

[Unofficial translation from Norwegian for information only. Legal authenticity remains with the original Norwegian version.]

Regulations on EEA requirements related to radio equipment

*Laid down by the Norwegian Communications Authority on 14.04.2015 pursuant to the Electronic Communications Act of 4 July 2003 no. 83, sections 1-4, 2-3, 8-1, 8-2 and 10-1, cf. Regulations of 14 June 2013 no. 619 on the division of authority within the telecommunications sector.
EEA references: EEA agreement Annex II chap. XVIII no. 4zr (Directive 2014/53/EU).*

Chapter 1. Introductory provisions

Section 1. Purpose

The purpose of these regulations is to ensure the functioning of the internal market, and that radio equipment has an adequate level of electromagnetic compatibility and uses the radio spectrum effectively, meets the requirements for the protection of the health and safety of persons and of domestic animals and the protection of property.

Section 2. Scope

These regulations apply to radio equipment as defined in Section 3. These regulations do not apply to:

- a) equipment covered by regulations 15 June 1999 no. 709 related to EEA approval of maritime radio equipment and regulations on EEA requirements related to maritime radio equipment which enter into force on 18 September 2016 repealing the former regulations.
- b) equipment covered by regulations 22 June 2007 no. 89 related to electromagnetic compatibility (EMC) for electronic communication and regulations on EEA requirements related to maritime radio equipment which enter into force on 20 April 2016 repealing the former regulations.
- c) equipment covered by regulations 27 September 2005 no 1094 in safety in electronic communications networks and regulations on EEA requirements related to equipment for electronic communication which enter into force on 20 April 2016.
- d) equipment covered by regulations 26 February 2013 no. 219 on common safety rules in the field of civil aviation and establishing a European Aviation Safety Agency (EASA regulations)
- e) equipment permitted to be used in accordance with regulations 5 November 2009 no. 1340 on amateur radio licence, unless the equipment is made available on the market. Radio kits for assembly and use by radio amateurs, radio equipment modified by and for the use of radio amateurs and equipment constructed by individual radio amateurs for experimental and scientific purposes related to amateur radio shall not be regarded as being made available on the market.

- f) custom-built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes.
- g) radio equipment and telecommunications terminal equipment which only is used to ensure security of the State or other public security, which only is used by the Military or initiative by the Government in the legal area.

Radio equipment covered by this regulation may be given individual approval according to the Electronic Communications Act section 8-1 second paragraph for use in the Svalbard area.

Section 3. Definitions

For the purpose of these regulations the following definitions apply

- a) radio equipment:
 - 1. From 13 June 2016 to 31 December 2016: product or parts of a product that intentionally emit or receive electromagnetic waves transmitted in free space, except equipment that solely receives broadcasting
 - 2. From 1 January 2017: an electrical or electronic product, which intentionally emits and/or receives radio waves for the purpose of radio communication and/or radiodetermination, or an electrical or electronic product which must be completed with an accessory, such as antenna, so as to intentionally emit and/or receive radio waves for the purpose of radio communication and/or radiodetermination
- b) radio communication: communication by means of radio waves
- c) radiodetermination: 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
- d) radio waves: electromagnetic waves of frequencies lower than 3 000 GHz, propagated in space without artificial guide
- e) electromagnetic disturbance: any electromagnetic phenomenon which may degrade the performance of equipment; an electromagnetic disturbance may be electromagnetic noise, an unwanted signal or a change in the propagation medium itself
- f) making available on the market: any supply of radio equipment for distribution, consumption or use in EEA in the course of a commercial activity, whether in return for payment or free of charge
- g) placing on the market: the first making available of radio equipment in EEA
- h) putting into service: the first use of radio equipment in the EEA by its end-user
- i) manufacturer: any natural or legal person who manufactures radio equipment or has radio equipment designed or manufactured, and markets that equipment under his name or trade mark

- j) authorised representative: any natural or legal person established within the EEA who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks
- k) importer: any natural or legal person established within the EEA who places radio equipment from a third country on the market in EEA
- l) distributor: any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes radio equipment available on the market
- m) economic operators: the manufacturer, the authorised representative, the importer and the distributor
- n) technical specification: a document that prescribes technical requirements to be fulfilled by radio equipment
- o) harmonised standard: an European standard prepared by the European standardisation organisations CEN, CENELEC and ETSI, and adopted on the basis of a request made by the European Commission for the application of EEA harmonisation legislation
- p) conformity assessment: the process demonstrating whether the essential requirements of these regulations relating to radio equipment have been fulfilled
- q) notified body: a body appointed by national authorities to performs conformity assessment activities
- r) recall: any measure aimed at achieving the return of radio equipment that has already been made available to the end-user
- s) withdrawal: any measure aimed at preventing radio equipment in the supply chain from being made available on the market
- t) CE marking: a marking by which the manufacturer indicates that the radio equipment is in conformity with the applicable requirements set out in the EEA harmonisation legislation providing for its affixing
- u) electromagnetic compatibility: the ability of radio equipment to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbances to other equipment in that environment.

