsible person for a Fixed installation has a responsibility for ensuring that parties connecting to and/or using the installation do not cause an unacceptable electromagnetic environment there is also an obligation on the manufacturers of equipment and the users of that equipment to ensure that the equipment is suitable for use in that environment. Equipment above certain ratings may be subject to conditional connection under the harmonised standards for precisely this reason. Where an electromagnetic disturbance is identified as being due to the inappropriate connection of equipment it will be for the person causing the disturbance (once identified) to take the necessary correcting and/or mitigating action to ensure that the disturbance does not exceed an acceptable level. Where the cause of the disturbance cannot be identified, it will be for the responsible person (for the Fixed installation) to demonstrate that his installation has been designed and built in accordance with the EMC Directive i.e. by applying good engineering practice.

In assessing any mitigation measures necessary to allow sensitive equipment to operate as intended the responsible person (for the Fixed installation) should consider the requirements for the electromagnetic environment that will be necessary to ensure that equipment within the Fixed installation will operate as intended. The person responsible must consider the effects of radiated and conducted disturbances and the location of possible sources of these disturbances with respect to the installation. Consideration

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should be given to the relevant compatibility level standard: EN 61000-2-2, EN 61000-2-4 and EN 61000-2-12.

The immunity of equipment used within the fixed installation must be carefully considered against the consequences of the performance varying when subjected to a specific disturbance. For example under transient overvoltages some DC power supplies might switch off their output whilst others will continue to operate unaffected. Both these may comply with the appropriate standards since degradation of output is permitted under such conditions. The consequences of a recoverable interruption to the output of the DC power supply are quite different if the unit is supplying an indicator lamp as opposed to if the unit is supplying a programmable logic controller.

As with considerations for mitigation and control of conducted emissions, conducted disturbances may, to a certain extent, be mitigated by appropriate selection of the design and rating of the electrical power connections. Where the installation is particularly susceptible to the types of typical disturbances which may be expected on public electricity supply networks it may be necessary to consider additional active mitigation measures to provide the additional protection required against these external conducted influences.

Control of disturbances caused by radiated emissions might require that the person responsible for the Fixed installation considers employing either as part of the Apparatus within the installation or as part of the overall construction of the Fixed installation additional electromagnetic shielding, filtering and cabling precautions.

Fault conditions either on the public electricity distribution network or on Fixed installations connected to the public electricity supply network may give rise to a variety of electromagnetic phenomena, including; Voltage Dips, due the short circuit and RF emissions due to the fault arcing. The effect of some of these phenomena may be more localised such as RF emissions due to arcing whilst others such as a voltage dip may be experienced over a wider area. In recognition of these exceptional events it is good engineering practice to install protection devices to both limit any damage caused to the fixed installation and also to minimise the number of customers affected by the resulting outage. The total operating time of these protection devices, from inception of the event to removal of the interference could be up to 3 seconds. It is not possible to guarantee that the emissions from the fixed installations will not exceed normal operating levels during these exceptional events. Therefore it might be appropriate for the persons responsible for the fixed installations to advise network users and manufacturers of the potential risks to the performance of as a result of these unavoidable disturbances. It will then be for the third parties to identify the level of immunity required in order to ensure that their equipment operates satisfactorily during the period of the exceptional event. In particular, the correct operation of safety critical equipment should be ensured.

The operation of large numbers of items of equipment within a Fixed installation might result in the generation of electromagnetic disturbances which if not adequately controlled would exceed the immunity levels of other Apparatus within the EMC environment of the Fixed installation. Therefore, all Apparatus that can be used in an uncontrolled manner, ie without the specific authorisation of the person responsible for

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the fixed installation, must be manufactured in accordance with the requirements of the EMC directive. This policy is aimed at ensuring the free movement of goods without the risk that the operations of some goods will adversely affect the use of others.

4.4.2. *Issues for persons planning a fixed installation*

It is a requirement of the EMC Directive that Fixed installation shall be installed applying “good engineering practices” and that these practices shall be documented and that this documentation should be held by the responsible person for inspection. Therefore the responsible person will need to identify the electromagnetic environment within which his installation must operate and requirements of his installation. For electrical installations there are standards which specify EMC compatibility levels: EN 61000-2-2, EN 61000-2-4 and EN 61000-2-12. The responsible person for an electrical installation should consider using procedures /codes of practice for the design and operation (including connection assessments) that will allow his installation to meet the requirements of these standards.

