



Regulation

ON CONFORMITY ASSESSMENT, MARKING AND DOCUMENTS RELATING TO TELECOMMUNICATIONS TERMINAL EQUIPMENT, NETWORK EQUIPMENT AND FIXED INSTALLATION

Issued in Helsinki on 19 January 2007

The Finnish Communications Regulatory Authority (FICORA) has, by virtue of the Act on Radio Frequencies and Telecommunications Equipment (1015/2001; amendments up to 11/2007 included), prescribed as follows:

Chapter 1

Scope of application and definitions

Section 1

Scope of application

This Regulation lays down provisions on

- 1) the protection requirements relating to electromagnetic compatibility of telecommunications terminal equipment, network equipment and fixed installation of the network equipment;
- 2) the marking and other information relating to telecommunications terminal equipment and network equipment;
- 3) the conformity assessment procedure of telecommunications terminal equipment and related documentation;
- 4) documents relating to network equipment intended to be used at a predefined fixed installation and not provided for sale; and
- 5) the documentation and the procedure to be followed when fixed installations are made.

Section 2

Scope restrictions

This Regulation does not apply to

- 1) telecommunications terminal equipment referred to in section 24(1)(5) of the Act on Radio Frequencies and Telecommunications Equipment, or to
- 2) telecommunications terminal equipment being wholly or partly radio equipment as referred to in the Act on Radio Frequencies and Telecommunications Equipment, as provisions on conformity assessment and marking of such equipment are laid down separately.

Conformity assessment and marking requirements of chapter 2 and chapter 4 of this Regulation do not apply to network equipment which, according to section 21e(2) of the Act on Radio Frequencies and Telecommunications Equipment, is intended for incorporation into a given fixed installation and not provided for sale.

Section 3

Definition

Equipment means in this Regulation telecommunications equipment and fixed installations referred to in the Act on Radio Frequencies and Telecommunications Equipment as well as any other apparatus that may be affected by electromagnetic circumstances or generate electromagnetic disturbance.

Chapter 2

Technical requirements and standards

Section 4

Protection requirements relating to electromagnetic compatibility

Telecommunications terminal equipment, network equipment and fixed installation shall be constructed with regard to technology so that

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

2) the equipment 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.

Section 5

Applying harmonised standards

Telecommunications terminal equipment, network equipment and fixed installation is considered to fulfil the essential technical requirements referred to in section 20(1) of the Act on Radio Frequencies and Telecommunications Equipment and section 4 of this Regulation, if it complies with the relevant harmonised standards.

If a harmonised standard contains defects concerning essential requirements as referred to in section 20(1) of the Act on Radio Frequencies and Telecommunications Equipment, *telecommunications terminal equipment, network equipment and fixed installation* is considered to fulfil the essential technical requirements, if the harmonised standard is applied according to interpretation guidelines or conditions given by the European Commission, published in the Official Journal of the European Union.

Chapter 3

Documentation relating to telecommunications equipment and fixed installation

Section 6

Technical documentation relating to telecommunications terminal equipment

In addition to the *declaration of conformity* to the essential requirements referred to in section 21(2) of the Act on Radio Frequencies and Telecommunications Equipment, the manufacturer of the equipment, or his

authorised representative referred to in section 5 of the Act, shall in the conformity assessment procedure referred to in section 21(1)(1) (*internal product control*) or section 21(1)(3a) (*opinion of the notified body*) of the Act for the telecommunications terminal equipment establish a *technical documentation* which enables the conformity with the essential technical requirements to be assessed.

The manufacturer or his authorised representative referred to in section 5 of the Act shall further ensure that the technical documentation is applied in the manufacture of the telecommunications terminal equipment.

The technical documentation shall cover the design, manufacture and operation of the telecommunications terminal equipment, and

- 1) a general description of the product;
- 2) conceptual design and manufacturing drawings and schemes of, at least, components, sub-assemblies and circuits;
- 3) descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product;
- 4) a list of the harmonised standards applied and descriptions and explanations of the solutions adopted to meet the essential technical requirements where harmonised standards have not been applied or do not exist;
- 5) results of design calculations made, examinations carried out, etc.; and
- 6) test reports.

Section 7

Presenting technical documentation to notified body

In case conformity of telecommunications terminal equipment is assessed by means of quality control including an opinion of the notified body referred to in section 21(1)(3a) of the Act on Radio Frequencies and Telecommunications Equipment, the manufacturer or his authorised representative referred to in section 5 of the Act shall present the technical documentation referred to in section 6 above to a notified body referred to in section 4 paragraph 9 of the Act. At the same time each of the notified bodies must be informed of others who have received the technical documentation.