In addition the definitions in the Electronic Communications Act apply.

Chapter 2. Requirements to radio equipment

Section 4. Conditions for making radio equipment available on the market and putting into service

Radio equipment may be placed on the market when it complies with the essential requirements in section 6 and is correctly marked according to section 28.

Radio equipment may be put into service if it complies with the requirements of the first paragraph, is correctly installed in good repair and used appropriately.

Frequency license under the Electronic Communications Act 4 July 2003 no. 83 chapter 6 may be required.

Section 5. *Trade fairs, exhibitions etc.*

Radio equipment can be displayed at trade fairs, exhibitions and similar events even if the equipment does not comply with the requirements in these regulations, provided that a visible sign clearly indicates that the radio equipment may not be made available on the market or put into service until it has been brought into conformity with these regulations.

Demonstration of radio equipment may only take place provided that adequate measures have been taken to avoid harmful interference, electromagnetic disturbances and risk to the health or safety of persons or of domestic animals or to property.

Section 6. *Essential requirements*

Radio equipment shall be constructed and manufactured so that it

- a) does not cause harm to the life and health of persons and of domestic animals and the risk of property damage. The radio equipment, together with its component parts, shall be made in such a way as to ensure that it can be safely and properly assembled and connected. The radio equipment shall be designed and manufactured in accordance with recognized technological practice for electrical safety, so that the equipment during installation, maintenance and intended use ensures protection against the hazards caused by:
 1. direct or indirect contact with the radio equipment
 2. temperatures, arcs or radiation
 3. non-electrical danger caused by the radio equipment
 4. that the insulation of the radio equipment is not suitable for foreseeable conditions
 5. that the radio equipment does not meet the expected mechanical requirements
 6. that the radio equipment is not resistant to non-mechanical influences under expected environmental conditions
 7. overload and other foreseeable faults,
- b) the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment and other equipment cannot operate as intended; and it has a level of immunity to the electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use,
- c) both effectively uses and supports the efficient use of radio spectrum in order to avoid harmful interference,
- d) supports certain features ensuring access to emergency services in accordance with section 7 to section 11.

Section 7. *Special requirements to radio equipment covered by the regional arrangement concerning the radiotelephone service on inland waterways*

Radio equipment to be used on waterways in Germany, Austria, Belgium, Bulgaria, Croatia, France, Hungary, Luxembourg, Moldova, Holland, Poland, Romania, Russia, Slovakia, Switzerland, Czech republic, Ukraine, Yugoslavia, covered by the arrangement concerning the radiotelephone service on inland waterways concluded in Basel on 6 April 2000 in countries where the arrangement is to be implemented, and which is operating in the specified frequency bands, shall use the automatic transmitter identification system (ATIS).

Radio communication equipment on the service categories 'ship-to-ship', 'ship-to-port-authorities' and 'onboard-communication', laid down by the arrangement shall not be able to transmit at transmitter power higher than 1 Watt.

Section 8. *Special requirements to radio equipment which is intended to be fitted on vessels not covered by SOLAS-74*

Radio equipment to be used in the maritime mobile service or the maritime mobile satellite service as defined in the articles S1.28 and S1.29 of the International Telecommunications Union Radio Regulations, and are intended for use on all vessels to which the 1974 International Convention for the Safety of Life at Sea as amended (SOLAS) do not apply, and which are intended to participate in the Global Maritime Distress and Safety System (GMDSS), as laid down in Chapter IV of the SOLAS convention, shall be designed so as to ensure correct functioning under exposure to a marine environment, meet all the operational requirements of the GMDSS applicable to non-SOLAS vessels, and are in accordance with the relevant provisions of the International Maritime Organisation (IMO).

The radio equipment covered by the first paragraph shall be designed so as to provide clear and robust communications with a high degree of fidelity of the analogue or digital communications link.

Section 9. *Special requirements to maritime radio equipment in Automatic Identification System (AIS) service*

Radio equipment to be used in the maritime mobile service and the maritime mobile satellite service as defined by the International Telecommunications Union Radio Regulations Articles 1.28 and 1.29 shall be constructed so that it is functioning properly in the environment for which it is intended.