In the process of identifying the electromagnetic environment in which a Fixed installation will be located the responsible person will need to carry out an assessment of the proximity of other sources of disturbance and their likely affect on the operation of the Fixed installation and the equipment within it and also the location of possible victims to any disturbances that might be caused by the operation of the Fixed installation.

To meet these requirements the EMC Directive, the responsible person must take account of a variety of [electromagnetic phenomena](#) which must be controlled and protected against.

Guidance on how to classify the electromagnetic environment applicable to equipment can be found in IEC 61000-2-5. This technical report describes classification of environments according to the electromagnetic phenomena expected.

Guidance on general considerations and techniques for earthing and cabling for the mitigation of disturbances in installations can be found in IEC 61000-5-1 and IEC 61000-5-2 respectively.

4.5. Requirements for specific apparatus

The general rule is that all apparatus, as defined in the EMC directive, are subject to all the relevant provisions of this directive for apparatus. **This applies also fully to apparatus that will be incorporated into fixed installations.**

However the EMC directive has foreseen a possibility of exception for some apparatus that may in common language be called “customer made”: these are apparatus intended for incorporation in a given fixed installation and which are otherwise **not commercially available.**

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The two underlined words in the previous sentence fix essentially the conditions under which this possible exemption is allowed. It means in particular that this exemption **shall never** be used for apparatus placed on the market which may become available to the general public.

It is also not applicable for any mass-produced apparatus.

For the specific apparatus which may benefit from this exemption, the essential requirements for the apparatus considered in isolation when placed on the market, the assessment procedure for apparatus, the subsequent declaration of conformity and the specific marks and information for apparatus are not compulsory.

Specific apparatus for which use is made of this exemption possibility shall **NOT** bear the CE marking as a proof of conformity with the EMC directive

The CE marking may however be required to show conformity to other directives applicable to the apparatus)

4.5.1. Obligations for specific apparatus using the exemption clause

The manufacturer of the concerned apparatus shall indicate in the accompanying documentation type, batch, serial number or any other information allowing for the identification of the apparatus as well as the name and address of the manufacturer and, if he is not established within the Community, the name and address of his authorised representative or of the person in the Community responsible for placing the apparatus on the Community market.

He shall furthermore indicate the precautions to be taken for the incorporation of the apparatus in order not to compromise the conformity of the given fixed installation. 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.

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

- (1) Specific apparatus made according to particular specifications indicated in an order addressed by a (generally) industrial customer to the manufacturer and intended for a well-defined fixed installation.
- (2) Apparatus designed according to a specific specification given by a potential client for its own purposes,
- (3) Apparatus derived from a generic apparatus adapted to the specific need of the client for its own purpose or to the specificity of any particular location.
- (4) Apparatus made in small series and which need a special adaptation by the manufacturer to each specific fixed installation they are intended for.

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- (5) Apparatus made in small series and delivered by the manufacturer for incorporation into a well defined type of fixed installations, each of them at the final location necessitating appropriate EMC adjustments by the user or the installer according to the instructions of the manufacturer of the apparatus.

5. ENFORCEMENT OF THE DIRECTIVE

5.1. Market Surveillance

5.1.1. General concept

Market surveillance is an essential tool for the enforcement of the EMC Directive and based on [Article 10 of the EC Treaty](#) . It requires Member State to take all appropriate measures to ensure fulfilment of their obligations, by taking measures to check that products meet the requirements of the EMC Directive and that action is taken to bring non-compliant products into compliance, and that sanctions are applied when necessary.

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:

- (1) take all necessary measures to ensure that products may be placed on the market and put into service only if they comply with the EMC Directive;
- (2) make sure that products do not:
 - endanger the necessary required protection against EM disturbances,
 - present a potential or actual risk to radio-communications, electrical supply and telecommunications networks, as well as equipment connected thereto,
 - endanger other interests covered by the EMCD,

when products are correctly constructed, installed and maintained, and used in accordance with their purpose.

