STATUTORY INSTRUMENTS.

S.I. No. 248 of 2017

EUROPEAN UNION (RADIO EQUIPMENT) REGULATIONS 2017

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I, DENIS NAUGHTEN Minister for Communications, Climate Action and Environment, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972), and for the purpose of giving effect to Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014[1], and of giving full effect to Regulation (EC) No 765/2008 of 9 July 2008[2] hereby make the following regulations:

PART 1

PRELIMINARY

Citation

1. These Regulations may be cited as the European Union (Radio Equipment) Regulations 2017.

Interpretation

2. (1) In these Regulations—

"accreditation" has the meaning assigned to it by Article 2.10 of Regulation (EC) No 765/20082;

"authorised officer" means a person appointed under Regulation 40;

"authorised representative" means a person established within the Union who has received a written mandate from a manufacturer to act on the manufacturer's behalf in relation to specified tasks;

"CE marking" means a marking by which a manufacturer indicates that the radio equipment is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;

"competent authority" means the body designated as the competent authority under Regulation 6;

"conformity assessment" means the process, in accordance with Regulation 16, demonstrating whether the essential requirements have been fulfilled;

"conformity assessment body" means a person who performs conformity assessment procedures laid down in Schedule 2, 3 or 4;

[1]OJ No. L153, 22.5.2014, p. 62
[2]OJ No. L218, 13.8.2008, p 30

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 9th June, 2017.

"Directive" means Directive 2014/53/EU of the European Parliament and of the Council of 16 April 20141;

"direction" means a direction given by the market surveillance authority under Regulation 5(3)(*b*), 31(4), 34(1), or 35(1)(*a*);

"distributor" means any person in the supply chain, other than the manufacturer or importer, who makes radio equipment available on the market;

"economic operator" means a manufacturer, an authorised representative, an importer or a distributor;

"electromagnetic disturbance" has the meaning assigned to it by Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014[3] on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast);

"essential requirements" in relation to radio equipment, means essential requirements specified in Regulation 4(1);

"EU declaration of conformity" means a declaration of conformity drawn up in accordance with the requirements of Regulation 17;

"harmful interference" has the meaning assigned to it by the European Communities (Electronic Communications Networks and Services)(Framework) Regulations 2011 (S.I. No. 333 of 2011);

"harmonised standard" means harmonised standard as defined in Article 2 (1)(*c*) of Regulation (EU) No 1025/2012[4];

"importer" means any person established within the Union who places radio equipment from a third country on the Union market;

"making available on the market" means any supply of radio equipment for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

"manufacturer" means a person who manufactures radio equipment or has radio equipment designed or manufactured and markets that equipment under the person's name or trade mark;

"market surveillance authority" means the body designated as the market surveillance authority under Regulation 30;

"Minister" means Minister for Communications, Climate Action and Environment;

"notified body" means a conformity assessment body whose appointment has been notified to the European Commission—

[3]OJ No. L96, 29.3.2014, p.79
[4]OJ No. L316, 14.11.2012, p. 12

(*a*) by the notifying authority in accordance with Regulation 23, or

(*b*) by another Member State,

and whose appointment has been notified to the European Commission and the other Member States pursuant to Article 22 of the Directive;

"notifying authority" means the body designated as the notifying authority under Regulation 20;

"national accreditation body" means the Irish National Accreditation Board;

"placing on the market" means the first making available of radio equipment on the Union market;

"putting into service" means the first use of radio equipment in the Union by its end-user;

"radio communication" means communication by means of radio waves;

"radiodetermination" means the determination of the position, velocity or other characteristics of an object, or the obtaining of information relating to those parameters, by means of the propagation properties of radio waves;

"radio equipment" means an electrical or electronic product, which intentionally emits or receives radio waves for the purpose of radio communication or radiodetermination, or an electrical or electronic product which must be completed with an accessory, such as antenna, so as to intentionally emit or receive radio waves for the purpose of radio communication or radiodetermination;