Radio Equipment covered by first paragraph, to be used in the AIS service as described in provision 19 of Chapter V of SOLAS and to be used on board non-SOLAS vessels or shore stations, shall comply with all applicable operational requirements for AIS.

Section 10. *Special requirements to avalanche beacons intended to locate people submerged by snow following an avalanche*

Avalanche beacons operating on 457 kHz to locate people submerged by snow following an avalanche shall be designed so as to be able to interwork with new beacons as well as with

the installed base of beacons, and which complies with the requirements in European Standard ETS 300 718.

The equipment shall be so constructed that it will function reliably after having been exposed to an avalanche and continue to function when being submerged in snow for a longer period.

Section 11. *Special requirements to emergency locator beacons*

Emergency locator beacons that are not covered by Section 8 and transmitting on the emergency frequency 406 MHz within the Cospas-Sarsat system shall be so constructed that they functioning properly under the external influences equipment may be exposed.

The equipment covered by the first paragraph shall under distress conditions provide clear and robust communication with a high degree of fidelity by meeting all the requirements of the Cospas-Sarsat system.

Chapter 3. Obligations of economic operators

Section 12. *Manufacturers*

Before radio equipment is placed on the market the manufacturer shall draw up the technical documentation in accordance with section 27, carry out or have it carried out conformity assessment in accordance with chapter 4, ensure marking in accordance with section 28 and information to the user in accordance with section 25.

Where compliance of radio equipment with the requirements has been demonstrated, the manufacturer shall draw up a declaration of conformity in accordance with section 26 and affix the CE marking in accordance with section 28.

The manufacturer shall keep the technical documentation and the declaration of conformity for ten years after the radio equipment has been placed on the market.

Manufacturer shall make available to the Norwegian Communications Authority information on which economic operators the manufacturer has supplied radio equipment for ten years after the radio equipment was supplied.

When placing their radio equipment on the market, the manufacturer shall ensure that it has been designed and the manufactured in accordance with the essential requirements set out in section 6. The manufacturer shall ensure that radio equipment shall be so constructed that it can be operated in at least one country within EEA without infringing applicable requirements on the use of radio spectrum.

The manufacturer shall ensure that procedures are in place for series production to remain in conformity with these regulations. Changes in radio equipment design or characteristics and changes in the harmonised standards or in other technical specifications by reference to which conformity of radio equipment is declared shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by radio equipment, manufacturers shall, to protect the health and safety of end-users, carry out sample testing of radio equipment made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming radio equipment and radio equipment recalls, and shall keep distributors informed of any such monitoring

Manufacturer who consider or have reason to believe that radio equipment which they have placed on the market is not in conformity with these regulations shall immediately take the corrective measures necessary to bring that radio equipment into conformity, to withdraw it or recall it, if appropriate.

Where the radio equipment presents a risk, manufacturer shall immediately inform the Norwegian Communications Authority giving details, in particular, of the non-compliance, of any corrective measures taken and of the results thereof.

Section 13. *Authorised representatives*

The manufacturer may, by a written mandate, appoint an authorised representative to act on behalf of the manufacturer. The obligation to draw up technical documentation laid down in section 27 and the obligations to ensure that the radio equipment is designed and manufactured in accordance with the essential requirements in section 6 shall not form part of the authorised representative's mandate.

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

- a) keep the declaration of conformity and the technical documentation at the disposal of Norwegian communications Authority for ten years after the radio equipment has been placed on the market,
- b) on request from the Norwegian Communications Authority provide all the information and documentation necessary to demonstrate the conformity of radio equipment,
- c) cooperate with the Norwegian Communications Authority at their request, on any action taken to eliminate the risks posed by radio equipment covered by the authorized representative's mandate.

Section 14. *Importer*

When making radio equipment available on the market the importer shall ensure that

- a) the conformity assessment procedure referred to in chapter 4 has been carried out by the manufacturer,
- b) the radio equipment is so constructed that it can be operated in at least one EEA country without infringing applicable requirements on the use of radio spectrum,

- c) that the manufacturer has drawn up the technical documentation in accordance with section 27,
- d) the radio equipment is marked correctly in accordance with section 28,
- e) the radio equipment is accompanied by instructions and safety related information in accordance with the requirements of section 25.

Where an importer considers or has reason to believe that radio equipment is not in conformity with the essential requirements set out in section 6, he shall not place the radio equipment on the market until it has been brought into conformity. Where the radio equipment presents a risk, the importer shall inform the manufacturer and the Norwegian Communications Authority to that effect.

Importers shall ensure that, while radio equipment is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in section 6.