This obligation for market surveillance is complementary to [Article 4.1 of the EMC Directive](#) that requires Member States to allow free movement of products that are in compliance with the Directive.

Market surveillance is only a responsibility of [public authorities](#). This is to guarantee the impartiality of market surveillance operations.

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

This requires that efficient administrative cooperation between national authorities be in place so that an equivalent level of protection can be ensured throughout the EEA, in spite of the competence for market surveillance being limited to each Member State's territory.

The administrative cooperation between the national market surveillance authorities for the EMCD takes place in the EMC ADCO Group (Administrative Co-operation Group). This ADCO Group deals with any issue relating to market surveillance activities under the EMCD.

As market surveillance is more efficient if the national surveillance authorities allocate their resources in such a way that a maximum number of different product types could be covered in each sector, the ADCO Group coordinates market surveillance actions at large scale, including cross-border control campaigns. To avoid duplication of investigations for market surveillance purposes by national authorities, ADCO applies a mechanism to exchange reports of investigations.

The authorities are independent, and carry out the operation in an impartial and non-discriminatory way. Further, the authority carries out market surveillance respecting the principle of proportionality: actions are taken in accordance with the degree of risk or non-compliance and the impact on the free circulation of products is no more than necessary for achieving the objectives of market surveillance.

Notes:

- 1. Although market surveillance cannot, basically, take place during the design and production stages, the authority may make a check on the production premises after a non-compliance has been discovered to verify whether or not a constant error can be established and to prevent the further placing on the market of non-compliant products.*
- 2. No products will be excluded from market surveillance operations, even if they have been subject to any voluntary certification scheme or other voluntary initiatives, or have been assessed involving a Notified Body.*

Market surveillance covers all applicable provisions of the EMC Directive. Tasks for authorities under the EMC Directive are (where applicable):

- (1) Monitoring products placed on the market;
- (2) Verification of the correct identification of the apparatus;

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- (3) Verification of name, address data of manufacturer or authorised representative or other person responsible for placing the apparatus on the market;
- (4) Verification of the identification and signature of the person empowered to bind the manufacturer or his authorised representative;
- (5) Verification of the correct choice and application of the conformity assessment procedure;
- (6) Verification of compliance with the essential requirements;
- (7) Verification the CE marking and its affixing, including principles regarding any additional markings and marks;
- (8) Verification of the availability and the content of the EC declaration of conformity;
- (9) Verification of the validity of the Notified Body Statement;
- (10) Verification of the availability and the content of the technical documentation and other information (accompanying the product), such as related to:
 - any specific precautions that have to be taken, when the apparatus is assembled, installed, maintained or used;
 - clear indication of the restriction of use of apparatus for which compliance with the protection requirements is not ensured in residential areas;
 - use in accordance with the intended purpose of the apparatus;
 - identifying the fixed installation and its EMC characteristics and indicate the precautions to be taken for the incorporation of the apparatus into the fixed installation;
 - identification of the person or persons responsible for the establishment of compliance of a fixed installation.

Notes:

1. *Surveillance authorities do not limit their activities to monitoring products placed on the market, and to taking the necessary corrective actions. Informal contacts and other collaboration between the authority and the manufacturers and suppliers may help in preventing the placing on the market of non-compliant products. For instance, the authority can provide general advice and guidance to the manufacturers on the application of the EMC Directive. Further, the authority should also consider the possibilities of raising the awareness of*

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consumers and other users, for example on issues relevant to their health and safety.

- 2. Complaints from consumers or other users about a product, or from manufacturers or distributors about unfair competition may also provide adequate background information for authorities to initiate a market surveillance action.*
- 3. The EMC Directive enables surveillance authorities to receive information on the product, 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.*

5.1.2. Future issues.

Market Surveillance Enforcing Authorities will also take a more communal approach to internet-market surveillance, often called “desktop market surveillance”. This form of surveillance refers to electronic market surveillance, in particular the surveillance of market parties that trade products via Internet. It is expected that desktop surveillance:

- makes a contribution to more efficient market surveillance;
- provides the market surveillance with a faster insight into new product developments, and;
- allows the authorities to respond more quickly to equipment-developments.

