

Decision on making available on the market of radio equipment

On grounds of the provisions of the Art. 108 of the Constitution of Romania, republished, of Art. 22 paragraph (1) of the Government Ordinance no. 111/2011 on the electronic communications, approved, with amendments and completions, by Law no. 140/2012, with subsequent amendments and completions, as well as of art. II of the Government Ordinance no. 8/2012 amending the Government Ordinance no. 20/2010 on the establishment of some measurements for the harmonized enforcement of the European Union legislation which harmonizes the rules on products marketing, approved with amendments and completions by Law no. 55/2015,

Romanian Government adopts the present decision

Chapter I – General provisions

Art. 1. – (1) The subject matter of the present decision is to lay down:

- a) the essential requirements of the radio equipment;
- b) conditions for placing on the market, making available on the market and/or putting into service of radio equipment;
- c) conditions and requirements in order to notify the conformity assessment bodies.

(2) Radio equipment that falls within the scope of this decision are not subject to Government Decision no. 409/2016 establishing the conditions for placing on the market of low-voltage electrical equipment, except as provided in Art. 3 paragraph (1) a).

(3) The present decision shall not apply to:

- a) equipment provisioned in annex no. 1;
- b) radio equipment exclusively used for activities concerning national defense, public order and State security, including protection of the economic interests of the State, whether these interests concern the State security, and the activities of the State in the area of criminal law.

Art. 2. – (1) For the purposes of this decision, the following definitions apply to:

- 1) *accreditation* – within the meaning of art. 2 point 10 of the Regulation (EC) no. 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the products marketing and repealing Regulation (EEC) no. 339/93;
- 2) *radio equipment class* – means the group including certain categories of radio equipment considered similar under this decision and the radio interfaces for which this radio equipment is intended;
- 3) *radio communications* – means communications via radio waves;
- 4) *distributor* – means any natural or legal person in the distribution and supply chain, other than the manufacturer or the importer, who makes radio equipment available on the market;
- 5) *radio equipment* – means an electrical or electronic product that transmits and/or receives deliberately radio waves in order to perform radio communications and/or radio determination either an electrical or electronic product which must be

completed with an accessory, such as an antenna, so as to transmit and/or receive deliberately radio waves on the purpose of radio communication and/or radio determination;

6) *conformity assessment* – means the process which examines how the essential requirements provisioned in this decision relating to radio equipment were fulfilled;

7) *importer* – means any natural or legal person, established in Romania or in other Member States of the European Union, who places radio equipment from a third country on the Union market or from another Member State of the Union;

8) *radio interface* – means technical specification on the regulated use of radio spectrum;

9) *harmful interference* – within the meaning of the definition provisioned in Art. 4 par. (1) point 12 of the Government Ordinance no. 111/2011 on the electronic communications, approved, with amendments and completions, by Law no. 140/2012, with subsequent amendments and completions

10) *placing on the market* – means the first making available of radio equipment on the market in Romania or from another Member State of the European Union;

11) *Union harmonization legislation* – in accordance with the definition provided in Art. 2 point 21 of the Regulation (EC) no. 765/2008;

12) *EC marking* – means a marking by which the manufacturer indicates that the radio equipment is in conformity with the applicable requirements set out in Union harmonization legislation providing for its affixing;

13) *radio station operator* – means any person to put into service or use a radio station under the law;

14) *economic operators* - means the manufacturer, the authorized representative, the importer and the distributor;

15) *conformity assessment body* - means a body that performs a public service under the public power, consisting of conformity assessment activities including calibration, testing, certification and inspection;

16) *national accreditation body* - within the meaning of the definition provisioned in Art. 2 point 11 of the Regulation (EC) no. 765/2008;

17) *harmful interference* – within the meaning of the definition provisioned in Art. 2 paragraph (1) point 18 of the Government Decision no. 487/2016 on the electromagnetic compatibility;

18) *manufacturer* - means any natural or legal person who manufactures radio equipment or for which such equipment is designed or manufactured, and markets that equipment under his name or trade mark;

19) *putting into service* – means the first use of radio equipment in the Union by its end-user;

20) *making available on the market* - means any supply of a radio equipment for distribution, consumption or use on the market in Romania or in another Member State of the European Union market in the course of a commercial activity, whether in return for payment or free of charge;

21) *radio determination* – means the determination of the position, velocity and/or other characteristics of an object, or the obtaining of information relating to those parameters, by means of the propagation properties of radio waves;

22) *recall* - means any measure aimed at achieving the return of radio equipment that has already been made available to the end-user;

23) *authorized representative* - means any natural or legal person established in Romania or in a Member State of the European Union, who has received a written

mandate from a manufacturer to act on his behalf in relation to specified tasks;

24) *withdrawal* - means any measure aimed at preventing radio equipment in the supply and distribution chain from being made available on the market;

25) *technical specification* - means a document that prescribes technical requirements to be fulfilled by radio equipment;

26) *harmonized standard* – within the meaning of the definition provisioned in Art. 2 point 1 letter c) of the Regulation (EU) no. 1025/2012 of the European Parliament and of the Council of 25 October 2012 on the European standardization, amending Directives 89/686/EEC and 93/15/EEC of the Council and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Decision 87/95/EEC of the Council and Decision no. 1673/2006/EC of the European Parliament and of the Council;

27) *traceability* – means identification of persons responsible for the manufacturing, import, intra-Community purchasing, placing on the market and making available on the market of radio equipment;

28) *radio waves* – means electromagnetic waves with frequencies below 3000 GHz, propagated in space without an artificial guide.

(2) The provisions of paragraph (1) is completed properly with provisions of Art. 4 paragraph (1) of the Government Emergency Ordinance no. 111/2011, approved with amendments and completions by Law no.140/2012, with subsequent amendments and completions, as well as those of Regulation (EC) No. 765/2008.

Art. 3. – (1) Radio equipment shall be constructed to comply with the following requirements:

a) the protection of health and safety of persons and of domestic animals, and the protection of property including the objectives with respect to safety requirements set out in the Government Decision no. 409/2016, but with no voltage limit applying;

b) an adequate level of the electromagnetic compatibility as it is set out in Government Decision no. 487/2016.

(2) Radio equipment shall be so constructed that it both effectively uses and supports the efficient use of radio spectrum in order to avoid harmful interference.

(3) Radio equipment within certain categories or classes shall be so constructed that it complies with the following essential requirements:

a) radio equipment interworks with accessories, in particular with common chargers;

b) radio equipment interworks via networks with other radio equipment;

c) radio equipment can be connected to interfaces of the appropriate type throughout the Union;

d) radio equipment does not harm the network or its functioning nor misuse network resources, thereby causing an unacceptable degradation of service;

e) radio equipment incorporates safeguards systems to ensure that the personal data and privacy of the user and of the subscriber are protected;

f) radio equipment supports certain features ensuring protection from fraud;

g) radio equipment supports certain features ensuring access to emergency services;

h) to have certain features that facilitated its use by persons with disabilities;

i) radio equipment supports certain features in order to ensure that software can only be loaded into the radio equipment where the compliance of the combination of the radio equipment and software has been demonstrated.

Art. 4. – (1) Manufacturers of radio equipment and of software allowing radio equipment to be used as intended and which are part of those categories or classes of radio equipment provided by the European Commission must provide the National Authority for Management and Regulation in Communications, hereinafter referred to as *ANCOM*, and the European Commission information on the compliance of radio equipment and software combinations provided with the essential requirements set out in Art. 3.

(2) Such information provided at paragraph (1) shall result from a conformity assessment carried out in accordance with Art. 18 and 19 and shall be given in the form of a UE statement of compliance which includes the elements set out in Annex no. 6.

(3) Depending on the specific combinations of radio equipment and software, the information provisioned at paragraph (1) shall precisely identify the radio equipment and the software which have been assessed, and it shall be continuously updated.

Art. 5. – (1) As from 12 June 2018, manufacturers shall register in the system provided by the European Commission, radio equipment types within categories of radio equipment affected by a low level of compliance with the essential requirements set out in Art. 3.

(2) Registering is done before the radio equipment within categories provisioned at paragraph (1) to be placed on the market.

(3) When registering such radio equipment types provisioned at paragraph (1), manufacturers shall provide some, or where justified, all elements of the technical documentation listed at letters a) and d) - i) of Annex no. 5.

Art. 6. – (1) It shall allow the placing on the market, putting into service and/or use only of radio equipment if it complies with the requirements of this Directive when it is properly installed, maintained and used for its intended purpose.

(2) Notwithstanding the provisions of paragraph (1), the temporary display and/or demonstrations of radio equipment which does not comply with this Directive are allowed at trade fairs, exhibitions and similar events, provided that a visible sign clearly indicates that such radio equipment may not be made available on the market or put into service until it has been brought into conformity with this Directive.

(3) Use of radio equipment demonstrations can take place only if appropriate measures are taken, as provided by ANCOM in order to avoid harmful interference, electromagnetic disturbances, and risks of health or safety of persons and of domestic animals and the protection of property.

Art. 7. – (1) Authorization of putting into service and use of radio equipment, if it complies with the requirements of this decision, is fulfilled by ANCOM in accordance with the provisions of the Government Emergency Ordinance no. 111/2011, approved, with amendments and completions, by Law no. 140/2012, with subsequent amendments and completions.