When deemed appropriate with regard to the risks presented by radio equipment, importers shall, to protect the health and safety of end-users, carry out sample testing of radio equipment made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming radio equipment and radio equipment recalls, and shall keep distributors informed of any such monitoring.

Importer who consider or have reason to believe that radio equipment which they have placed on the market is not in conformity with these regulations shall immediately take the corrective measures necessary to bring that radio equipment into conformity, to withdraw it or recall it, if appropriate.

In case the radio equipment presents a risk, importer shall immediately inform the Norwegian Communications Authority giving details, in particular, of the non-compliance and of any measures taken to bring the radio equipment into conformity with the regulations.

The importer shall, for ten years after the radio equipment has been placed on the market, keep a copy of the declaration of conformity at the disposal of the Norwegian Communications Authority and ensure that the technical documentation can be made available upon request.

The importer shall be able to present information to the Norwegian Communications Authority on any economic operator who has supplied them with radio equipment, and on any economic operators to whom they have supplied radio equipment for ten years after they have supplied the radio equipment.

An importer placing radio equipment on the market under his name or trademark, or modifies radio equipment already placed on the market in such a way that it may affect compliance with the requirements of these regulations, shall be regarded as the manufacturer with the obligations arising from these regulations.

Section 15. *Distributor*

When making radio equipment available on the market the importer shall ensure that

- a) the radio equipment is marked correctly with the CE-making in accordance with section 28, that the radio equipment is accompanied by declaration of conformity in accordance with section 26 and by the instructions and safety information in accordance with section 25,
- b) the manufacturer and the importer have complied with the following requirements:
 1. The radio equipment is so constructed that it can be operated in at least one country within EEA without infringing applicable requirements on the use of radio spectrum.
 2. The radio equipment placed on the market is marked with type, batch or serial number or similar elements in accordance with section 28 second paragraph allowing identification of the equipment.
 3. The radio equipment is marked with the name of the manufacturer and the importer, registered trade name or registered trade mark and the postal address at which they can be contacted in accordance with section 28 first paragraph.
 4. Information to the user is in accordance with section 25.

Where a distributor considers or has reason to believe that radio equipment is not in conformity with the essential requirements set out in section 6, he shall not make the radio equipment available on the market until it has been brought into conformity. In case the radio equipment presents a risk, the distributor shall inform the manufacturer and the Norwegian Communications Authority.

Distributors shall ensure that, while radio equipment is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in section 6.

Distributors who consider or have reason to believe that radio equipment which they have made available on the market is not in conformity with these regulations shall make sure that the corrective measures necessary to bring that radio equipment into conformity, to withdraw it or recall it, if appropriate, are taken.

In case the radio equipment presents a risk, the distributor shall immediately inform the Norwegian Communications Authority giving details, in particular, of the non-compliance and of any measures taken to bring the radio equipment into conformity with the regulations.

The distributor shall be able to present information to the Norwegian Communications Authority on any economic operator who has supplied them with radio equipment, and on any economic operators to whom they have supplied radio equipment for ten years after they have supplied the radio equipment.

An distributor placing radio equipment on the market under his name or trademark or modifies radio equipment already placed on the market in a way that it may affect compliance with the requirements of these regulations shall be regarded as the manufacturer with the obligations arising from these regulations.

Chapter 4. Conformity assessment

Section 16. *Presumption of conformity*

Radio equipment which is in conformity with harmonised 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 Section 6 covered by those standards or parts thereof.

Section 17. *Conformity assessment procedures*

Manufacturer shall demonstrate compliance of radio equipment with the essential requirements set out in section 6 first paragraph letters a and b using any of the following conformity assessment procedures:

- a) module A - conformity assessment procedure based on internal production control set out in in section 18
- b) modules B and C - conformity assessment procedure based on EU-type examination that is followed by the conformity to type based on internal production control set out in section 19 and section 20
- c) module H - conformity assessment procedure based on full quality assurance set out in section 21 – section 24.

Where, in assessing the compliance of radio equipment with the essential requirements set out in section 6 first paragraph letters c and d, the manufacturer has applied harmonised 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) module A - conformity assessment procedure based on internal production control set out in in section 18
- b) modules B and C - conformity assessment procedure based on EU-type examination that is followed by the conformity to type based on internal production control set out in section 19 and section 20
- c) module H - conformity assessment procedure based on based on full quality assurance set out in section 21 – section 24.