5.2. Corrective actions

The national authorities must take action to enforce conformity, when they discover that a product is not in compliance with the EMCD.

Before any action is taken, the party concerned should be notified and (unless the matter is urgent) given the possibility of being consulted.

Any corrective action depends on the degree of non-compliance and, thus, must be in accordance with the principle of proportionality. However, the difference between non-substantial and substantial non-compliance is usually decided on a case-by-case basis.

The EMCD does not specify any penalty; Member States remain thus free to choose the sanctions to be used when infringements take place. These penalties must be analogous to those applicable to infringements of national law of a similar nature and importance. In addition, these penalties must be effective, proportionate and dissuasive.

Corrective action can also take place if the necessary measures are taken (for example the product is modified or withdrawn from the market), either as a result of consultations carried out by the surveillance authority or as a result of formal or informal warnings. In

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all cases the surveillance authority must establish accompanying measures to ensure that conformity is enforced.

5.3.Special measures

5.3.1. Regarding products at trade fairs, etc.

Article 4.3 of the EMC Directive states:

“Member States shall not create any obstacles to the display and/or demonstration at trade fairs, exhibitions or similar events of equipment which does not comply with this Directive, provided that a visible sign clearly indicates that such equipment may not be placed on the market and/or put into service until it has been brought into conformity with this Directive. Demonstration may only take place provided that adequate measures are taken to avoid electromagnetic disturbances.”

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

The EMC Directive allows the display and/or demonstration of not yet compliant products under specific circumstances, i.e. provided that a visible sign clearly indicates that the products may not be marketed or put into service until they have 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 disturbance.

Market surveillance authorities 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 product being removed from the trade fair, exhibition or similar event as well as issuing warnings.

5.3.2. Clarification of Article 4 procedures

Article 4 of the EMC Directive intends to provide the tools to a Member State for handling **exceptional** situations. This enables the Member State to set-up customised regulations.

It should be noted in general that the previous EMC Directive contained a similar Article (Article 6) which has never been applied by one of the Member States. This is an indication of the exceptional character of this provision.

Enforcement Agencies dealing with any complaints related to these potential situations will be able to convince parties to take account of the need to apply extra precaution for specific situations without the need to formally enter the Article 4 procedures.

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Notes:

1. *The protection measures taken in the case of Article 4.2.a are only to be applied at a specific site, they cannot be applied in general.*
2. *The protection measures taken in the case of Article 4.2.b can be taken for an area or if necessary apply to the whole Member State area, but it can only be applied for well defined spectrum situations (fixed radio service parameters, that are being applied!)*
3. *“Safety purposes” means the purposes of safeguarding human life or property.*

Some examples of these exceptional cases requiring special measures:

– For 4.2.a: LOFAR Radio Telescope

Traditional radio telescopes combine electronic signals from giant steerable dish antennas, which are very expensive to build and usually too small to focus the long wavelengths that are necessary to see galaxy formation.

LOFAR is completely different. It will detect the incoming radio signals using an array of inexpensive omni-directional antennas, each shaped like a hollow pyramid. The antennas will convert the radio waves into tiny electronic currents, and these currents will be converted into digital form – simple numbers – that get transported along optical fibre cables to a supercomputer where software adds and multiplies these numbers to emulate a conventional radio telescope. In essence, LOFAR is 25.000 antennas, connected with a super high speed network to the supercomputer into a single telescope.

Although LOFAR has very good abilities to rule out many types of disturbances it is not capable to overcome all potential disturbing sources. In order to protect LOFAR, as a high cost scientific instrument, detecting very low signals, there may be a necessity to provide specific extra locally protection by taking some special measures around the antenna's, such as restricting or banning the use of certain products in those area's

– For 4.2.b Coast Station

A maritime coastal radio station is involved in safety issues such as monitoring the emergency radio frequency channels and coordinating safety operations that include life saving activities.

With the planning of the location of this radio station some protection is already being provided as the use of potential disturbing products in close proximity to the radio station is probably low.

