

The New EMC Directive 2004/108/EC

In the process of the review I have tried to spell out in words what is often referred to as a section number. This helps reduce the need to flip pages as one reads this. Please understand, this is a summary and the “Official Directive” is the final word.

The new EMC directive is broken down into three sections.

1. Why, Goals and Requirements

It begins with why the old directive was modified, and the goals and requirements of the new directive.

The introduction describes the reasons for reviewing the old directive and how the SLIM Committee reviewed it. It articulates that the member states are responsible for ensuring protection, that protection should be fair and effective, and that the provisions should be harmonized to ensure free movement of goods. Additionally, it explains that the directive should cover both apparatus and fixed installations. Separate provisions should be made for each. An apparatus is described as a type of equipment that moves freely within the community, whereas fixed installations are permanently installed assemblies of various types of apparatus and other appropriate devices for use at a predefined location.

Radio Equipment and Telecommunication Terminal Equipment (R&TTE), should not be covered by this directive because they are already regulated by their own directive, as are aircraft and equipment intended to be fitted into aircraft. The directive need not regulate equipment inherently benign in terms of electromagnetic compatibility. The new directive should not cover safety, as it is handled by a separate national legislation. The directive should refer to finished apparatus commercially available for the first time in the community market. Certain components or subassemblies should, under certain conditions, be considered an apparatus, as they are made available to the end-user. The principles of the directive shall be based on the new approach using technical harmonized standards. In accordance with that approach the design and manufacture of equipment is subject to the essential requirements of electromagnetic compatibility. Standards written by the committee's of CEN, CENELEC and ETSI shall be recognized as competent instructions for meeting the directive.

A standard reflects generally state-of-the-art knowledge once its references are published in the official journal of the European Union. Compliance with it should give a presumption of conformity with the relevant essential requirements, although other means of demonstrating such conformity should be permitted. Compliance with a harmonized standard means conformity with its provisions.

Manufacturers of equipment intended to be connected to networks shall design such equipment in a way that prevents the network from suffering unacceptable degradation of service when used under normal operating conditions. Network operators should construct their networks in such a way that the manufacturer of equipment likely to be connected to the networks do not suffer a disproportionate burden in order to prevent networks from suffering unacceptable degradation of service.

Once the manufacturer has met the requirements, it should be possible to place the apparatus on the market and put it into service once it bears the CE marking attesting to compliance with this directive. Conformity assessment should be the responsibility of the manufacturer, and does not need to involve an independent conformity assessment body (Notified Body). Manufacturers should be free to use the services of such a body if they so desire. The conformity assessment obligation should require the manufacturer to perform an electromagnetic compatibility assessment based on relative phenomenon in order to determine whether or not the apparatus meets the protection requirements of the directive. When the apparatus is capable of having different configurations, electromagnetic compatibility

assessment should confirm whether the apparatus meets the protection requirements in the configurations foreseeable by the manufacturer as representative of normal use in the intended application. In such cases, it should be sufficient to perform an assessment on the basis of the configuration most likely to cause the maximum emission disturbance and the configuration most susceptible to disturbance.

Fixed installations, including large machines and networks, may generate electromagnetic disturbance or be affected by it. Fixed installations and apparatus should be subject to a coherent and comprehensive regime of essential requirements. It should be possible to use harmonized standards for fixed installations in order to demonstrate conformity with the essential requirements covered by such standards. Fixed installations need not be subject to the fixation of the CE marking or the declaration of conformity. It is not required to test the apparatus used in the fixed installations isolated from the installations. Such apparatus should therefore be exempted from the conformity assessment procedures normally applicable to apparatus. However, such apparatus shall not be permitted to compromise the conformity of the fixed installations, into which it is incorporated. Should the apparatus be incorporated into more than one identical fixed installation, identifying the electromagnetic compatibility characteristics of these installations should be sufficient to ensure the conformity assessment procedure.

A transitional period is necessary in order to ensure manufacturers and other concerned parties are able to adapt to the new regulatory requirements. The objective of this directive is, namely, to ensure the functioning of the internal market by requiring equipment to comply with adequate levels of electromagnetic compatibility that cannot be sufficiently achieved by member states. Thus, by reason of its scale and effect, it is better achieved at the community level. This directive does not go beyond what is necessary in order to achieve that objective. The directive, 89/336/EEC should therefore be repealed.