"radio interface" means the specification of the regulated use of radio spectrum;

"radio waves" means electromagnetic waves of frequencies lower than 3,000GHz (gigaherz) propagated in space without artificial guide;

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

"Regulations of 2001" means the European Communities (Radio Equipment and Telecommunications Terminal Equipment) Regulations 2001 (S.I. No. 240 of 2001);

"technical documentation" in relation to radio equipment, means technical documentation drawn up in accordance with Regulation 19;

"technical specification" means a document that prescribes technical requirements to be fulfilled by radio equipment;

"Union" means the European Union within the meaning of the European Communities Act 1972 (No. 27 of 1972);

"Union harmonisation legislation" means any Union legislation harmonising the conditions for the marketing of products;

"withdrawal" in Part 6, means any measure aimed at preventing radio equipment in the supply chain from being made available on the market;

(2) A word or expression that is used in these Regulations and is also used in the Directive has, unless the contrary intention appears, the same meaning in these Regulations as it has in the Directive.

PART 2

SCOPE AND APPLICATION

Application

3. (1) These Regulations apply to radio equipment other than radio equipment specified in Schedule 1.

(2) These Regulations shall not apply to radio equipment used exclusively by the Garda Síochána or the Permanent Defence Force, for the purpose of State security (including the economic wellbeing of the State in the case of activities pertaining to State security matters), and in the activities of the State in the enforcement of criminal law.

(3) Other than as provided by Regulation 4(1)(*a*), the European Union (Low Voltage Electrical Equipment) Regulations 2016 (S.I. No. 345 of 2016) shall not apply to radio equipment to which these Regulations apply.

Making Available on the Market, Putting into Service and Essential Requirements

4. (1) Radio equipment shall be constructed to comply with the following essential requirements:

(*a*) to protect the health and safety of persons and domestic animals and to protect property and so to comply (other than in relation to voltage limits) with the safety requirements of the European Union (Low Voltage Electrical Equipment) Regulations 2016;

(*b*) to have an adequate level of electromagnetic compatibility in compliance with the European Communities (Electromagnetic Compatibility) Regulations 2017 (S.I. No. 69 of 2017);

(*c*) to both effectively use, and support the efficient use of, radio spectrum in a manner that avoids harmful interference.

(2) A person shall make available on the market radio equipment only if it complies with these Regulations.

(3) A person shall put into service radio equipment only if it complies with these Regulations when properly installed, maintained and used in accordance with its intended purpose.

Free Movement

5. (1) Nothing in these Regulations shall impede the making available on the market of radio equipment which complies with these Regulations.

(2) Nothing in these Regulations shall impede the demonstration of radio equipment that does not comply with these Regulations at trade fairs, exhibitions, and similar events provided that a clearly visible sign is displayed at any such trade fair, exhibition or similar event that indicates that the radio equipment concerned—

(*a*) does not comply with these Regulations, and

(*b*) shall not be made available on the market or put into service until they so comply.

(3) (*a*) Not less than 6 weeks before a demonstration, a person intending to demonstrate radio equipment under paragraph (2) shall, by notice in writing, provide to the competent authority information regarding the operational and technical characteristics of the radio equipment together with the measures the person intends to take, in carrying out the demonstration, to avoid harmful interference, electromagnetic disturbances and risk to the health or safety of persons or domestic animals or to property.

(*b*) Having considered the notice under subparagraph (*a*) the competent authority may give a direction to the person concerned not to carry out the demonstration or to carry out the demonstration subject to conditions.

(*c*) The person shall take the measures notified to the competent authority under subparagraph (*a*) when carrying out the demonstration where the competent authority does not give a direction to the person in relation to the notice.

(*d*) The person shall not carry out the demonstration, or, as the case may be, shall carry out the demonstration in accordance with the direction, where the competent authority gives a direction to the person under subparagraph (*b*).

(*e*) A person who has given a notice in writing under subparagraph (*a*) may presume that the competent authority does not intend to give a direction under subparagraph (*b*) if the authority has not given the direction on or by the day that is 14 days before the first of day of the demonstration.