Electronic and electric products in use close to this radio station fulfil of course the protection requirements according to the EMC directive e.g. by complying with the limits given in the harmonised standards. These limits already take

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account of certain safety operations but still in a general manner as the products have free circulation

If, while monitoring the emergency radio channels, potential disturbing signals are being detected, the Member State Enforcement Agency will deal with such complaint with the highest priority and can take whatever action is necessary within the context of [Article 10](#) of the Directive.

However during life saving operations the the signal to noise ratio could become so low that the operation is seriously being affected. In such case it may be necessary to have some extra protection locally in force and thus the provisions of Article 4.2.b. can be applied, e.g. applying specific rules for shutting down the use of electronic products within a certain area around the radio station.

5.3.3. *Applying Article 4.*

If however applying Article 4 would imply a technical barrier to trade then the procedures of [98/34/EC](#) should be followed. Taking this in a broad sense, this means that any measure (even a local one) can be understood as a barrier to trade. However, the [98/34/EC](#) procedure does not apply for measures directed towards one product or one manufacturer or one user.

Without prejudice to Directive [98/34/EC](#), Member States shall notify these measures to the Commission and to the other Member States.

5.4.Solving disturbance complaints

5.4.1. *For Apparatus*

Individual interference problems with products are in principle not related to the market access process and/or the free movement of goods, because the equipment is already on the market and/or has been taking into service. In this respect general market surveillance and dealing with disturbance complaints are separate activities.

Notes:

- 1. All Member States are fully authorized to deal with disturbance complaints, however the manner the work on disturbance investigations is organised varies greatly between the Member States and depends on the national regulation.*
- 2. In some Member States the disturbance complaint work is being carried out by a single organisation, while in other Member States the work is carried out by several different organisations.*
- 3. In most Member States the Market Surveillance authority and the authority dealing with disturbance complaints are the same.*

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As the EMCD is not aiming at avoiding all interference at any cost and in any location there will be the possibility that even equipment complying with the essential requirements of the EMCD can cause interference or be subject to interference.

Harmonised standards for products are established in order that products, systems and installations operate as intended in the majority of application cases and under normal operation conditions. It should be very unlikely that products that comply with the harmonised standards (or can be shown to meet the essential requirements by analysis) while operated as intended are electromagnetically incompatible with each other.

As the EMC Directive (in case of apparatus) covers 2 essential requirements (emission and immunity) there can be 3 kinds of interference complaints, those caused by the emission of a product, by a lack of immunity of a product or by a combination of the 2 situations.

In the event of an interference occurring, authorities should deal with it in a structured, transparent, proportionate and non-discriminatory way. This could be achieved by using an interference complaints procedure containing all elements of the process of resolving the interference complaint.

Member States authorities could apply a method of setting priorities for investigating a disturbance complaint and this will affect the manner of handling the investigation in terms of timing.

The priority criteria for investigations are in most Member States:

- interference on frequency bands for international air and maritime safety and control services;
- Interference on frequency bands for other services on primary basis such as broadcast;
- Interference on license-free frequency bands

Actual investigation is often initiated if more complaints are received related to the same subject in a certain area.

Does the apparatus involved meet the relevant requirements and are they used and maintained as intended?

In the case of an interference between electronic or electric equipment under the scope of the EMCD and radio and telecommunications equipment or other equipment, the responsible national authority should investigate whether the victim equipment and the interfering equipment are used (and maintained) as intended and comply with their relevant parameter requirements including if applicable complying with the essential immunity requirements of the EMC Directive or other product Directives;

Notes:

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1. *Complaints could be related to equipment that:*

- *was marketed before the regime of the EMC Directive (or other Directives covering EMC aspects) which would mean that no CE marking may be affixed, or;*
- *was marketed under the regime of the EMCD and contains a CE marking;*
- *has been modified by the end user.*

That means that the disturbing equipment or the equipment being disturbed may not necessarily need to conform to the essential requirements of the Directive. The authorities will take account of this when treating complaints and initiating any corrective actions.