(2) Additional to the requirements set out in Art. 6 paragraph (1), ANCOM may impose requirements on the putting into service and/or use of radio equipment, requirements on use of used radio frequencies, for reasons relating to:

- a) effective and efficient use of radio spectrum;
- b) avoidance of harmful interference or electromagnetic disturbance;

c) transgression of the benchmarks set under the law on limitation of general population exposure to electromagnetic fields.

(3) Requirements set out in paragraph (2) can be imposed without this being in contradiction with provisions of Art. 6 paragraph (1) applicable to the radio equipment on making available on the market, putting into service and/or use of equipment or with usage conditions of radio frequencies established by law.

(4) In order to comply with rules limiting public exposure to electromagnetic fields effects, putting into service and use of radio communication stations are subject to the documentation that includes the necessary data on the performance of the essential requirement provided in Art. 3 paragraph (1) letter a) including non-ionizing electromagnetic radiation measurements.

(5) For existing radio stations, the documents referred to in paragraph (4) shall be made within 12 months from the date of entry into force of this decision. For radio stations to be installed after the effective date of entry into force of this decision, the documentation shall be made within 30 days from the date of its putting into service.

(6) In order to continuously ensure essential requirement provisioned in Art. 3 paragraph (1) letter a), radio communication stations are re-checked at intervals not exceeding 24 months. In this situation, the documents referred to in paragraph (4) are updated with data obtained after rechecking.

(7) ANCOM may apply at any time, in order to ensure the compliance with paragraph (2) letter c) the presentation of documentation made according to paragraphs (4)-(6).

Art. 8. – ANCOM notifies, in accordance with the procedure laid down in Government Decision no. 1016/2004 on measures for the organization and exchange of information on technical standards and regulations and of rules on information society services between Romania and the Member States of the European Union and the European Commission, with subsequent amendments and completions, radio interfaces they intend to regulate, except:

a) radio interfaces that fully comply and without any divergence the provisions of the European Commission on the harmonized use of radio spectrum adopted under Decision No. 676/2002/EC of the European Parliament and of the Council of 7 March 2002 on a regulatory framework for policy management of radio spectrum in the European Community (Decision for radio spectrum); and of

b) radio interfaces that correspond to certain radio equipment which can be put into service and used without restrictions within the European Union, in accordance with the documents adopted by the European Commission.

Art. 9. – (1) It cannot be prevented making available on the market of radio equipment which complies with the provisions of this decision.

(2) In Romania are prohibited the manufacture, import, possession, advertising, placing on the market, making available on the market, putting into service and/or use of radio equipment or devices designed to cause harmful interference

Chapter II – Obligations of economic operators

Art. 10 - Manufacturers have the following obligations:

a) to affix on the radio equipment placed on the market the registration number assigned by the European Commission for each type of radio equipment registered under Art. 5;

- b) to ensure that radio equipment placed on the market have been designed and manufactured in accordance with the essential requirements set out in Art. 3;
- c) to ensure that the radio equipment is constructed so that it can be used without violating the applicable requirements on the use of radio spectrum;
- d) to establish the technical documentation provided in Art. 23 and carry out the relevant conformity assessment procedure provided in Art. 18 and 19 or have it carried out;
- e) to draft EU declaration of conformity and to affix the EC mark, where it has been demonstrated the compliance of the radio equipment with the applicable requirements by the conformity assessment procedure provided in Art. 18 and 19;
- f) to keep the technical documentation and the EU declaration of conformity for 10 years after the radio equipment was placed on the market;
- g) to establish procedures that ensure continued conformity of series production with the provisions of this decision and to ensure that changes in the design or changes to radio equipment features and changes of the harmonized standards under Art. 17 paragraph (1), or of other technical specifications in relation to which the conformity of radio equipment is declared are properly taken into account;
- h) to conduct in order to protect the health and safety of end-users, whenever this is justified by the risks of radio equipment, technical tests at random on the radio equipment made available on the market, investigate and, where appropriate, to keep a register of complaints on non-compliant radio equipment and their recalls;
- i) to inform distributors about the monitoring activities referred to letter h);
- j) to ensure that on the radio equipment they place on the market is marked type, batch or serial number or any other element allowing their identification; where the size or nature of radio equipment does not allow it, to ensure that the required information is provided on the packaging or in a document accompanying the radio equipment;
- k) to indicate on radio equipment the name, trade name or registered trademark and mailing address at which they can be contacted; where the size or nature of radio equipment does not allow it, this information is provided on the packaging or in a document accompanying the radio equipment; the address specified by the manufacturer must indicate a single contact point and the contact details have to be in Romanian;
- l) to ensure that the radio equipment is accompanied by user instructions and safety information referred to in Art. 11, written in Romanian;
- m) to ensure that each radio equipment is accompanied by a copy of the EU declaration of conformity or a simplified EU declaration of conformity, written in Romanian; the simplified EU declaration of conformity must contain the exact Internet address where you can obtain the full text of the EU declaration of conformity;
- n) to mention, on radio equipment packaging and in user instructions, the restrictions concerning its putting into service, geographic areas or regions where an authorization for radio spectrum usage is necessary, as the case may be;
- o) to take immediately any necessary corrective action to bring the radio equipment into conformity, to withdraw and/or recall it, as appropriate, if they have evidence or information that a radio equipment which they have placed on the market does not comply with the provisions of this decision;
- p) to inform immediately the market surveillance and radio equipment control authorities if the radio equipment which they have placed on the market poses a risk,

giving details, in particular, on the non-compliance, on any corrective actions taken and on their outcome;

q) to provide, upon reasoned request received from the market surveillance and radio equipment control authorities and without exceeding the deadline they indicated, on paper or electronic format, all required information and documentation necessary to demonstrate the compliance of radio equipment with the provisions of this decision;

r) to cooperate with market surveillance and radio equipment control authorities, upon their request, on any action taken to eliminate the risks of radio equipment which they have placed on the market.

Art. 11. – (1) Instructions provisioned at Art. 10 letter l) shall be clear, understandable, intelligible and relevant and shall include:

a) necessary information on the use of radio equipment conforms for its intended purpose;

b) a description of accessories and of components, including the software, that allows radio equipment to function for its intended purpose;

c) the frequency band(s) in which the radio equipment operates intentionally emitting radio waves and maximum radio-frequency power transmitted in the frequency band(s) in which it operates.

(2) Information provided at paragraph (1) is provided as a user manual written in Romanian, in paper format. Information may also be provided in electronic format, only after receiving the approval from the end-user.

Art. 12. – (1) A manufacturer may, by a written mandate, appoint an authorized representative.

(2) The obligations lay down in Art. 10 letter b) and d) shall not form part of the authorized representative's mandate.

(3) An authorized representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorized representative to do at least the following:

a) keep the EU declaration of conformity and the technical documentation at the disposal of national market surveillance authorities and radio equipment control for 10 years after the radio equipment has been placed on the market;

b) further to a reasoned request from a national market surveillance authorities and radio equipment control, in paper or electronic format, with all the information and documentation necessary to demonstrate the conformity of radio equipment;

c) cooperate with the national market surveillance authorities and radio equipment control, at their request, on any action taken to eliminate the risks posed by radio equipment covered by the authorized representative's mandate.

Art. 13. – Importers have the following obligations:

a) to ensure that the radio equipment placed on the market is compliant with the provisions of this decision;

b) to ensure, before placing on the market of radio equipment that the appropriate conformity assessment procedure referred to in Art. 18 and 19 was met by the manufacturer and that the radio equipment is constructed so that it can be used without violating the applicable requirements on the use of radio spectrum established by law;

c) to ensure that the manufacturer has drawn up the technical documentation, that the radio equipment bears the EC marking and meets the requirements of Art. 21 that it is accompanied by the information and documents provided in Art. 10 letter l) -n) and that the manufacturer has complied with the requirements of Art. 10 letter j) -k);

d) not to place on the market the radio equipment in case they have evidence or information that it does not comply with the essential requirements set out in art. 3, before being brought into conformity, and, for safety reasons, to inform the manufacturer and the market surveillance and radio equipment control authorities;

e) to indicate on the radio equipment the name, trade name or the registered trademark and the mailing address at which they can be contacted or, if this is not possible, if the size of radio equipment does not allow it, or should open the packaging to fill in the name and address on the radio equipment, on the packaging or in a document accompanying the radio equipment; the contact details must be in Romanian;

f) to ensure that radio equipment accompanied by the user instructions and safety information referred to in Art. 10 letter l) meets the requirements provisioned in Art. 11;

g) to ensure that as long as the radio equipment is under their responsibility, the storage or transport conditions do not jeopardize its compliance with the essential requirements set out in Art. 3;

h) to conduct, in order to protect the health and safety of end users, whenever this is justified by the risks of radio equipment, technical tests at random on the radio equipment made available on the market, investigate and, where appropriate, to keep a register of complaints on non-compliant radio equipment and their recalls;

i) to inform the distributors of any monitoring activities referred to letter h);

j) to take immediately any necessary corrective action to bring the radio equipment into conformity, to withdraw and/or recall it, as appropriate, if they have evidence or information that a radio equipment which they have placed on the market does not comply with the provisions of this decision and immediately inform the market surveillance and radio equipment control authorities if the radio equipment poses a risk that can affect its operation or the operation of other radio equipment or for safety reasons, giving details, in particular, on the non-compliance and on any corrective actions taken;

k) to keep a copy of the EU declaration of conformity for 10 years after the radio equipment was placed on the market and to ensure that the technical documentation can be made available to the market surveillance and radio equipment control authorities, upon their request;

l) to provide the market surveillance and radio equipment control authorities, upon their reasoned request and without exceeding a deadline, on paper or electronic format, all information and documentation necessary to demonstrate the compliance of radio equipment with the provisions of this decision;

m) to cooperate with the market surveillance and radio equipment control authorities, upon their request, on any action taken to eliminate the risks of radio equipment which they have placed on the market.