Where, in assessing the compliance of radio equipment with the essential requirements set out in section 6 first paragraph letters c and d, the manufacturer has not applied or has applied only in part harmonised standards the references of which have been published in the Official Journal of the European Union, or where such harmonised standards do not exist, radio equipment shall be submitted with regard to those essential requirements to either of the following procedures:

- a) modules B and C - conformity assessment procedure based on EU-type examination that is followed by the conformity to type based on internal production control set out in section 19 and section 20
- b) module H - conformity assessment procedure based on full quality assurance set out in section 21 – section 24.

The conformity assessment shall take into account all intended operating conditions and, for the essential requirement set out in section 6 first paragraph letter a, the assessment shall also take into account the reasonably foreseeable conditions. 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 section 6 in all possible configurations.

Section 18. Module A – Conformity assessment procedure by internal production control

When the manufacturer applies the conformity assessment procedure by internal production control to verify that radio equipment meets the essential requirements of these regulations section 6, the manufacturer shall:

- a) establish the technical documentation in accordance with section 27
- b) take all measures necessary so that the manufacturing process ensure compliance of the manufactured radio equipment with essential requirements and with the technical documentation
- c) manufacturer or its authorised representative within the EEA shall affix the CE marking in accordance with section 28 on radio equipment that satisfies the requirements of these regulations
- d) manufacturer or its authorised representative within the EEA shall draw up a written declaration of conformity and keep it together with the technical documentation for ten years after the radio equipment has been placed on the market.

§ 19. Module B – conformity assessment procedure by EU-type examination

When the manufacturer applies the conformity assessment procedure by EU-type examination the notified body shall examine the technical design of the radio equipment and verifies that the technical design of the radio equipment meets the essential requirements set out in section 6.

Notified body shall carry out assessment of the technical design of the radio equipment through examination of the technical documentation and documentations submitted in connection with the assignment. The notified body shall not examine the physical specimen. The notified body shall draw up a report that records the activities undertaken and their outcomes.

The manufacturer or its authorised representative shall lodge an application for EU-type examination with a notified body. The application shall include:

- a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well
- b) a written declaration that the same application has not been lodged with any other notified body
- c) technical documentation, including analysis and assessment of the risk(s), making it possible to assess if the radio equipment fulfills the requirements of these regulations. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design and operation of the radio equipment. The technical documentation shall contain, wherever applicable, the elements set out in annex 3
- d) supporting evidence for the adequacy of the technical design solution, including any documents that have been used, in particular where the relevant harmonised standards have not been applied or have not been fully applied. The supporting evidence 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.

Where the type meets the requirements of these regulations 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 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 these regulations, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

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 these regulations, 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 these regulations section 6 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.

Notified body shall unsolicited report to Ministry of Transport and Communications concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn.

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.

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 ten years after the radio equipment has been assessed or until the expiry of the validity of that certificate.

The manufacturer or its authorised representative shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation for ten years after the radio equipment has been placed on the market.

Section 20. Module C – Conformity assessment procedure to type based on internal production control

When the manufacturer applies the conformity assessment procedure based on internal production control to declares that the radio equipment concerned is in conformity with the type described in the EU-type examination certificate and satisfies the essential requirements of section 6 of these regulations, then

a) 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 applicable requirements of these regulations,

b) the manufacturer or its authorized representative within the EEA shall affix the CE marking in accordance with section 28 to each item of radio equipment that is in conformity with the applicable requirements of these regulations,

c) the manufacturer shall draw up a written declaration of conformity in accordance with section 26 and keep it together with the technical documentation for ten years after the radio equipment has been placed on the market. The declaration of conformity shall identify the radio equipment type for which it has been drawn up.

Section 21. Module H – conformity assessment procedure based on full quality assurance

When the manufacturer applies the conformity assessment procedure based on full quality assurance to declare that the radio equipment concerned is in conformity with requirements of these regulations, the provisions of this section shall be fulfilled.

The manufacturer shall operate an approved quality system for design, manufacture, final radio equipment inspection and testing in accordance with third paragraph, and shall be subject to surveillance of notified body in accordance with section 23.

The quality system shall ensure compliance of the radio equipment with the requirements of these regulations. 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 programmes, plans, manuals and records. It shall, in particular, contain an adequate description of:

- a) the quality objectives and the organisational structure, 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 harmonised standards will not be applied in full, the means that will be used to ensure that the essential requirements of these regulations will be met,
- c) the design control and design verification techniques, processes 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, processes 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.

Notified body shall inform the Ministry of Transport and Communications of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to the Ministry of Transport and Communications the list of quality system approvals refused, suspended or otherwise restricted.

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.