2. *Meeting the requirements of the EMC Directive may thus not prevent individual equipment from causing interference under certain operation and environmental conditions. This is due to the fact that it is impossible to apply the essential requirements in such a manner that all disturbance is avoided at any location or under any circumstance and due to the fact that the users of both victim and interfering equipment:*

- *may not abide the user instructions made in order to avoid disturbance;*
- *may not operate and maintain the equipment in the manner instructed by the manufacturer;*
- *are in general not restricted to modify equipment in whatever manner.*

National authorities could decide not to deal with an interference complaint because they consider the complaint as not justified for reasons of (for example):

- *the user of the equipment is directly confronted with the fact that the complaint is due to his own actions (for example in the case of complaints related to electric discharge – ESD);*
- *the complaint is caused by the operation of his own equipment on other equipment that is under his control;*

it is clear that the complaint is due to a lack of maintenance or insufficient quality of the equipment.

The complainant will in most cases be able to take direct action himself, involving either the manufacturer of the product, or the shop where he bought the equipment or not bother about the complaint.

Most of the complaints that are being treated by the authorities are those where the emission of an equipment is disturbing other equipment not under the control of the

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owner of the disturbing equipment (“third party equipment”). In most cases the owner of the victim equipment may also not be aware of the actual source of the disturbance and is lacking the means to take action himself.

However, although dealing with interference complaints is dealing with an individual case at a specific location under specific conditions of use, it may give rise to suspicion that a product is involved that was marketed without complying with the essential requirements. If that is the case dealing with the complaint could lead to further enforcement action that is the competence of [market surveillance](#).

Not all complaints being dealt with by the authorities are related to EMC problems caused by equipment not fulfilling the EMC essential protection requirements but may be triggered by aspects such as:

- Frequency management problems;
- Problem of sharing of frequencies;
- Non-conformity of the (radio) network;
- Influence of foreign radio stations and pirate stations
- Equipment shortcomings, lack of sufficient maintenance

Some examples of interference complaints which normally can not, or will not be further investigated needs to be accepted by parties are:

- Mutual interference on common frequencies;
- Radio services disturbed by equipment using official ISM frequencies;
- Technical defects at the receiver site or lack of receiver technical quality;
- Lack of signal strength in the case of radio (television) broadcast reception;
- Actual Interference not observed or identified.

5.4.2. *Complaints resolution process*

If the equipment involved meets the relevant requirements and is used and maintained as intended, then the process of interference resolution starts

For successful detection and elimination of interference sources it is necessary for the authorities to gather appropriate detailed data on the interference source as well as the victim equipment.

Enforcement personnel should be given the necessary access to obtain that information.

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Most of the complaints can be solved thanks to the professional guidance given by the Enforcement personnel of the National Authorities.

Regardless of meeting the requirements of the EMC directive, in exceptional cases National Authorities can take special measures under article 4.2 in order to overcome an existing or predicted EMC problem.

5.4.3. *Specific situation for fixed Installations*

Where there are indications of non-compliance of a fixed installation, in particular, where there are complaints about disturbances being generated by the installation, the authorities concerned may request evidence of compliance of the fixed installation, and, when appropriate, initiate an assessment. Where non-compliance is identified, the competent authorities may impose appropriate measures. The manner of dealing with complaints of fixed installations is comparable to that of dealing with complaints of apparatus.

6. NOTIFIED BODIES

6.1. General concept

In most Directives Notified Bodies play a specific mandatory role in the conformity process, e.g. as an independent test house or certification body carrying out the conformity assessment procedures specified in those Directives and based on the [modules](#) as described in the [Blue Guide](#).

The EMC Directive is different in the sense that the involvement of the NB in the process is **totally voluntary** and the service of the NB is only by helping the manufacturer, or his authorised representative within the Community in the conformity assessment process for his apparatus.

Actually the EMC Directive applies module A (Internal control of production) of the Blue Guide which does not require the mandatory involvement of a NB.

The difference between any other third party providing the manufacturer help and the service of the NB, is only that the NB takes some limited form of responsibility in areas of public interest and, therefore, is answerable to the Competent National Authority that designated the NB.

Member States take final responsibility for the competence of the NB; therefore, they must verify the competence of the NB. This is based on the [minimum criteria](#) given in Annex IV of the EMC Directive in conjunction with essential requirements and the task of the NB in question.