Art. 14. – Distributors have the following obligations:

a) to ensure that the way in which they make available the radio equipment on the market is not likely to affect the essential requirements set out in this decision;

b) to check, before to make available the radio equipment on the market, if they bear the EC mark and meet the requirements of Art. 21, if they are accompanied by the documentation referred to in this decision, as well as by user instructions and safety information referred to in Art. 10 letter l), with due observance as well of the

requirements of Art. 11 and that the manufacturer and the importer have complied with the requirements of Art. 10 letter c) letters j) -n), respectively Art. 13 lit. e);

c) not to make available the radio equipment on the market, if they have evidence or information that the radio equipment is not compliant with the essential requirements set out in Art. 3 before it is brought into compliance and, for safety reasons, to inform the manufacturer or importer, as well as the market surveillance and radio equipment control authorities;

d) to ensure that, as long as the radio equipment is under their responsibility, storage or transport conditions do not jeopardize its compliance with the essential requirements set out in Art. 3;

e) to take immediately any necessary corrective action to bring the radio equipment into conformity, to withdraw and/or recall it, as appropriate, if they have evidence or information that a radio equipment which they made available on the market does not comply with the provisions of this decision and immediately inform the market surveillance and radio equipment control authorities of the Member States where the radio equipment was made available on the market, if the radio equipment poses a risk that can affect its operation or the operation of other radio equipment or for safety reasons, giving details, in particular, on the non-compliance and on any corrective actions taken;

f) to provide the market surveillance and radio equipment control authorities, upon their reasoned request and without exceeding a deadline, on paper or electronic format, all information and documentation necessary to demonstrate the compliance of radio equipment with the provisions of this decision;

g) to cooperate with the market surveillance and radio equipment control authorities, upon their request, on any action taken to eliminate the risks of radio equipment which they have made available on the market.

Art. 15. –An importer or distributor is considered a manufacturer under this directive and is subject to the obligations of the manufacturer according to Art. 10, where the radio equipment is placed on the market under his name or trademark or modifies a radio equipment already placed on the market in a manner which may affect its compliance with the provisions of this decision.

Art. 16. – (1) Economic operators are required to provide, upon request of the market surveillance and radio equipment control authorities, the identification data for:

a) any economic operator who has supplied radio equipment;

b) any economic operator to whom they have supplied radio equipment.

(2) Economic operators have the obligation to preserve and present the information referred to in paragraph (1) for 10 years after the radio equipment has been supplied to them and for 10 years after they have supplied the radio equipment.

Chapter III – Conformity of radio equipment

Art. 17. – (1) Radio equipment which is in conformity with the provisions of the Romanian standards and/or with national standards of other member states of the European Union which adopt harmonized standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential requirements set out in Art. 3, covered by those standards or parts thereof.

(2) Harmonized standards referred to in paragraph (1) are not binding, being permitted any other means to prove compliance.

(3) If it is considered that a harmonized standard referred to in paragraph (1) does not fully meet the essential requirements set out in Annex 1, ANCOM notifies the Standing Committee referred to in Art. 13 paragraph (1) of the Government Decision no. 1016/2004, with subsequent amendments and completions.

(4) In the situation provided in paragraph (3) ANCOM will state, in its information, with arguments, its reasons, as well.

Art. 18. – (1) The manufacturer shall perform a conformity assessment of the radio equipment with a view to meeting the essential requirements set out in Art. 3.

(2) The conformity assessment of radio equipment shall take into account all intended operating conditions.

(3) For the essential requirement set out in paragraph (1) letter (a) of Art. 3, the assessment shall also take into account the reasonably foreseeable conditions.

(4) Where the radio equipment is capable of taking different configurations, the conformity assessment shall confirm whether the radio equipment meets the essential requirements set out in Art. 3 in all possible configurations.

Art. 19. – (1) Manufacture shall demonstrate compliance of radio equipment with the essential requirements set out in Art. 3 paragraph (1) using any of the following conformity assessment procedures:

a) internal production control set out in Annex 2;

b) EU-type examination that is followed by the conformity to type based on internal production control, set out in Annex 3;

c) conformity based on full quality assurance set out in Annex 4.

(2) Where, in assessing the compliance of radio equipment with the essential requirements set out in Art. 3 paragraph (2) and (3), the manufacturer has applied harmonized standards the references of which have been published in the *Official Journal of the European Union*, he shall use any of the following procedures:

a) internal production control set out in Annex 2;

b) EU-type examination that is followed by the conformity to type based on internal production control set out in Annex 3;

c) conformity based on full quality assurance set out in Annex 4.

(3) Where, in assessing the compliance of radio equipment with the essential requirements set out in Art. 3 paragraphs (2) and (3), the manufacturer has not applied or has applied only in part harmonized standards the references of which have been published in the *Official Journal of the European Union*, or where such harmonized standards do not exist, radio equipment shall be submitted with regard to those essential requirements to either of the following procedures:

a) EU-type examination that is followed by the conformity to type based on internal production control set out in Annex 3;

b) conformity based on full quality assurance set out in Annex 4.

Art. 20. – (1) The EU declaration of conformity written in accordance with Art. 10 letter e), shall state that the fulfilment of the essential requirements set out in Art. 3 has been demonstrated.

(2) The EU declaration of conformity is drawn and shall contain all the elements set out in

Annex no. 6. The EU declaration of conformity shall be continuously updated.

(3) The EU declaration of conformity is written in Romanian.

(4) The simplified EU declaration of conformity referred to in Art. 10 letter m) shall contain all the elements set out in Annex 7 and shall be continuously updated.

(5) The simplified EU declaration of conformity for radio equipment placed or made available on the market in Romania shall be drawn in Romanian.

(6) Where radio equipment is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up by the manufacturer in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned including their publication references.

(7) By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the radio equipment with the requirements laid down in this Directive.

Art. 21. – (1) The EC marking shall be subject to the general principles set out in Art. 30 of Regulation (EC) No 765/2008.

(2) On account of the nature of radio equipment, the height of the EC marking affixed to radio equipment may be lower than 5 mm, provided that it remains visible and legible.

(3) The EC marking shall be affixed before the radio equipment is placed on the market.

(4) The EC marking shall be affixed visibly, legibly and indelibly to the radio equipment or to its data plate, unless that is not possible or not justified on account of the nature of radio equipment. The EC marking shall also be affixed visibly and legibly to the packaging.

(5) The EC marking shall be followed by the identification number of the notified body where the conformity assessment procedure set out in Annex no. 4 is applied. The identification number of the notified body shall have the same height as the EC marking.

(6) In the situation provided in paragraph (5), the identification number of the notified body shall be affixed by the notified body itself or, under its instructions, by the manufacturer or his authorized representative.

Art. 22. – If the staff of the market surveillance and control radio equipment finds that the EC marking has not been properly applied, the manufacturer or his authorized representative established in Romania work to bring radio equipment in accordance with the EC marking.

Art. 23. – (1) The technical documentation shall contain all relevant data or details of the means used by the manufacturer to ensure that radio equipment complies with the essential requirements set out in Art. 3. It shall, at least, contain the elements set out in Annex 5.

(2) The technical documentation shall be drawn up before radio equipment is placed on the market and shall be continuously updated.

(3) The technical documentation and correspondence relating to any EU-type examination procedure drawn up by a body notified by the Ministry of Communications and Informational Society hereinafter referred to as *MCSI*, is written in Romanian.

(4) Where the technical documentation does not comply with paragraphs (1) -(3) of this Article, and in so doing fails to present sufficient relevant data or means used to ensure compliance of radio equipment with the essential requirements set out in Art. 3, ANCOM or National Authority for Consumer Protection, hereinafter referred to as *ANPC*, as the case may be, may ask the manufacturer or the importer to have technical tests performed by a body acceptable to the

relevant market surveillance and radio equipment control authority.

(5) Technical tests provisioned in accordance with paragraph (4) are performed in order to verify compliance with the essential requirements set out in Art. 3, at the expense of the manufacturer or the importer.

CHAPTER IV – Notification of conformity assessment bodies

Art. 24. – (1) MCSI as a notification of conformity authority shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Art. 28.

(2) MCSI shall notify the European Commission and the relevant authorities in the other Member States of the European Union and European Economic Area on the bodies authorized to perform conformity assessment activities.