2. General provisions.

Subject matter and scope.

The new directive regulating electromagnetic compatibility of equipment aims to ensure the functioning of the internal market by requiring equipment to comply with adequate levels of electromagnetic compatibility. Equipment is defined in article 2 (Definitions).

This directive shall not apply to equipment when covered under the radio equipment and telecommunication terminal directive R&TTE, nor aeronautical products, parts and apparatus, nor radio equipment used by amateur radio operators. This latter exemption applies to kits of components to be assembled by the radio amateurs and commercial equipment modified by radio amateurs, but does not exempt the equipment that is available commercially.

The directive shall not apply to equipment incapable of generating or contributing to electromagnetic emissions and/or operates without unacceptable degradation in the presence of electromagnetic disturbance as normally seen in its intended use (begin equipment).

When the equipment referred to by this directive is wholly or partially laid down more specifically by other community directive(s) (covering electromagnetic compatibility) this directive shall not apply to that equipment.

Article 2

Definitions

Equipment: any apparatus or fixed installation.

Apparatus: any finished appliance or combination thereof, made commercially available as a single functioning unit intended for the end-user and liable to generate electromagnetic disturbances or be affected by such disturbances.

Fixed installations: a particular combination of several types of apparatus and are applicable to other devices, which are assembled, installed and intended to be used primarily at a predefined location.

Electromagnetic compatibility: the ability of equipment to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbances to other equipment.

Electromagnetic disturbances: any electromagnetic phenomena that may degrade the performance of the equipment

Immunity: the ability of equipment to perform as intended.

Safety purposes: the purpose of safeguarding human life or property.

Electromagnetic environment: all electromagnetic phenomena observed in a given location.

The following shall be defined as apparatus:

Components or subassemblies intended to be incorporated into an apparatus by the end-user.

Mobil installations defined as combination of apparatus and where applicable, other devices intended to be moved and operated in a range of locations.

Article 3

Placing on the market or putting into service.

Member's states shall take all appropriate measures to ensure the equipment placed on the market complies with the requirements of the directive when installed properly, maintained, and used in its intended purpose.

Article 4

Free movement of equipment

Member's states shall not impede the putting into service of equipment that complies with the directive. The directive shall not prevent the application of any member states having special concerns to overcome an existing or predicted electromagnetic compatibility problem at a specific site, and/or measurements taken for safety reasons to protect public telecommunication networks or receiving or transmitting stations when used for safety purposes in well-defined spectrum situations.

The special measures which have been accepted shall be published in the Official Journal.

Member states shall not create any obstacle for displaying or demonstrating at trade fairs exhibits or similar events, equipment which does not comply with this directive, provided a visible sign clearly indicates that such equipment may not be placed on the market and/or put into service until it is brought into conformity with this directive. Demonstration may only take place provided that the adequate measures are taken to avoid electromagnetic disturbances. (I would interpret this to mean immunity testing is not required but emission testing should be done to demonstrate equipment will not interfere at a show or special measures need to be taken to prevent interference).

Article 5

Essential requirements

See annex I (Essential requirements). Basically the apparatus should not interfere nor be interfered with.

Article 6

Harmonized standards

Harmonized standards: a technical specification adopted by and recognized by the European commission. The compliance of equipment with the relevant harmonized standards using references published in the Official Journal shall show a presumption on the part of the member states of conformity with essential requirements. A presumption of conformity is limited to the scope of the harmonized standards applied and the relevant essential requirements covered in such standards. When the member states or the commission considers the harmonized standards do not entirely satisfy the essential requirements referred to in Annex 1, they shall bring the matter before the standing standard committees stating its reasons.

Article 7

Conformity assessment procedure for apparatus.