The Competent Authority will thus assess that the NB is competent and capable of carrying out its task, and that it can demonstrate the required level of independence, impartiality and integrity. Furthermore, the competence of the NB is subject to surveillance by the Authority, which is carried out at regular intervals.

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To be eligible a NB must be either:

- a legal entity established on the territory of the EU Member State and, thus, come under its jurisdiction, or
- a legal entity established on the territory of the State that has an MRA in operation with the European Union, covering the EMC Directive and its application and, thus, come under its jurisdiction.

Notes:

1. *Mutual Recognition Agreements - MRA are established between the Community and the Government of third countries, which are on a comparable level of technical development and have a compatible approach concerning conformity assessment. Six MRA 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](#)*
2. *In all cases where this Guide mentions Notified Bodies it automatically includes the CABs in other Countries designated under Directive 2004/108/EC. Where Notifying or Designating Member State Authorities are mentioned in this Guide it also includes those in MRA countries.*

6.2. Selection of a Notified Body by the Manufacturer

The EU Commission publishes in the Official Journal of the European Union a list of NB and keeps it up to date. However there is a website list of appointed EU NB's and MRA EMC CAB's. The lists include the address details of each organisation as well as the tasks (scope of Designation) for which it has been notified.

When selecting a notified body, manufacturers shall consider the following

- (1) A Notified body can only render its services within its scope of designation which may be limited for certain categories of apparatus, certain essential requirements or certain other specific aspects.
- (2) The NB is free to offer its services, within its scope of notification, to any manufacturer established either inside or outside the Community. The NB may carry out its activities on the territory of other Member States or any other third country and at any premises (for example at manufacturers' premises). Although the NB must be established on the territory of the Notifying Member State, it may have activities or personnel outside that Member State.
- (3) Manufacturers are free to choose any NB that has been designated, either from those established within the EU Member States or within the MRA countries. 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.

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- (4) 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 products. This also applies to situations where modifications to the original assessed apparatus are being carried out.
- (5) The EMC Directive does not restrict the manufacturer in asking more than one NB for help for the same apparatus. Also there is no obligation for the NB to ask the manufacturer whether or not another NB has been involved (or is involved) in the process of performing an assessment.
- (6) If the apparatus is also subject to other Directives that require the intervention of a NB then there may be advantage in selecting a NB that can also operate for those other Directives. However there is no obligation for the manufacturer to select one NB capable to cover all the necessary Directives applicable to his apparatus.

6.3.Rights and Obligations of Notified Bodies

Notified bodies are advisory bodies. However, unlike private expertise, they are obliged to fulfil certain obligations, as stated in Annex III (in terms of involvement in the conformity assessment procedure) and in Annex VI of the Directive.

When participating to the conformity assessment procedure, the notified body shall:

- (1) process the data in an expeditious manner,
- (2) communicate to the manufacturer that either the technical documentation properly demonstrates that the requirements of the Directive have been met or that it does not,
- (3) provide the manufacturer or authorised representative with a NB statement, if the compliance of the apparatus is confirmed. The statement shall not be conditional or limited in time. The statement (opinion) must be based on its own professional assessment of compliance with the requirements of the EMC Directive, based on the material provided by the manufacturer.
- (4) make adequate arrangements to ensure confidentiality of the information obtained in the course of conformity assessment. These arrangements must ensure that no results or other information is disclosed to any other party than the National Competent Authority in question, and to the client (manufacturer).
- (5) have under its control the necessary personnel, who have sufficient knowledge and experience relating to the apparatus and conformity assessment procedure in question, and who are subject to appropriate training. In particular, knowledge and experience should relate to relevant regulatory requirements and enforcement policies, European and international standardisation activities, relevant technologies, production methods and verification procedures, and normal conditions of use of the apparatus in question.

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- (6) have documented procedures for the identification, review and resolution of all cases where conflict of interest is suspected or proven, to safeguard objectivity, impartiality and operational integrity the NB and its staff responsible for the activities carried out as a NB.
- (7) be adequately insured to cover its activity. The scope and overall financial value of liability insurance must correspond to the level of activity of the NB.