(3) MCSI shall inform the European Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

Art. 25. – (1) MCSI, as a notification authority has the following obligations:

a) to fulfil the requirements set out in Art. R¹⁵ paragraph (1) in Annex I of Decision 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on common framework for the marketing of products, and repealing Council Decision 93/465/EEC;

b) to safeguard the objectivity and impartiality of its activities;

c) to ensure that each decision relating to notification of a conformity assessment body is taken on the suggestions or results of the analysis of competent persons, holding training or qualifications required in electronic communications, electronics or their equivalents, different from those who carried out the assessment;

d) to fulfil the requirements set out in article R¹⁵ paragraph (4) in Annex I of Decision 768/2008/EC;

e) to fulfil the requirements set out in Art. R¹⁵ paragraph (5) in Annex I of Decision 768/2008/EC;

f) to have a competent personnel at its disposal holding training or qualifications required to check the fulfilment of the requirements set out in Art. 26, and a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

(2) The provisions of paragraph (1) letter a) shall apply the provisions of Law no. 161/2003 on measures to ensure transparency in the exercise of public dignities, public functions and in business, to prevent and punish corruption, with subsequent amendments and completions.

Art. 26. – (1) For the purposes of notification to the European Commission and to the competent authorities in the other Member States of the European Union and European Economic Area, the conformity assessment body shall meet the following requirements:

a) shall be established under national law and have legal personality;

b) shall be a third-party body independent of the organization or the radio equipment it assesses; a body belonging to a business association or a professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of radio equipment which it assesses may, on condition that its independence and the absence of any conflict of interest which could influence the objectivity of carrying out the tasks that are its responsibilities under the legislation in

force, as it is provisioned in Art. R¹⁷ paragraph (3) in Annex I to the Decision 768/2008/EC, are demonstrated, be considered such a body.

c) requirements provisioned in Art. R¹⁷ paragraph (4) in Annex I to Decision 768/2008/EC;

d) shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of that radio equipment they assess, or represent the parties engaged in those activities; the requirement also influences the top level management and the personnel responsible for carrying out the conformity assessment tasks and shall in particular apply to consultancy services;

e) shall not engage in any activity that affect their impartiality or professional integrity in carrying out the conformity assessment activities for which are notified; the requirement also influences the top level management and the personnel responsible for carrying out the conformity assessment tasks and shall in particular apply to consultancy services;

f) shall ensure that the activities of their subsidiaries or subcontractors, as the case may be, do not affect the confidentiality, objectivity or impartiality of their conformity assessment;

g) shall carry out the conformity assessment activities with professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities; the requirement also influences the personnel responsible for carrying out the conformity assessment;

h) shall be capable of carrying out all the conformity assessment tasks assigned to it by Annexes 3 and 4 in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

i) at all times and for each conformity assessment procedure and for each kind or category of radio equipment in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

1) necessary personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

2) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures; it shall have appropriate policies and procedures in place that clearly distinguish between tasks it carries out as a notified body and other activities;

3) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of radio equipment technology in question and the mass or serial nature of the production process.

j) shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and to have access to all necessary equipment and facilities;

k) shall participate in information sessions, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardization activities, the regulatory activities in the area of radio equipment and frequency planning, and the activities of the notified body coordination group established under the relevant Union harmonization legislation;

l) shall apply as general guidance or guidelines the administrative decisions and

documents produced as a result of the work provisioned at letter k);

m) shall ensure that the personnel responsible for carrying out the conformity assessment tasks shall observe the requirements provisioned in paragraph (2);

n) the impartiality of the top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed and their remuneration shall not depend on the number of assessments carried out or on the results of those assessments;

o) requirement provisioned at Art. R¹⁷ paragraph (9) in Annex I to Decision 768/2008/EC.

(2) The personnel responsible for carrying out conformity assessment tasks shall have the following:

a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;

b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

c) appropriate knowledge and understanding of the essential requirements set out in Art. 3, of the applicable harmonized standards provisioned in Art. 17 paragraph (1), and of the relevant provisions of Union harmonization legislation and of national legislation;

d) the necessary ability to draw up EU-type examination certificates, records and reports demonstrating that assessments have been carried out.

e) shall fulfill the requirement set out in Art. R¹⁷ paragraph (10) in Annex I to the Decision 768/2008/EC with all the information obtained as a result of fulfilling the tasks under Annexes no. 3 and 4 or any other provisions of national law on its enforcement, except the relationship with notification and market surveillance and radio equipment control authorities in the Member State where it operates; intellectual property rights are protected under the provisions of the applicable national law.

Art. 27. –Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonized standards or parts thereof the references of which have been published in the *Official Journal of the European Union* it shall be presumed to comply with the requirements set out in Art. 26 in so far as the applicable harmonized standards cover those requirements.

Art. 28. – (1) The conformity assessment body may decide, with the agreement of the client, to subcontract certain tasks on the conformity assessment or may carry them out by a subsidiary.

(2) In the case under paragraph (1) conformity assessment body takes into account the following requirements:

a) the subcontractor or subsidiary shall perform the tasks in Art. 26 and shall inform MCSI accordingly;

b) shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established;

c) shall keep at the disposal of MCSI the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annexes no. 3 and 4.

Art. 29. – (1) The application for notification of the conformity assessment body submitted at MCSI, shall be accompanied by:

a) a description of the conformity assessment activities, the conformity assessment

module or modules and the radio equipment for which that body claims to be competent;
b) an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Art. 26;

(2) Where the conformity assessment body concerned cannot provide an accreditation certificate provisioned in paragraph (1) letter b), it shall provide MCSI with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Art. 26.

Art. 30. – (1) MCSI may notify only conformity assessment bodies which have satisfied all the requirements laid down in Art. 26.

(2) Notification provisioned in paragraph (1) is forwarded to the Commission and the competent authorities from other Member States of the European Union and European Economic Area using the electronic notification tool developed and managed by the Commission.

(3) The notification shall include:

a) full details of the conformity assessment activities, the conformity assessment module or modules and the radio equipment concerned and the relevant attestation of competence of the conformity assessment body.

b) documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that the body will be monitored regularly and will continue to satisfy the requirements laid down in Art. 26, where the notification of the authority is not based on an accreditation certificate.

(4) The body concerned is considered notified and may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within:

a) two weeks of a notification where an accreditation certificate is used

b) two months, for the situation provisioned in paragraph (3) letter b)

(5) MCSI shall notify the Commission and the competent authorities from the other Member States of the European Union and European Economic Area of any subsequent relevant changes to the notification according to the conditions set out in paragraph (1)-(4).

Art. 31. – (1) Where MCSI has ascertained as a result of the regular monitoring or has been informed that a notified body no longer meets the requirements laid down in Art. 26, or that it is failing to fulfil its obligations set out in accordance with Annexes 3 and 4, it shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations.

(2) In the event of any disposition of the measures referred to in paragraph (1), MCSI shall immediately inform the Commission and the competent authorities from the other Member States of the European Union and European Economic Area.

(3) In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, MCSI shall take appropriate steps to ensure that the files of that body are:

a) either processed by another notified body;

b) kept available for MCSI, ANCOM and/or ANPC, at their request.

(4) The measures provided in paragraph (1) shall be arranged by the order of the Minister of Communications and Information Society, which will determine their type and duration. Order shall be published in the Official Gazette of Romania, Part I, and may be challenged under Law no. 554/2004, with subsequent amendments and completions.

Art. 32. –If an investigation of the European Commission, according to Art. 33 paragraph (1) of Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonization of the legislation of Member States relating to making available on the market of radio equipment and repealing Directive 1999/5/EC as regards competence of a notified body or the continued fulfilment by it of the requirements and responsibilities placed on it, MCSI shall forward, upon request, all information on the basis of notification or the maintenance of the competence of the notified body concerned.

Art. 33. – (1) Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided in Annexes 3 and 4, taking into account the provisions of paragraph (2).

(2) The conformity assessment bodies:

- a) shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the radio equipment technology in question and the mass or serial nature of the production process;
- b) shall respect the degree of rigor and the level of protection required for the compliance of the radio equipment with this Directive;
- c) shall require that manufacturer to take appropriate corrective actions and shall not issue an EU-type examination certificate or a quality system approval, where it finds that the essential requirements set out in Art. 3 or corresponding harmonized standards or other technical specifications have not been met;
- d) shall require the manufacturer to take appropriate corrective actions and shall suspend or withdraw the EU-type examination certificate or the quality system approval if necessary, where, in the course of the monitoring of conformity following their issue it finds that radio equipment no longer complies.

(3) Shall restrict, suspend or withdraw any certificate as appropriate, where corrective action shall not be taken, according to paragraph (2) letter c) and d) or do not have the required effect. In this situation, the notified body shall inform MCSI, ANCOM, and/or ANPC, as appropriate.

Art. 34. – An appeal procedure against decisions of conformity assessment bodies is possible in accordance with Law no. 554/2004, with subsequent amendments and completions.

Art. 35. – (1) Notified bodies shall inform MCSI of the following:

- a) any refusal, restriction, suspension or withdrawal of an EU-type examination certificate or a quality system approval in accordance with the requirements of Annexes 3 and 4;
- b) any circumstances affecting the scope of or conditions for notification;
- c) any request for information which they have received from the market surveillance and radio equipment control authorities regarding conformity assessment activities;
- d) conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

(2) The information provided in paragraph (1) letter d) is made available at the request of MCSI.