Section 22. Module H - conformity assessment procedure based on full quality assurance - notified body

Manufacturer using conformity assessment procedure according to section 21 shall lodge an application for assessment of his quality system with the notified body of his. The application shall include:

- a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
- b) the technical documentation in accordance with section 27 for each radio equipment type intended to be manufactured,
- c) the documentation concerning the quality system in accordance with section 21,
- d) a written declaration that the same application has not been lodged with any other notified body.

The notified body shall assess the quality system to determine whether it satisfies the requirements set out in section 21. The assessment shall be carried out using at least one member experienced as an assessor in the relevant radio equipment technology concerned. The assessment shall include an assessment visit to the manufacturer's premises. 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 harmonised standard. The manufacturer or his authorised representative within EEA shall be notified of the results of the assessment. The notification shall contain the conclusions of the examinations and the reasoned assessment decision

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.

The manufacturer or its authorised representative 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 set out in section 21 or whether a reassessment is necessary.

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

Section 23. Module H - conformity assessment procedure based on full quality assurance – responsibility for surveillance

Manufacturer using conformity assessment procedure according to section 21 shall 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) the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc,

- c) the quality records 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.

The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system.

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.

Section 24. Module H - conformity assessment procedure based on full quality assurance - marking requirement etc.

Manufacturer that use conformity assessment procedure according to section 21 shall either themselves or by authorised representative within the EEA, affix the CE marking and notified body's identification number in accordance with section 28.

The manufacturer or its authorised representative within EEA shall draw up a written declaration of conformity in accordance with section 26 for each radio equipment type.

The manufacturer or its authorised representative within EEA shall, for a period ending ten years after the radio equipment has been placed on the market, keep the technical documentation, the documentation concerning the quality system, the changes and decisions and reports of the notified body referred to in section 21 to section 23.

Chapter 5. Requirements to documentation, information and marking

Section 25. Information to user

Radio equipment shall be accompanied by instructions and safety information. Instructions and safety information shall be in at least one of the following languages: Norwegian, Swedish, Danish or English. Instructions shall include the information required to use radio equipment in accordance with its intended use. Such information shall include, where applicable, a description of accessories and components, including software, which allow the radio equipment to operate as intended.

In cases of restrictions on putting into service or of requirements for authorisation of use, information available on the packaging shall allow the identification of the country within EEA or the geographical area within a country within EEA where restrictions on putting into service or requirements for authorisation of use exist. Such information shall be completed in the instructions accompanying the radio equipment.

In case of radio equipment intentionally emitting radio waves the manufacturer shall in addition ensure to include information on frequency band(s) in which the radio equipment

operates, and maximum radio-frequency power transmitted in the frequency band(s) in which the radio equipment operates.

Each item of radio equipment shall be accompanied by a copy of either the full or the simplified declaration of conformity. The declaration of conformity shall meet the requirements of these regulations section 26.

Section 26. *Declaration of conformity*

The declaration of conformity shall state that the essential requirements set out in section 6 are met.

The declaration of conformity shall have the model structure and contain the elements set out in annex 1, and shall be continuously updated.

The declaration of conformity shall be issued in Norwegian, Swedish, Danish or English.

Section 27. *Technical documentation*

The technical documentation shall contain all relevant documentation of the means used by the manufacturer to ensure that radio equipment complies with the essential requirements set out in these regulations section 6, and it shall be continuously updated. At least, it shall contain the elements set out in annex 3.

The technical documentation and correspondence relating to any EU-type examination procedure shall be drawn up in an official language of the country in which the notified body is established or in a language acceptable to that notified body.

Section 28. *Marking*

Radio equipment shall be marked with the name of the manufacturer, registered trade name or registered trade mark and the postal address at which they can be contacted or, where the size or nature of radio equipment does not allow it, on its packaging, or in a document accompanying the radio equipment. The contact details shall be in Norwegian, Swedish, Danish or English.

Radio equipment shall be marked with type, batch or serial number or other element allowing its identification, or, where the size or nature of the radio equipment does not allow it, that the required information is provided on the packaging, or in a document accompanying the radio equipment

Before radio equipment is placed on the market, the manufacturer or manufacturer's authorized representative in the EEA shall, to radio equipment that complies with the regulations, affix the CE marking in accordance with the Act of 12 April 2013 no. 13 on the free movement of goods within the EEA (EEA trade law), Regulation (EC) no. 765/2008 Annex II .

The affixing to a product of markings, signs or inscriptions which are likely to mislead third parties regarding the meaning or form of the CE marking shall be prohibited. Any other marking may be affixed to the product provided that the visibility, legibility and meaning of the CE marking is not thereby impaired.