The equipment may be placed on the market four weeks after the technical documentation has been presented to a notified body or as soon as the notified body has issued its opinion about it. The notified body must inform the other notified bodies to whom the technical documentation was presented of its *negative* opinion.

Section 8

Documentation relating to telecommunications terminal equipment in full quality assurance

If conformity of telecommunications terminal equipment is assessed by applying the full quality assurance procedure referred to in section 21(1)(4) of the Act on Radio Frequencies and Telecommunications Equipment, the manufacturer shall, in addition to the *declaration of conformity* referred to in section 21(2) of the Act, also draw up documents regarding the designed products and the quality system used in the design, manufacture and inspection, to be presented to the notified body. Contents of the documentation and description of the full quality assurance procedure is given in Annex 1.

Section 9

Documentation relating to network equipment intended for fixed installation

The manufacturer or his authorised representative shall draw up the technical documentation relating to network equipment to be incorporated for a given fixed installation. The documentation shall include the following:

- 1) identification information: type, batch, serial number or any other information allowing for the identification of the apparatus;
 - 2) the name and address of the manufacturer or his authorised representative as referred to in section 5 of the Act on Radio Frequencies and Telecommunications Equipment;
 - 3) information about the fixed installation the equipment is intended for;
- and

4) precautions that must be taken when the equipment is installed in order to ensure that the fixed installation meets the requirements of section 4 of this Regulation.

Section 10

Documentation relating to fixed installation of network equipment

Technical implementation of a fixed installation shall be documented so that the documents contain information about the intended use of the components and the precautions for network equipment installation referred to in section 9, and how it has been ensured that the fixed installation as a whole meets the protection requirements referred to in section 4 of this Regulation.

The documentation shall also include the name of the person responsible for the fixed installation referred to in section 21e(3) of the Act on Radio Frequencies and Telecommunications Equipment.

The holder of the fixed installation is responsible for drawing up and keeping the documents. The holder is also responsible for keeping the documents regarding network equipment incorporated for a fixed installation. The documentation shall be held at the disposal of the relevant authorities for inspection purposes for as long as the fixed installation is in operation.

Chapter 4

Marking of equipment and other information

Section 11

Responsibility for markings and other information

The manufacturer or his authorised representative as referred to in section 5 of the Act on Radio Frequencies and Telecommunications Equipment is responsible for the marking of telecommunications terminal equipment and network equipment and for information about network equipment.

No other markings than those specified in this chapter may be affixed to the telecommunications terminal equipment and network equipment, if affixing

another marking reduces the visibility and legibility of the marking referred to in this chapter.

Section 12

Identification of telecommunications equipment

Telecommunications terminal equipment and network equipment shall be identified by means of type, batch or serial number and by the name of the manufacturer or the person responsible for placing the equipment on the market.

Section 13

CE marking of telecommunications equipment

Telecommunications terminal equipment and network equipment complying with the requirements referred to in section 20(1) of the Act on Radio Frequencies and Telecommunications Equipment shall bear the CE marking described in Annex 2 following this way to applicable extent a law on affixing the CE marking on certain products (1376/1994).

The CE marking shall be affixed so that the marking is visible, legible and indelible. The marking shall be affixed

- a) to the telecommunications terminal equipment or to its data plate and to the packaging and to the accompanying documents and
- b) to the network equipment or to its data plate, or if this is not possible due to the nature of the equipment, to the packaging and to the documents.

Markings that can be confused with the CE marking shall not be affixed to the equipment, to its packaging, or to the instructions for its use.

Section 14

Identification number of the notified body

Where conformity of *telecommunications terminal equipment* is assessed through the procedure referred to in section 7 or 8, the CE marking shall be

accompanied by the identification number of the notified body. The identification number shall be as high as the CE marking.

Section 15

Other information of the network equipment

Network equipment shall be accompanied by instructions for use or another document containing the following information:

- 1) information necessary for the use of the equipment according to the intended purpose;
- 2) information on any specific precautions that must be taken when the equipment is assembled, installed, maintained or used, in order to ensure that, when put into service, the equipment is in conformity with the protection requirements set out in section 4; and
- 3) information on restriction of use, if compliance with the protection requirements is not ensured in residential areas. Indication of such restriction of use shall also be on the packaging.

Chapter 5

Entry into force and information

Section 16

Entry into force

This Regulation enters into force on 20 July 2007 and will remain in force until further notice.

This Regulation repeals FICORA's Regulation of 6 June 2003 on the conformity assessment and marking of telecommunications terminal equipment (FICORA 22 F/2003 M).

Section 17

Information and publication

This Regulation is included in the Series of Regulations issued by the Finnish Communications Regulatory Authority and it can be obtained from the FICORA Customer Service Office:

Office address	Itämerenkatu 3 A, HELSINKI
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Helsinki 19 January 2007

Director-General

Rauni Hagman

on behalf of the Director
Deputy Director

Pekka Koskenheimo

Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC.