(3) Notified bodies shall, in accordance with the requirements of Annexes 3 and 4, provide the other bodies notified at European Union level carrying out similar conformity assessment

activities covering the same categories of radio equipment with relevant information on issues relating to negative conformity assessment results.

(4) On request, notified bodies shall provide with positive conformity assessment results.

(5) Notified bodies shall fulfil information obligations under Annexes 3 and 4.

Art. 36. –Conformity assessment bodies shall directly participate in, or ensure that an appointed representative will take part at the sectorial group of the notified bodies under the coordination of the European Commission.

Chapter V – Market surveillance

Art. 37. – (1) The market surveillance and control activity in order to fulfil the provisions of this decisions and the obligations of the economic operators arising from EU regulations as well as the traceability of radio equipment in the supply and distribution chain, shall be exercised by ANCOM and ANPC, hereinafter referred to *the market surveillance and radio equipment control authorities* that work by specialized personnel or staff specialized empowered for this purpose.

(2) ANPC market surveillance and control activity regards the radio equipment conformity belonging to the consumer under Government Ordinance no. 21/1992 on consumers' protection, republished, with subsequent amendments and completions.

(3) ANCOM and ANPC organize and operate the market surveillance and control activity in accordance with the provisions of Art. 15 paragraph (3) and Art. 16-29 of the Regulation (EC) no. 765/2008.

(4) ANCOM and ANPC may conclude for the enforcement of this decision, a cooperation protocol which aims to ensure the exchange of information to improve measures to identify non-compliant products and undertake the necessary actions to eliminate them.

Art. 38. – (1) In the process of enforcement of this Decision, authorized personnel of ANCOM or ANPC, as appropriate, shall be entitled to require economic operators or any end-user - natural or legal person - any information necessary to exercise powers relating to market surveillance.

(2) Persons provided in paragraph (1) shall make the information available to ANCOM or ANPC, where appropriate, under the terms and conditions they specified.

Art. 39. – The end-user, natural or legal person has the obligation to communicate, at the reasoned request from market surveillance and radio equipment control authorities the registered trade name/name of the economic operator from where he has purchased the radio equipment.

Art. 40. – (1) ANCOM or ANPC, according to their duties in accordance with this decision may decide at any time to carry out technical tests to check the conformity of radio equipment with the applicable essential requirements based on standards or relevant technical specifications set out in the EU declaration of conformity.

(2) If in the EU declaration of conformity, standards or technical specifications are set out improperly or are missing or there is no EU declaration of conformity, technical tests are carried out on the basis of harmonized standards provided for in Art. 17 paragraph (1).

Art. 41. – (1) In order to perform technical tests according to Art. 40 paragraph (1), manufacturer, authorized representative, importer or distributor, as the case may be, has the

obligation to allow the control staff to carry out on a minute, for free, a representative number of samples from the radio equipment which will be tested. Sampling can be ordered on the radio equipment at the end-user if there are indications that the radio equipment causes electromagnetic disturbances, harmful interference or presents a risk affecting the health and/or safety or property of persons.

(2) ANCOM or ANPC shall bear the costs resulting from technical tests laid down in Art. 40 paragraph (1) from its annual budget approved for this purpose.

(3) Where following technical tests results that the radio equipment does not meet the essential requirements, the manufacturer or his authorized representative shall support all the costs of the tests laid down in Art. 40 paragraph (1). Where the manufacturer or his authorized representative is not established on the national territory, the importer or distributor, as applicable, shall bear the costs entirely.

(4) If the importer cannot be identified or controlled economic operator does not provide any information that leads to his identification, the economic operator control shall bear the costs.

(5) With regard to the costs incurred by ANCOM, individualizing them in order to establish the amount to be recovered in accordance with paragraph (3) or (4) is achieved by decision of the president of ANCOM, being applicable the provisions of Art. 14 paragraph (2) of the Government Emergency Ordinance no. 22/2009 on the establishing the National Authority for Management and Regulations in Communications of Romania, approved by Law no. 113/2010, with subsequent amendments and completions.

(6) If the technical tests laid down in Art. 40 paragraph (1) are made by ANCOM own laboratory, the provisions of paragraph (3) and (4) do not apply for the surveillance and control actions carried out by the specialized personnel of ANCOM.

(7) In order to perform the technical tests laid down in Art. 40 paragraph (1) the manufacturer or his authorized representative or the importer established on the national territory, as appropriate, has the obligation to provide ANCOM or ANPC, as appropriate, upon request and within the deadline they decide, with the software used by the manufacturer when performing their own technical tests carried out to check compliance with the essential requirements.

Art. 42. – (1) Subsequently to carrying out technical tests under Art. 40 and 41, the radio equipment is returned to the person from whom it was taken.

(2) Where, due to technical tests on the radio equipment, it becomes unusable or is destroyed for reasons of exclusive fault of the personnel who carried out technical tests, the market surveillance and radio equipment control authority that has made technical tests shall bear the equivalent value of the radio equipment.

Art. 43. – (1) Where ANCOM or ANPC have sufficient reason to believe that radio equipment presents a risk to the health or safety of persons or to other aspects of public interest protection covered by this Directive, they shall carry out an evaluation in relation to the radio equipment concerned.

(2) Evaluation provisioned in paragraph (1) covers all relevant requirements laid down in this Directive.

(3) The relevant economic operators over which control actions are taken in accordance with paragraph (1) and (2) shall cooperate as necessary with the market surveillance and radio equipment control authorities for that purpose.

Art. 44. – (1) Where, in the course of the evaluation referred to in Art. 43 paragraph (2), ANCOM or ANPC finds that the radio equipment does not comply with the requirements

laid down in this Directive, they shall without delay require the relevant economic operator to take all appropriate corrective actions to bring the radio equipment into compliance with those requirements or to withdraw the radio equipment from the market, and/or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe. The time interval is determined by the circumstances of each case taking into account the number of radio equipment on which follows to be arranged the necessary corrective actions, and where they are located, as well.

(2) In the situation provided in paragraph (1), ANCOM or ANPC, as appropriate, shall inform the relevant notified body that achieved the compliance assessment of the measures taken.

(3) Provisions of Article 21 of the Regulation (EC) no. 765/2008 shall apply to the measures referred to in paragraph (1).

(4) Corrective actions provisioned in paragraph (1) are ordered by a decision of ANCOM President or by order of ANPC President, as appropriate.

Art. 45. –Where ANCOM or ANPC, as appropriate, consider that non-compliance of radio equipment is affecting products that were or can be delivered in other Member States of the European Union or in the European Economic Area, it shall inform the Commission and the market surveillance and radio equipment control authorities in the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

Art. 46. – Economic operator against which measures under Art. 44 were ordered has the obligation to apply the necessary corrective actions for all radio equipment concerned that it has made available on the market.

Art. 47. – (1) Where the economic operator does not apply corrective measures provisioned under Art. 44 paragraph (1) and (4), ANCOM or ANPC, as appropriate, takes all provisionally appropriate actions to prohibit or restrict the making available on the market of radio equipment, to withdraw and/or recall it from the market. Measures are ordered by decision of ANCOM President or by order of ANPC President, as appropriate.

(2) The market surveillance and radio equipment control authority that ordered the measures shall notify, without delay, the Commission and the market surveillance and radio equipment control authorities from the other Member States of the European Union and European Economic Area of the provisionally measures ordered under paragraph (1).

(3) Information provisioned in paragraph (2) shall include at least, the following:

- a) data necessary to identify non-compliant radio equipment;
 - b) origin of radio equipment;
 - c) nature of ascertained non-conformity and the risk involved;
 - d) nature and duration of the national measures taken;
 - e) the arguments presented by the economic operator;
 - f) whether non-conformity is due to failure to comply with the relevant essential requirements referred to in Art. 3;
 - g) whether the non-conformity is due to deficiencies on harmonized standards referred to in Art. 17 paragraph (1) which provides a presumption of conformity.
- (4) Where, within three months of receipt of the information referred to in the first paragraph, no objection has been raised by either a Member State or the Commission in respect of the measures taken that measures shall be deemed justified.

(5) If the European Commission adopts an act by which establishes that the provisional measure(s) are not justified, the market surveillance and radio equipment control authorities shall withdraw the measures they ordered.

(6) If the measures are considered justified, the market surveillance and radio equipment control authorities shall require that provisional measures provided in paragraph (1) shall be applied permanently.

Art. 48. – (1) Where, having carried out an evaluation under Art. 40 paragraph (2), finds that although radio equipment is in compliance with this Directive, it presents a risk to the health or safety of persons or to other aspects of public interest protection covered by this Directive, ANCOM or ANPC, as appropriate, shall require the economic operator to take all appropriate corrective actions to ensure that the radio equipment concerned no longer presents that risk or to withdraw the radio equipment from the market and/or to recall it within a reasonable period, commensurate with the nature of the risk. The period of time for taking corrective actions is determined by the circumstances of each case taking into account the number of radio equipment on which the necessary corrective actions are taken, and where they are located.

(2) The economic operator shall ensure that all appropriate corrective actions are taken in respect of all the radio equipment concerned that he has made available on the market.