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

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

The CE marking shall be followed by the identification number of the notified body where the conformity assessment procedure set out in section 21 to section 23 is applied. The identification number of the notified body shall have the same height as the CE marking. The identification number of the notified body shall be affixed by the notified body itself or, under its instructions, by the manufacturer or his authorised representative.

Chapter 6. Notified body

Section 29. Appointment of notified body

The Ministry of Transport and Communications appoints notified bodies for radio equipment covered by the regulations under the Act 16 June 1994 no. 20 concerning notified bodies that has the task to carry out conformity assessments.

Application for appointment as a notified body shall be submitted to the Ministry of Transport and Communications. The application shall be accompanied by a description of the conformity assessment activities, the conformity assessment modules and the radio equipment for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by Norwegian Accreditation attesting that the body fulfils the requirements laid down in section 30 and section 31.

Where the notified body concerned cannot provide an accreditation certificate, it shall provide with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in section 30 and section 31.

Section 30. Requirements for notified bodies - organisation and personnel

Notified body shall be a legal person and meet the following requirements:

- a) Notified body shall be a third-party body independent of the organisation or the radio equipment it assesses. However, this shall not preclude the notified body to belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of radio

equipment which it assesses, on condition that its independence and the absence of any conflict of interest are demonstrated.

- b) The top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the radio equipment which they assess, nor the representative of any of those parties. This shall not preclude the use of assessed radio equipment that is necessary for the operations of the conformity assessment body or the use of such radio equipment for personal purposes.
- c) The top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of that radio equipment, or represent the parties engaged in those activities. They shall not engage in any activity, including consultancy services, that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified.
- d) Notified bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.
- e) Notified body and their personnel shall carry out the conformity assessment activities with the highest degree of 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.
- f) A notified body shall be capable of carrying out all the conformity assessment tasks assigned to it according to chapter 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.
- g) The notified body shall have the necessary description of the procedures and equipment needed for the administrative and technical tasks connected with the conformity assessment activities in an appropriate manner.
- h) Notified body shall have at its disposal the necessary personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks.
- i) Notified body shall have 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 distinguish between tasks it carries out as a notified body and other activities.
- j) Notified body shall have 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.

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 section 6 of these regulations, of the applicable harmonised standards and of the relevant provisions of EEA harmonisation legislation and of national legislation,
- d) the ability to draw up EU-type examination certificates or quality system approvals, records and reports demonstrating that assessments have been carried out.

The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

Notified body shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation 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 harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Where a notified body demonstrates its conformity with the criteria laid down in the relevant harmonised 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 this provision in so far as the applicable harmonised standards cover those requirements.

Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in this provision. The notified body shall inform the Ministry of Transport and Communications about such activity. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

Conformity assessment activities of notified body may be subcontracted or carried out by a subsidiary only with the agreement of the client.

Notified bodies shall keep at the disposal of the Ministry of Transport and Communications the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them.

Notified body shall take out liability insurance.

For notified bodies the rules on secrecy apply according to law on 10 February 1967 concerning procedure of treatment in central government administration Section 13 to 13 f.

Section 31. *Operational obligations of notified body*

Notified body shall carry out conformity assessments in accordance with chapter 4. Where the notified body finds that the manufacturer meets relevant requirements of these regulations, it shall issue an EU-type examination certificate or a quality system approval.

Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Notified body shall perform its 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. In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the radio equipment with these regulations.

Where notified body finds that the essential requirements set out in section 6 or corresponding harmonised standards or other technical specifications have not been met by the manufacturer, it shall require that the manufacturer to take appropriate corrective measures.

Where, in the course of the monitoring of conformity following the issue of an EU-type examination certificate or a quality system approval, notified body finds that radio equipment no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the EU-type examination certificate or the quality system approval if necessary.

Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any EU-type examination certificates or quality system approvals, as appropriate.

Section 32. *Information obligation on notified body*

Notified body shall inform the Ministry of Transport and Communications of the following:

- a) any refusal, restriction, suspension or withdrawal of an EU-type examination certificate or a quality system approval,
- b) any circumstances affecting the scope of or conditions for notification,
- c) any request for information which they have received from Norwegian Communications Authority regarding conformity assessment activities,

- d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

Notified body shall provide the other bodies notified under these regulations carrying out similar conformity assessment activities covering the same categories of radio equipment with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Chapter 7. Surveillance and reactions

Section 33. *Surveillance*

Persuant to the Electronic Communications Act the Norwegian Communications Authority is carrying out enforcement with the provisions of these regulations or decisions pursuant to the regulations.