Conformity can be met in two ways: (1) through the use of harmonized standards, and (2) using an Annex III (technical documentation file) which may or may not be presented to a Notified Body. The harmonized standard procedure is referred to in Annex II (called the internal production control or Harmonized standards route). This would allow the correct application of all relevant harmonized standards to references having been published in the official journal and shall be equivalent to carrying out the electromagnetic compatibility assessment. When the apparatus is capable of taking different configurations, a compatibility assessment shall confirm whether these apparatus meet the protection requirements and all possible configurations identified by the manufacturer as representative of its intended use.

The manufacturer shall draw up technical documentation providing evidence of the conformity of the apparatus with essential requirements of the directive. The manufacturer or his authorized representative in the community shall hold the technical documentation at the disposal of a competent authority for at least 10 years after the date of which such apparatus was last manufactured.

If neither the manufacturer, nor his authorized representative is established within the community, the application to hold the EEC declaration of conformity in the technical documentation at disposal of the competent authority shall be a person who places the apparatus on the community market. The manufacturer must take all measures to ensure the products are manufactured in accordance with the

technical documentation and with the provisions of the directive. Technical documentation should be drawn up in accordance with Annex IV (Technical Documentation and EC Declaration of Conformity).

Article 8

CE marketing.

Apparatus, which complies with all directives, shall bear the CE marking, which attests to that fact. The affixing of the CE marking shall be the responsibility of the manufacturer or his authorized representative in the community. Annex V describes the CE mark itself. If a competent authority establishes that the CE marking has been unduly affixed, the manufacturer or his authorized representative shall bring the apparatus into conformity with the provisions under the conditions imposed by the member state concerned.

Article 9

Other marks and information.

Each apparatus shall be identified in terms of type, batch, serial number or any other information, allowing for the identification of the apparatus. Each apparatus shall be accompanied by the name and address of the manufacturer, or, if they are not established within the community, the name and address of the authorized representative or person in the community for placing the apparatus on the market. The manufacturer shall provide information on any specific precautions that must be taken into account when the apparatus is assembled, installed, or maintained in order to ensure conformity.

Apparatus for which compliance with protection requirements is not insured in residential areas shall be accompanied by a clear indication of this restriction or use where appropriate, also on the packaging. The information required to enable the apparatus to be used in accordance with the intended purpose of apparatus shall be contained in the instructions accompanying the apparatus.

Article 10

Safeguards

When member states ascertain that the apparatus bearing the CE marking does not comply, they shall take all appropriate measures to withdraw the apparatus from the market, prohibit it from being placed on the market or being put into service, or restrict its free movement. The member state shall immediately inform the commission.

Article 11

Decisions to withdraw, prohibit or restrict the free movement of apparatus

Any decision taken to withdraw shall state the exact reason upon which it is based and shall notify without delay the party concerned. In addition, they shall notify them of available remedies. The parties shall have an opportunity to respond unless there is an urgency to the matter.

Article 12

Notify bodies

Member states shall notify the commission of the bodies designated to carry out the tasks referred to in Annex III (technical documentation file). This notification shall state whether the designated body is covered for all apparatus or whether the scope of the designation is limited to certain specific aspects. Bodies, which comply with assessment criteria established by the relevant harmonized standards for Notified Bodies, shall be presumed to comply with the criteria set in Annex VI (Criteria for Notified Bodies) covered by such harmonized standards. The commission shall publish in the official journal a list of Notified Bodies. If the member state finds a Notified Body no longer meets the criteria, they shall inform the commission.

Article 13

Fixed installations.

Apparatus, which has been placed on the market and may be incorporated into a fixed installation, is subject to all relevant provisions for the apparatus set out in the directive. However, **the provisions of Article 5, 7, 8 and 9 (Essential requirements, conformity assessment for apparatus, CE Marking and other marks of information) shall not be compulsory for apparatus that is intended to be incorporated into a given fixed installation and is otherwise not commercially available.** Note: **this would be taken into account in the assessment of the installation.** The accompanying documentation shall identify a fixed installation and its electromagnetic characteristics and shall indicate the precautions being taken to incorporate the apparatus into the fixed installation. When there are complaints about a disturbance being generated by the installation, the competent authorities on the member state concern may request evidence of compliance of the fixed installation and, when appropriate, initiate an assessment. When noncompliance is established, the competent authority may impose appropriate measures to bring the fixed installation into compliance. Member states shall set out the necessary provisions for identifying the person or persons responsible for the establishment of compliance of a fixed installation with the relevant essential requirements.