(3) Corrective actions provisioned in accordance with paragraph (1) and (2) are ordered by a decision of ANCOM President or by order of ANPC President, as appropriate.

(4) ANCOM or ANPC shall immediately inform the Commission and the market surveillance and radio equipment control authorities in the other Member States of the Union and the European Economic Area on the actions taken according to paragraph (1).

(5) That information provisioned in paragraph (4) shall include all available details, in particular the data necessary for the identification of the radio equipment concerned, the origin and the supply and distribution chain of radio equipment, the nature of the risk involved and the nature and duration of the national measures taken.

Art. 49. – Without excluding measures ordered under Art. 43-48, ANCOM or ANPC may require the economic operator to bring radio equipment in accordance with the provisions of this decision, within 15 days, if it finds the following:

a) the EC marking has been affixed in violation of Art. 30 of Regulation (EC) No 765/2008 or of Art. 21 of this Directive;

b) the EC marking has not been affixed;

c) the identification number of the notified body, where the conformity assessment procedure set out in Annex 4 is applied, has been affixed in violation of Art. 21 or has not been affixed;

d) the EU declaration of conformity has not been drawn up;

e) the EU declaration of conformity has not been drawn up correctly;

f) technical documentation is either not available or not complete;

g) the information referred to in Art. 10 letters j) or k) or Art. 13 letter e) is absent, false or incomplete;

h) the information on the intended use of radio equipment, the EU declaration of conformity or usage restrictions as set out in Art. 10 letters l), m) and n) does not accompany the radio equipment;

i) requirements on identification of economic operators set out in Art. 16 are not fulfilled;

j) article 5 is not complied with.

Art. 50. – ANCOM or ANPC staff, as appropriate, may decide to apply seals on radio equipment or on batches of radio equipment upon which measures have been taken under this decision.

Chapter VI – Contraventions and sanctions

Art. 51. – (1) The following deeds shall be deemed contraventions, insofar they are not committed under such conditions that might cause them to be considered, under the criminal law, as offences:

- 1) trespass of the obligation set out in Art. 10, letter a) by not recording radio equipment and the failure of the manufacturer or his authorized representative thereof, to affix the registration number of radio equipment in terms of Art. 5;
- 2) deed of the manufacturer to place on the market radio equipment without meeting the essential requirements set out in Art. 3 as provided in Art. 10 letter b);
- 3) failure of the manufacturer to comply with the obligation set out under Art. 10 letter c) to build radio equipment so that it can be used without violating the applicable requirements on the use of radio spectrum;
- 4) failure of the producer to comply with the obligations set out under Art. 10 letter d) to draw up the technical documentation pursuant to Art. 23 or the obligation to perform the conformity assessment relevant procedure;
- 5) failure of the manufacturer or his authorized representative thereof, to draw up the EU declaration of conformity, obligation set out under Art. 10 letter e);
- 6) failure of the manufacturer or his authorized representative thereof, to affix the EC marking, obligation set out under Art. 10 letter e);
- 7) failure of the manufacturer or his authorized representative thereof, to comply with the obligation set out under Art. 10 letter f) to keep the technical documentation and EU declaration of conformity for 10 years after placing on the market the radio equipment;
- 8) failure of the manufacturer or his authorized representative thereof, to comply with the obligation set out under Article 10 letter g);
- 9) failure of the manufacturer or his authorized representative thereof, or importer to comply with the obligation set out under Art. 10 letter h) and Art. 13 letter h) to carry out through survey the technical tests of radio equipment made available on the market, investigate and keep a register of complaints of non-conforming radio equipment and radio equipment recalls;
- 10) failure of the manufacturer or his authorized representative thereof, to comply with the obligation set out under Art. 10 letter i) to keep distributors informed on monitoring performed according to Art. 10 letter h);
- 11) deed of the manufacturer or his authorized representative to place on the market radio equipment which do not bear elements allowing its identification or are not accompanied by the required information set out Art. 10 letter j);
- 12) failure of the manufacturer or his authorized representative thereof, or importer to comply with the obligation set out under Art. 10 letter k) and Art. 13 letter e) to indicate on the radio equipment their name, registered trade name or registered trade mark and the postal address at which they can be contacted;
- 13) failure of the manufacturer or his authorized representative thereof, to comply with the obligation set out under Art. 10 letter l) to supply with the instructions and safety

information of radio equipment, with compliance of the requirements provisioned in Art. 11;

14) failure of the manufacturer or his authorized representative thereof, to comply with the obligation set out under Art. 10 letter m) to ensure that each item of radio equipment is accompanied by a copy of the EU declaration of conformity or by a copy of a simplified EU declaration of conformity;

15) failure of the manufacturer or his authorized representative thereof, to comply with the obligation set out under Art. 10 letter n) to indicate on the packaging of radio equipment and in the instructions, the restrictions on putting into service or the sectors or the geographical area where requirements for authorization of use exist;

16) failure of the controlled economic operator to comply with the obligation set out in Art. 10 letter o) and letter p), Art. 13 letter j) or Art. 14 letter e) to take the necessary corrective measures where he considers or has reason to believe that a radio equipment which they have placed on the market or made available on the market is not in conformity with this Directive or with the obligation to immediately inform the market surveillance and radio equipment control authorities if the radio equipment which they have placed on the market poses a risk, giving details, in particular, of the non-compliance, of any corrective measures taken and of the results thereof;

17) deed of the controlled economic operator not to take the measures provisioned under Art. 47 paragraph (1), under conditions set out in Art. 47 paragraph (6) or not to comply with the requirement set out in Art. 48 paragraph (2);

18) failure of the controlled economic operator to comply with the obligation set out in Art. 10 letter q), Art. 13 letter l) or Art. 14 letter f) to supply the market surveillance and radio equipment control authorities with the necessary information and documentation in order to demonstrate the radio equipment conformity;

19) failure of the controlled economic operator to comply with the obligation set out in Art. 10 letter r), Art. 13 letter m) or Art. 14 letter g) to cooperate with the market surveillance and radio equipment control authorities on any action taken to eliminate the risks posed by radio equipment which they have placed on the market or made available on the market;

20) failure of the controlled economic operator to comply with the obligation set out in Art. 16 to supply with the requested identification data;

21) failure by the importer to comply with the obligation set out in Art. 13 letter a) to ensure that the radio equipment they have placed on the market are compliant with the provisions of this decision;

22) failure of the importer to comply with the obligation set out in Art. 13 letter b) to check before placing the radio equipment on the market, that the manufacturer met the conformity assessment procedure set out in Art. 18 and 19;

23) failure of the importer to comply with the obligation set out in Art. 13 letter b);

24) failure of the importer to comply with the obligation set out in Art. 13 letter c) to check that the manufacturer complied with the obligation to draw up the technical documentation or that the manufacturer affixed the EC marking on the radio equipment;

25) failure of the importer to comply with the obligation set out in Art. 13 letter c) to check whether the manufacturer fulfilled his obligations in accordance with Art. 10 letters j) - n);

26) failure of the importer to comply with the obligation set out in Art. 13 letter d) not to place radio equipment on the market before they are compliant with the provisions of

this decision, where he considers or has reason to believe that the radio equipment is not in conformity with the essential requirements or with the obligation to immediately inform the manufacturer and the market surveillance and radio equipment control authorities if the radio equipment which they have placed on the market poses a risk;

27) deed of the importer or distributor to jeopardize the compliance of radio equipment with the essential requirements due to its inappropriate storage or transport conditions, obligation set out in Art. 13 letter g), and Art. 14 letter d);

28) failure of the importer to comply with the obligation set out in Art. 13 letter i) to keep the distributor informed on performed monitoring;

29) failure of the importer to comply with the obligation set out in Art. 13 letter k) to keep the EU declaration of conformity for 10 years after the radio equipment has been placed on the market;

30) failure of the distributor to comply with the obligation set out in Art. 14 letter a) to ensure that the way he makes the radio equipment available on the market shall not affect the essential requirements;

31) failure of the distributor to comply with the obligation set out in Art. 14 letter b) to check, before the radio equipment is made available on the market, whether the radio equipment bears the EC marking or is accompanied by the documents provisioned in this decision;

32) failure of the distributor to comply with the obligation set out in Art. 14 letter b) to check whether the manufacturer complied with the requirements provisioned in 10 letter c), letters j) - n), observing the requirements set out in Article 11 for the requirement provisioned in Art. 10 letter l) and whether the importer complied with the requirement provisioned in Art. 13 letter e);

33)) failure of the distributor to comply with the obligation set out in Art. 14 letter c) to ensure that the radio equipment is not made available on the market until it has been brought into conformity with this decision, where he considers or has reason to believe that the radio equipment does not comply with the essential requirements or with the obligation to inform the manufacturer or the importer and the market surveillance and radio equipment control authorities when the radio equipment presents a risk, according to Art. 14 letter c);

34) failure of the economic operators or by the end-user to comply with the obligation set out in Art. 41 paragraph (1) to allow carry out sample testing of radio equipment in order to have technical tests;

35) to display, by any person and/or demonstrations with radio equipment which does not comply with the decision in the context of trade fairs, exhibitions and similar events, not complying with the provisions set out in Art. 6 paragraphs (2) and (3);