The subject of surveillance shall get hold of equipment which is necessary for the Norwegian Communications Authority in respect of surveillance, even if the equipment is not available in stock. The radio equipment that is subject to surveillance shall be handed over to the Norwegian Communications Authority free of charge.

Section 34. *Reactions*

In the event of violations of the obligations the Norwegian Communications Authority may implement reactions according to the Act 4 July 2003 no. 83 relating to Electronic Communications, and the law 12 April 2013 no. 13 on free movement of goods within the EEA, regulation (EC) no. 765/2008.

Section 35. *Penalties*

Violations of these regulations are punishable to section 12-4 of Act 4 July 2003 no. 83 relating to Electronic Communications.

Chapter 8. Entry into force etc.

Section 36. *Exceptions*

If particular reasons are under consideration and if it is not in conflict with the EEA Agreement, the Norwegian Communications Authority can make exceptions from the requirements in these regulations.

Section 37. *Entry into force*

These regulations enter into force on 13 June 2016.

From the same date regulations 20 June 2000 no. 628 on EEA requirements related to radio equipment and telecommunications terminal equipment are repealed.

Section 38. *Transitional provision*

Radio equipment placed on the market before 13 June 2017 and which is covered by and meets the requirements of regulations 20 June 2000 no. 628 on EEA requirements related to radio equipment and telecommunications terminal equipment can be made available on the market and put into service.

Section 39. *Amendments to other regulations*

From the date these regulations enter into force the following amendments shall be made to other regulations:

Regulations 5 November 2009 no. 1340 on amateur radio licence, section 6 first paragraph first sentence shall read:

Amateur radio licence holders are permitted to use radio equipment that is not covered by the general permission granted in § 8-1 first paragraph of the Electronic Communications Act, cf. Regulation 15 April 2016 no. 377 on EEA requirements for radio equipment.

Section 6 second paragraph shall read:

Radio equipment that is not covered by the general permission granted in § 8-1 first paragraph of the Electronic Communications Act, cf. regulations no. 377 of 15 April 2016 on EEA requirements for radio equipment, shall be arranged and used in such a way that spurious radiated power outside the frequency band specified in § 5 is less than 2,5 microwatts above 30 MHz and less than 50 milliwatts below 30 MHz.

Regulations 15 March 2002 no 276 on the registration and requirements related to the import and the sales of radio and telecommunications terminal equipment section 1 first paragraph letter b first item shall read:

Regulations 15 April 2016 no. 377 on EEA requirements for radio equipment,

Section 4a with changes

Registration is not required for import of equipment that is approved by the authority or meets applicable requirements under regulations of 15 April 2016 no. 377 on EEA requirements for radio equipment, regulations on maritime equipment, regulations on EMC, regulations on electrical safety or aeronautical regulations, provided that the equipment is not for sale nor is to be handed over to others.

Section 5 second paragraph with changes:

Before a supplier sells or in any other way hand over radio equipment, telecommunications terminal equipment and network equipment to others, the equipment shall have equipment

approval of the Authority or meet the applicable requirements of regulations 15 April 2016 no. 377 on EEA requirements for radio equipment, regulations on EMC, regulations on electrical safety or aeronautical regulations.

Section 6 first paragraph with changes:

Before a supplier sells or in any other way hands over radio equipment, telecommunications terminal equipment and network equipment to others, the equipment shall have equipment approval of the Authority or meet the applicable requirements of regulations 15 April 2016 no. 377 on EEA requirements for radio equipment, regulations on EMC, regulations on electrical safety or aeronautical regulations.

Regulations 15 June 1999 no. 709 on EEA approval of maritime radio equipment section 1 third paragraph shall read:

For other types of maritime radio equipment please refer to regulation no. 377 of 15 April 2016 on EEA requirements for radio equipment.

Annex 1 Declaration of conformity (no. xxx) (Insertion of number is optional)

1. Radio equipment (product, type, batch or serial number):
2. Name and address of the manufacturer or his authorised 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 colour 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 harmonisation legislation:
 Directive 2014/53/EU
 Other harmonisation legislation within EEA where applicable:
6. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared. References must be listed with their identification number 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, 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):

Annex 2. Simplified declaration of conformity

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 declaration of conformity is available at the following internet address:

Annex 3. Technical documentation

The technical documentation shall 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 and 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 and the operation of the radio equipment
- d) a list of the harmonised 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 harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements set out in Article 3, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied
- e) copy of the EU declaration of conformity
- f) where the conformity assessment module described in section 9 to section 21 has been applied, 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 these regulations section 12 fifth paragraph and of the inclusion or not of information on the packaging in accordance with section 25 second paragraph.