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.

Conformity assessment procedure referred to in section 8 of this Regulation¹

Full Quality Assurance as referred to in section 21 of the Act on Radio Frequencies and Telecommunications Equipment

1. Full quality assurance is the procedure whereby the manufacturer who satisfies the obligations of point 2 ensures and declares that the products concerned satisfy the applicable requirements of section 20 of the Act on Radio Frequencies and Telecommunications Equipment and of this Regulation. The manufacturer must affix the markings referred to in section 22 of the Act on Radio Frequencies and Telecommunications Equipment and chapter 4 of this Regulation to each product and draw up a written declaration of conformity according to section 21(2) of the Act on Radio Frequencies and Telecommunications Equipment.

2. According to section 21(4) of the Act on Radio Frequencies and Telecommunications Equipment, the **manufacturer must operate an approved quality system** for design, manufacture and final product inspection and testing as **specified in point 3**. The manufacturer is subject to surveillance as specified in point 4.

3. Quality system

3.1 The manufacturer must lodge an application for assessment of his quality system with a notified body referred to in section 4 of the Act and Radio Frequencies and Telecommunications Equipment.

The application must include:

- all relevant information for the products envisaged;
- the quality system's documentation.

3.2 The quality system must ensure compliance of the products with the applicable requirements. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must ensure a common understanding of the quality policies and procedures such as quality programmes, plans, manuals and records.

It must contain in particular an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality,
- the technical specifications, including the harmonised standards and technical regulations as well as relevant test specifications that will be applied and, where the standards referred to in section 5 of the Regulation will not be applied in full, the means that will be used to ensure that the essential requirements of this Regulation that apply to the products will be met,
- the design control and design verification techniques, processes and systematic actions that will be used when designing the products pertaining to the product category covered,

¹ Directive 1999/5/EC Annex V

- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out, as well as the results of the tests carried out before manufacture where appropriate,
- the means by which it is ensured that the test and examination facilities respect the appropriate requirements for the performance of the necessary test,
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.,
- the means to monitor the achievement of the required design and product quality and the effective operation of the quality system.

3.3 The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It must presume compliance with these requirements in respect of quality systems that implement the relevant harmonised standard.

The notified body must assess in particular whether the quality control system ensures conformity of the products with the requirements of this Regulation in the light of the relevant documentation supplied in respect of points 3.1 and 3.2 including, where relevant, test results supplied by the manufacturer.

The auditing team must have at least one member experienced as an assessor in the product technology concerned. The evaluation procedure must include an assessment visit to the manufacturer's premises.

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

3.4 The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and to uphold it so that it remains adequate and efficient.

The manufacturer or his authorised representative must keep the notified body that has approved the quality system informed of any intended updating of the quality system.

The notified body must evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in point 3.2 or whether a reassessment is required.

It must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

4. EC surveillance under the responsibility of the notified body

4.1 The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2 The manufacturer must according to section 21(4) of the Act on Radio Frequencies and Telecommunications Equipment allow the notified body access for inspection purposes to the locations of manufacture, inspection, testing and storage and must provide it with all necessary information, in particular:

- the quality system documentation,
- the quality records as foreseen by the design part of the quality system, such as results of analyses, calculations, tests, etc.,
- the quality records as foreseen by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.3 The notified body must carry out audits at reasonable intervals to make sure that the manufacturer maintains and applies the quality system and must provide an audit report to the manufacturer.

4.4 Additionally, the notified body may pay unexpected visits to the manufacturer. At the time of such visits, the notified body may carry out tests or have them carried out in order to check the proper functioning of the quality system where necessary. It must provide the manufacturer with a visit report and, if a test has been carried out, with a test report.

5. The manufacturer must, according to section 21(5) of the Act on Radio Frequencies and Telecommunications Equipment, for a period ending at least 10 years after the last product has been manufactured, **keep** at disposal of the national authorities of states within the European Economic Area:

- the documentation referred to in the second indent of point 3.1,
- the updating referred to in the second paragraph of point 3.4,
- the decisions and reports from the notified body which are referred to in the final paragraph of point 3.4 and in points 4.3 and 4.4.

6. Each notified body must make available to the other notified bodies the relevant information concerning quality system approvals including references to the product(s) concerned, issued and withdrawn.

FICORA 22 G/2007 M

ANNEX 2

Markings of telecommunications terminal equipment:



CE-marking. Notified body
identification number²

The CE-marking must have a height of at least 5 mm, except where this is not possible on account of the nature of the apparatus.

² The notified body identification number shall be affixed only in situations referred to in section 7 or 8 of this Regulation.