36) failure of the radio equipment and software manufacturers to comply with the requirement set out in Art. 4 to submit to ANCOM information on the compliance of combinations of radio equipment and software;

37) failure of the conformity assessment bodies to comply with the requirements set out in Art. 28 paragraph (2) letters a) and c);

38) failure of the conformity assessment bodies to comply with the requirements set out in Art. 35 paragraphs (1), (3) and (4);

39) deed of the manufacturer or his authorized representative thereof, to affix the EC marking on products without complying with the provisions of Art. 21;

40) deed of any person to manufacture, have, import, advertise, place or make available on the market or use radio equipment or appliances designed to create harmful

interferences, obligation provisioned in Art. 9 paragraph (2);

41) refusal of the end-user to provide the market surveillance and radio equipment control authority, according to provisions set out in Art. 38 and Art. 39, necessary data and/or information in order to check the compliance with the provisions of this decision;

42) deed of the importer or a distributor to place, respective to make available on the market an equipment when the EC marking does not comply with the provisions of Art. 21;

43) deed of the notified body, manufacturer or his authorized representative thereof, not to affix the identification number of the notified body, under conditions set out in Art. 21 paragraph (6);

44) not to draw up/update by the operator of the radio station of the documentation on limiting public exposure to electromagnetic fields effects, in accordance with Art. 7 paragraphs (4) -(6);

45) failure of the radio station operator to submit the documentation made, in accordance with Art. 7 paragraph (7);

46) failure of the manufacturer of importer thereof, to comply with the requirement set out in Art. 41 paragraph (7) to provide with the software used for the technical tests in order to check the conformity with the essential requirements;

47) failure of the economic operators to comply with the requirement set out in Art. 49;

48) deed of the end-user to put into operation and/or use radio equipment which are non-compliant with Art. 6 paragraph (1).

(2) The contraventions identified under paragraph (1) shall be sanctioned as follows:

1) that under point 1, with fine ranging from RON 2.500 to RON 10.000;

2) that under points 2 and 3, with fine ranging from RON 10.500 to RON 50.000;

3) that under point 4, with fine ranging from RON 5.000 to RON 20.000;

4) that under points 5 and 6, with fine ranging from RON 5.500 to RON 30.000;

5) that under points 7 and 8 and point 29, with fine ranging from RON 2.500 to RON 20.000;

6) that under points 9 and 10, with fine ranging from RON 10.000 to RON 35.000;

7) that under points 11 and 12, with fine ranging from RON 5.000 to RON 25.000;

8) that under points 13 and 14, with fine ranging from RON 2.500 to RON 25.000;

9) that under point 15, with fine ranging from RON 2.500 to RON 35.000;

10) that under points 16-20 and point 36, with fine ranging from RON 10.000 to RON 50.000;

11) that under points 21-23, with fine ranging from RON 2.500 to RON 25.000;

12) that under points 24 and 25, with fine ranging from RON 5.500 to RON 25.000;

13) that under point 26 and point 33, with fine ranging from RON 7.500 to RON 35.000;

14) that under point 27, with fine ranging from RON 2.500 to RON 25.000;

15) that under point 28, with fine ranging from RON 2.500 to RON 15.000;

16) that under point 30, with fine ranging from RON 5.000 to RON 35.000;

17) that under points 31 and 32, with fine ranging from RON 2.500 to RON 22.500;

18) that under point 34 and point 42, with fine ranging from RON 10.000 to RON 50.000;

19) that under point 35, with fine ranging from RON 10.000 to RON 40.000;

20) that under points 37-39 with fine ranging from RON 20.000 to RON 50.000;

21) that under point 40, with fine ranging from RON 15.000 to RON 50.000;

22) that under points 41 and points 46-48, with fine ranging from RON 500 to RON 5.000;

23) that under point 43, with fine ranging from RON 7.500 to RON 30.000;

24) that under points 44 and 45, with fine ranging from RON 2.500 to RON 50.000.

Art. 52. – (1) The contraventions herein shall be assessed by the control personnel of the market surveillance and radio equipment control authorities, by means of the official report establishing the contravention and applying the sanction.

(2) The sanctions for the contraventions identified herein shall be applied:

a) by means of the official report establishing the contravention and applying the sanction by the specialized personnel of ANCOM for the contraventions identified under Art. 51 paragraph (1) points 1, 9 and 10, 16 and 17, 19, 26-28, 30, 33, 35 and 36, 41 and 43-46;

b) by means of written resolution of the president of ANCOM, inscribed on the official report establishing the contravention and applying the sanction, for the contraventions assessed by the personnel of ANCOM, in those cases referred to under Art. 51 paragraph (1) points 2-8, 11-15, 18, 20-25, 29, 31 and 32, 34, 39 and 40, 42 and 47 and 48 where the end-user is a legal person;

c) by means of the official report establishing the contravention and applying the sanction by the ascertaining agent, for the contravention assessed by ANPC personnel, in those cases referred to under Art. 51 paragraph (1) points 2, 21, 26, 33, 41 and 48 where the end-user is a natural person;

d) by means of the official report establishing the contravention and applying the sanction by empowered staff of MCSI, in those cases referred to under Art. 51 paragraph (1) points 37-38.

Art. 53. – (1) In case of the deeds provisioned under Art. 51 paragraph (1) points 2-8, 11-15, 18, 20-25, 29, 31 and 32, 34, 39 and 40, 42 and 47 and 48, ANCOM or ANPC, as the case, also decides as an additional sanction by means of the official report establishing the contravention and applying the sanction, one of the following:

a) to restrict or prohibit the apparatus's being placed on the market;

b) to restrict or prohibit the apparatus's being made available on the market;

c) to withdraw the apparatus from that market and/or to recall it, as the case;

d) to prohibit the usage of the apparatus.

(2) The additional sanction shall be applied by the persons and the procedure specified in accordance with Art. 52 paragraph (2) letters b) and c).

Art. 54. – Contraventions under this decision are applicable the provisions of the Government Ordinance no. 2/2001 on the legal regime of contraventions, approved with amendments and completions by Law no. 180/2002, with subsequent amendments and completions.

Chapter VII – Final and transitional provisions

Art. 55. – Annexes no. 1 – 7 are part of the present decision.

Art. 56. – (1) Market surveillance and radio equipment control authorities shall submit to the Commission regular reports on the application of this Directive by 12 June 2017 and at least, every two years thereafter.

(2) The reports provisioned under paragraph (1) shall contain a presentation of the market

surveillance activities and provide information on the compliance of radio equipment with the requirements of this Directive, including requirements on identification of economic operators.

Art. 57. – Radio equipment covered by this Directive which was placed on the market before 13 June 2017 and are compliant with the essential requirements provisioned under Government Decision no. 130/2015 on radio equipment and electronic communications terminal equipment and the mutual recognition of their conformity are allowed to be placed on the market and/or put into service.

Art. 58. – (1) The present decision shall enter into force within 30 days after it is published in the *Romanian Official Journal*, Part I.

(2) The Government Decision no. 130/2015 on radio equipment and electronic communications terminal equipment and the mutual recognition of their conformity published in the *Romanian Official Journal*, Part I, no. 202 as of 26 March 2015 is hereby repealed as from the date the present decision enters into force.

(3) Whenever another previously law refers to the repealed law in paragraph (2) the reference shall be deemed to be made to the corresponding provisions of this decision.

The present decision transposes Directive 2014/53/EU of the European Parliament and of the Council as of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC, published in the *Official Journal of the European Union* (JOUE) series L, no. 153 as of 22 May 2014.

Equipment not covered by this directive

1. Radio equipment used by radio amateurs within the meaning of Art. 1, definition 56, of the International Telecommunications Union Radio Regulations, unless the equipment is made available on the market.

The following shall be regarded as not being made available on the market:

- a) radio kits for assembly and use by radio amateurs
- b) radio equipment modified by and for the use of radio amateurs;
- c) radio equipment constructed by radio amateurs for individual experimental and scientific purposes related to amateur radio.

2. Marine equipment falling within the scope of Government Decision no. 494/2006 on marine equipment, with subsequent amendments and completions.

3. Airborne products, parts and appliances falling within the scope of Art. 3 of Regulation (EC) No 216/2008 of the European Parliament and of the Council on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC with subsequent amendments and completions.

4. Custom-built evaluation kits for professionals to be used solely at research and development facilities for such purposes.

Module A of conformity assessment

Internal production control

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2-4 of this Annex, and ensures and declares on his sole responsibility that the radio equipment concerned satisfies the essential requirements set out in Art. 3 of this decision.

2. Technical documentation

The manufacturer shall establish the technical documentation in accordance with Art. 23 of this decision.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured radio equipment with the technical documentation referred to in point 2 of this Annex and with the relevant essential requirements set out in Art. 3 of this decision.

4. EC marking and the EU declaration of conformity

4.1. The manufacturer shall affix the EC marking in accordance with Art. 21 of this decision, to each item of radio equipment that satisfies the applicable requirements of this Directive.

4.2. The manufacturer shall draw up a written EU declaration of conformity for each radio equipment type and keep it together with the technical documentation at the disposal of market surveillance and radio equipment control authorities for 10 years after the radio equipment has been placed on the market. The EU declaration of conformity shall identify the radio equipment for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available by the manufacturer to the Market surveillance and radio equipment control authorities upon their request.