Note : The NB formally can subcontract limited tasks, as long as these can be defined as a coherent part of the operation. However, the NB remains entirely responsible for the work carried out for it by the subcontractor. Subcontracting does not entail the delegation of powers or responsibilities. NB Statements are always solely issued in the name and under the responsibility of the NB. Subcontracting shall not breach the confidentiality of the information obtained.

The notified body is appointed by Member States to perform exclusively the tasks described in the directive. The notified body shall not go beyond this assignment. In particular, the Notified body shall not:

- (1) restrict its service to any specific party nor have any conditions applied if not specifically covered by the EMC Directive. (e.g. request to have the quality assurance system implemented by the manufacturer certified by the NB before the NB performs the task for the manufacturer according to the Directive)
- (2) Impose testing to be done in a specific laboratory or by a specific party, where the NB indicates that actual test data should be required in order to come to a positive statement.
- (3) impose that they assess the manufacturer's production system, test system or quality system but if any of these are relevant to the argument contained in the technical rationale it will be up to the manufacturer to demonstrate they are of a quality to fulfil their function.
- (4) give the impression that other activities are linked with the task described in Directive for the NB, when the Notified Body is part of an organisation that also performs other activities in the field of EMC (such as operating as EMC test laboratory).
- (5) offer or provide additional services under the name as NB. They should also ensure that their activities outside the scope of the Directive do not compromise or diminish confidence in their competence, objectivity, impartiality or operational integrity as NB.
- (6) as part of his activities as Notified body, provide or prepare for the manufacturer the EC Declaration of Conformity and/or the Technical Documentation of the apparatus,
- (7) require the manufacturer to mention the name number or logo of the NB on the manufacturers Declaration of Conformity.

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Additionally, The Notified Body cannot be the manufacturer of the product, the authorised representative, a supplier or their commercial competitor, nor offer or provide (or have offered or provided) consultancy or advice to any of these parties as regards the design, construction, marketing or maintenance of the products in question. This is to safeguard objectivity, impartiality and operational integrity the NB and its staff responsible for the activities carried out as a NB.

6.4.Coordination between Notified Bodies.

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

The Commission is represented in ECACB. Governmental experts and representatives of the authorities as well as the European standards organisations (CEN, CENELEC & ETSI) and relevant European federations or representatives of other interested parties can participate as observers in the ECACB.

Each NB (and MRA CAB) is entitled to be member of the ECACB and attend its meetings.

However, the NB's are not obliged to participate in meetings of ECACB, if they keep themselves informed of, and apply as general guidance, the administrative decisions and documents produced by the ECACB. The relevant working documents, meeting reports, recommendations and guidelines elaborated by ECACB are available to all NB, whether they have taken part in the meetings or not.

The ECACB issues information sheets ([Technical Guidance Notes – TGN](#)), which have been established in order to assist the NB in their task, in accordance with the terms of the EMC Directive.

These TGN's have been discussed by the EMCWP and no objection was raised to publish them as agreed position and make them available in the public domain. All parties should be aware of their existence; however, they shall keep in mind that they can use them only as general reference.

It is also advisable that NB's closely follow the developments in European EMC standardisation either by taking part directly or be represented in European standardisation, or otherwise ensure that they know the situation of relevant (harmonised) standards.

6.5.Complaints regarding the service of the NB

The NB shall have a policy and procedure for the resolution of complaints received from clients or other parties. This may be done in accordance [with ISO 10002](#) (Quality management -- Customer satisfaction -- Guidelines for complaints handling in organizations) or similar procedures. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the NB.

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Where a manufacturer has a complaint regarding the service of the NB performed, he should preferably first file a complaint with the NB in question.

Any complaint regarding the service of the NB can further be filed by the manufacturer to the National Designating Authority or the National Authority in control of market surveillance. If the complaint is related only to aspects that are covered by a National Accreditation Body then the complaint can be also filed with that body.

Where non-compliant apparatus has been subject to the conformity assessment procedure involving the service of a NB, and includes a positive statement from the NB regarding the particular essential requirement being in non-compliance, 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. Since the EMC Directive does not specify any penalty, Member States remain free to choose the sanctions to be used regarding the author. These penalties must be analogous to those applicable to sanctions of a similar nature and importance. In addition, these penalties must be effective, proportionate and dissuasive.