Final provisions.

Article 14

Repeal

Repeal the old directive (89/336/EEC) as of July 20, 2007.

Article 15

Transitional provisions

Member states shall not impede the placement on the market and/or putting into service equipment, which is compatible with the old directive prior to July 20, 2009. The new directive can be used as of July 20, 2007.

3. Annex I

Essential requirements referred to in Article 5

Protection requirements

Equipment shall be so designed and manufactured having regard to the state of art as to ensure the electromagnetic disturbance generated does not exceed the levels above which radio and telecommunication equipment or other equipment cannot operate as intended. It shall also have a level of immunity to electromagnetic disturbances to be expected in its intended use, which allows it to operate without unacceptable degradation of its intended use.

Specific requirements for fixed installations

A fixed installation shall be installed, applying good engineering practices and respecting the information on the intended use of its components, with a view to meeting the protection requirements set out above. These good engineering practices shall be documented and the documentation shall be held by a person who's responsible, at the disposal of the relevant national authorities for inspection purposes for as long as the fixed installation is in operation.

Annex II

Conformity Assessment procedure (using harmonized standards)

- 1. Assessment based on relevant phenomena using relevant harmonized standards.**
- 2. Take into account various configurations.**
- 3. Draw up technical documentation.**
- 4. Hold documentation for 10 years after last manufactured.**
- 5. Fill out a Declaration of Conformity.**
- 6. Have technical documentation available with person who places apparatus on market.**
- 7. Make sure apparatus is manufactured as described.**

Annex III

Conformity assessment procedure (using a Notified Body)

(Technical Documentation file)

This procedure consists of applying Annex II (internal protection control) as follows:

Manufacturer or his authorized representative in the community shall present the technical documentation to the Notified Body referred to in Article 12 (Notified Bodies) and request the Notified Body for an assessment. The manufacturer or his authorized representative in the community shall specify to the Notified Body the aspects of the essential requirements that must be assessed by the Notified Body. If compliance of the apparatus is confirmed, a Notified Body shall issue a statement to the manufacturer or his authorized representative in the community confirming the compliance of the apparatus. The statement shall be limited to those aspects of the essential requirements and, having been assessed by the Notified Body, the manufacturer shall add the statement to the technical documentation.

Annex IV

Technical documentation and EC declaration of conformity.

The technical documentation

Must enable the conformity of the apparatus with the essential requirements to be assessed. **It must cover the design and manufacture of the apparatus in particular, a general description of the apparatus, and evidence of compliance with the harmonized standards.** Where the manufacturer has not applied harmonized standards, or they are applied only in part, **a description or explanation of the steps taken to meet the essential requirements of the directive, including a description of electromagnetic compatibility assessment set out in Annex II (Emissions and Immunity), results of design calculations made, examinations carried out, test reports, etc, a statement from the Notified Body shall also be included when the procedure referred to in Annex III (Technical documentation file with a Notified Body) has been followed.**

EC declaration of conformity must contain

At least a reference to the directive, an identification of the apparatus in which it refers to, the name and address of the manufacturer and, where applicable, the name and address of the authorized representative in the community, and a date reference to the specifications under which the conformity is declared. To ensure the conformity of the apparatus with the provisions of this directive, **the declaration must contain the date of the declaration, and identify the person empowered to bind the Company and his authorized representative.**

Annex V

CE marking as referred to by the directive

Basically the same as previously described in the old directive. The CE marking is well defined by the new directive as it was previously.

Annex VI

Criteria for the assessment of bodies to be notified.

The Notified Bodies shall meet the following minimum criteria:

The Notified Body shall have available in its personnel technical competence and professional integrity, independence in preparing reports and performing validation, independence of staff and technical personnel in relation to all interested parties, maintenance of professional secrecy, and provisions for civil liability insurance. Fulfillment of these conditions should be verified at intervals by the competent authorities of the member state. This is basically the same as before. The principal difference is what was called Competent Bodies under 89/336/EEC is now called Notified Bodies under 2004/108/EC.