5. Authorized representative

The manufacturer's obligations set out in point 4 may be fulfilled by his authorized representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Conformity assessment modules B and C

Module B – EU-type examination

1. EU-type examination is that part of a conformity assessment procedure in which a notified body examines the technical design of the radio equipment and verifies and attests that the technical design of the radio equipment meets the essential requirements set out in Art. 3 of this decision.
2. EU-type examination shall be carried out by assessment of the adequacy of the technical design of the radio equipment through examination of the technical documentation and supporting documentation referred to in point 3, without examination of a specimen (design type).
3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

The application shall include:

- a) the name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address as well;
- b) a written declaration on his sole responsibility that the same application has not been lodged with any other notified body;

The application shall be accompanied by:

- a) the technical documentation. The technical documentation shall make it possible to assess the radio equipment's conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, information on the design, manufacture and operation of the radio equipment. The technical documentation shall contain, wherever applicable, the elements set out in Annex no. 5;
- b) the supporting documents for the adequacy of the technical design solution. That supporting documents shall mention any documents that have been used, in particular where the relevant harmonized standards have not been fully applied or have not been applied. The supporting documents shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

4. The notified body shall examine the technical documentation and supporting documents to assess the adequacy of the technical design of the radio equipment.
5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations as provided in point 8, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.
6. Where the type meets the requirements of this Directive that apply to the radio equipment concerned, the notified body shall issue an EU-type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the aspects of the essential requirements covered by the examination, the conditions (if any) for its validity and the necessary data for identification of the assessed type.

The EU-type examination certificate may have one or more annexes attached.

The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured radio equipment with the examined type to be evaluated and to allow for in-service control.

Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the radio equipment with the essential requirements of this Directive or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

8. Each notified body shall inform MCSI concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.

Each notified body shall inform the Member States of the European Union and of the European Economic Area of EU-type examination certificates it has issued and/or additions thereto in those cases where harmonized standards the references of which have been published in the *Official Journal of the European Union* have not been fully applied or have not been applied.

The European Commission, the Member States of the European Union and of the European Economic Area and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the European Commission and the Member States of the European Union and of the European Economic Area may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer for 10 years after the radio equipment has been assessed or until the expiry of the validity of that certificate.

9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of market surveillance and radio equipment control authorities for 10 years after the radio equipment has been placed on the market.

10. The manufacturer's authorized representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

Module C - Conformity to type based on internal production control

1. Conformity to type based on internal production control is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares that the radio equipment concerned is in conformity with the type described in the EU-type examination certificate and satisfies the requirements of this Directive that apply to it.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured radio equipment with the approved type described in the EU-type examination certificate and with the requirements of this Directive.

3. EC marking and EU declaration of conformity

3.1. The manufacturer shall affix the EC marking in accordance with Art. 21 to each item of radio equipment that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

3.2. The manufacturer shall draw up a written EU declaration of conformity for each radio equipment type and keep it at the disposal of the market surveillance and radio equipment control authorities for 10 years after the radio equipment has been placed on the market. The EU declaration of conformity shall identify the radio equipment for which it has been drawn up. A copy of the EU declaration of conformity shall be made available to the market surveillance and radio equipment control authorities upon their request.

4. Authorized representative

The manufacturer's obligations set out in point 3 may be fulfilled by his authorized representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Conformity assessment module H

Conformity based on full quality assurance

1. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares on his sole responsibility that the radio equipment concerned satisfies the requirements of this Directive that apply to it.

2. Manufacturing

The manufacturer shall operate an approved quality system for design, manufacture, final radio equipment inspection and testing of the radio equipment concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the radio equipment concerned.

The application shall include:

- a) the name and address of the manufacturer and, if the application is lodged by his authorized representative, his name and address as well;
- b) a written declaration that the same application has not been lodged with any other notified body.

The application shall be accompanied by:

- a) the technical documentation for each radio equipment type intended to be manufactured. The technical documentation shall contain, wherever applicable, the elements set out in Annex no. 5;
- b) the documentation concerning the quality system.

3.2. The quality system shall ensure compliance of the radio equipment with the requirements of this Directive that apply to it.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. That quality system documentation shall permit a consistent interpretation of the quality programs, plans, manuals and records or quality evidences.

It shall, in particular, contain an adequate description of:

- a) the quality objectives, the organizational structure and responsibilities and powers of the management with regard to design and product quality;
- b) the technical design specifications, including standards, that will be applied and, where the relevant harmonized standards will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the radio equipment will be met;
- c) the design control and design verification techniques, procedures and systematic actions that will be used when designing radio equipment pertaining to the radio equipment type covered;
- d) the corresponding manufacturing, quality control and quality assurance techniques, procedures and systematic actions that will be used;
- e) the examinations and tests that will be carried out before, during and after

manufacture, and the frequency with which they will be carried out;

f) the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel, etc.;

g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonized standard. In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant radio equipment field and radio equipment technology concerned, and knowledge of the applicable requirements of this decision. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1 paragraph 3 letter a) to verify the manufacturer's ability to identify the applicable requirements of this decision and to carry out the necessary examinations with a view to ensuring compliance of the radio equipment with those requirements.

The manufacturer or his authorized representative shall be notified of the assessment decision. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

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

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary. It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. 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 shall, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:

a) the quality system documentation;

b) evidences or the quality records as provided for the quality system, such as: results of analyses, calculations, tests, etc.;

c) the quality records or evidences as provided for by the manufacturing part of the quality system, such as: inspection reports and test data, calibration data, reports concerning the qualifications of the personnel, etc.

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may, if necessary, carry out radio equipment tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. CE marking and EU declaration of conformity

5.1. The manufacturer shall affix the EC marking in accordance with Art. 21 and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each item of radio equipment that satisfies the applicable requirements set out in Art. 3.

5.2. The manufacturer shall draw up a written EU declaration of conformity for each radio equipment type and keep it at the disposal of the market surveillance and radio equipment control authorities for 10 years after the radio equipment has been placed on the market. The EU declaration of conformity shall identify the radio equipment type for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the market surveillance and radio equipment control authorities upon their request.

6. The manufacturer shall, for a period ending 10 years after the radio equipment has been placed on the market, keep at the disposal of the market surveillance and radio equipment control authorities, the following:

- a) the technical documentation referred to in point 3.1 paragraph 3 letter a);
- b) the documentation concerning the quality system referred to in point 3.1 paragraph 3 letter b);
- c) the change referred to in point 3.5, as approved;
- d) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform MCSI of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to it the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

8. Authorized representative

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorized representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Contents of technical documentation

The technical documentation shall, wherever applicable, contain at least the following elements:

- a) a general description of the radio equipment including:
 - i) photographs or illustrations showing external features, marking and internal layout;
 - (ii) versions of software or firmware affecting compliance with essential requirements;
 - (iii) user information and installation instructions;
- b) conceptual design, manufacturing drawings and schemes of components, sub-assemblies, circuits and other relevant similar elements;
- c) descriptions and explanations necessary for the understanding of those drawings and schemes above mentioned and the operation of the radio equipment, as well;
- d) a list of the harmonized standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, and, where those harmonized standards have not been applied, descriptions of the solutions adopted to meet the essential requirements set out in Art. 3 of this decision, including a list of other relevant technical specifications applied. In the event of partly applied harmonized standards, the technical documentation shall specify the parts which have been applied;
- e) a copy of the EU declaration of conformity;
- f) where the conformity assessment module in Annex 3 has been applied, a copy of the EU-type examination certificate and its annexes as delivered by the notified body involved;
- g) results of design calculations made, examinations carried out, and other relevant similar elements;
- h) test reports;
- i) an explanation of the compliance with the requirement of Art. 10 letter c) and of the inclusion or not of information on the packaging in accordance with Art. 10 letter n).

EU Declaration of conformity (No XXX) ⁽¹⁾

1. Radio equipment (product, type, batch or serial number):
2. Name and address of the manufacturer or his authorized representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
4. Object of the declaration (identification of the radio equipment allowing traceability; it may include a color image of sufficient clarity where necessary for the identification of the radio equipment):
5. The object of the declaration described above is in conformity with the relevant Union harmonization legislation:
 - Directive 2014/53/EU
 - other Union harmonization legislation (where applicable)
6. References to the relevant harmonized standards used or references to the other technical specifications in relation to which conformity is declared. References must be listed with their identification numbers and version and, where applicable, date of issue: ...
7. Where applicable, the notified body ... (name, number) ... performed ... (description of intervention) and issued the EU-type examination certificate: ...
8. Where applicable, a description of accessories and components, including software, which allow the radio equipment to operate as intended and covered by the EU declaration of conformity: ...
9. Additional information:
Signed for and on behalf of: ... place and date of issue: ... name, function, signature: ...

⁽¹⁾ It is optional for the manufacturer to assign a number to the EU declaration of conformity.

Simplified EU declaration of conformity

The simplified EU declaration of conformity referred to in Art. 10 letter m) shall be provided as follows:

Hereby, [*Name of manufacturer*] declares that the radio equipment type [*designation of type of radio equipment*] is in compliance with Directive 2014/53/EU.

The full text of the EU declaration of conformity is available at the following internet address:

...