(*f*) In this paragraph "demonstration" relates to one trade fair, exhibition or similar event which may be of more than one day's duration.

Competent Authority

6. The Commission for Communications Regulation is designated as the competent authority for the purpose of these Regulations.

Additional Requirements for Putting into Service and Use

7. The competent authority may only introduce additional requirements for the putting into service and use of radio equipment for reasons related to—

(*a*) the effective and efficient use of radio spectrum,

(*b*) the avoidance of harmful interference,

(*c*) the avoidance of electromagnetic disturbances, or

(*d*) public health.

Notification of Radio Interface Specifications

8. (1) The competent authority shall notify to the European Commission, in accordance with the provisions of Directive (EU) 2015/1535[5], details of radio interfaces which it intends to regulate.

(2) The requirement to notify the European Commission under paragraph (1) shall not apply to:

(*a*) radio interfaces which fully and without any deviation comply with the European Commission decisions on the harmonised use of radio spectrum adopted pursuant to Decision No 676/2002/EC[6];

(*b*) radio interfaces which, in accordance with implementing acts adopted pursuant to Article 8(2) of the Directive, correspond to radio equipment which can be put into service and used without restrictions within the Union.

PART 3

OBLIGATIONS OF ECONOMIC OPERATORS

Obligations of Manufacturers

9. (1) A manufacturer shall ensure that radio equipment placed on the market by that manufacturer—

(*a*) has been designed and manufactured in accordance with the essential requirements, and

(*b*) is so constructed that it can be operated in at least one Member State without infringing requirements applying in that State relating to the use of radio spectrum.

(2) Before placing radio equipment on the market, the manufacturer of the equipment shall—

(*a*) draw up the technical documentation,

(*b*) either—

[6]O.J. No. L108,24.2.2002 p. 1

(i) carry out the conformity assessment applicable to the radio equipment, or

(ii) have that conformity assessment carried out,

(*c*) where compliance of radio equipment with the essential requirements has been demonstrated by the conformity assessment—

(i) draw up the EU declaration of conformity, and

(ii) affix the CE marking,

(*d*) ensure that the radio equipment bears a type, batch or serial number or other element allowing its identification, or where because of its size or nature that is not possible, on its packaging or in the document accompanying the component,

(*e*) ensure that procedures are in place for series production to remain in conformity with these Regulations, having regard to any changes in radio equipment design or characteristics or changes in the harmonised standards or in other technical specifications, by reference to which conformity of radio equipment is declared,

(*f*) indicate on the radio equipment or, where that is not possible, on its packaging or a document accompanying the radio equipment—

(i) the manufacturer's name, registered trade name or registered trade mark, and

(ii) the postal address which shall indicate a single point at which the manufacturer can be contacted,

(*g*) identify, on the packaging of the radio equipment, the Member State or geographical area within a Member State where restrictions on putting it into service are in place or requirements for authorisation of its use apply,

(*h*) ensure that the radio equipment is accompanied by instructions and safety information which shall—

(i) be clear and intelligible,

(ii) include information required to use the radio equipment in accordance with its intended use,

(iii) include where applicable, a description of accessories and components, including software, which allow the radio equipment to operate as intended,

(iv) include, in the case of radio equipment intentionally emitting radio waves, information in relation to:

(I) the frequency band or bands in which the radio equipment operates;

(II) the maximum radio-frequency power transmitted in the frequency band or bands in which the radio equipment operates,

(v) include, in the case of radio equipment referred to in subparagraph (*g*), supplemental information relating to the restriction or authorisation concerned to that on the packaging referred to in subparagraph (*g*),

(*i*) ensure that the radio equipment is accompanied by a copy of the EU declaration of conformity or, in accordance with Regulation 17(3), a simplified EU declaration of conformity, and

(*j*) ensure that the information required under subparagraphs (*f*) and (*h*) is provided in both the Irish and English languages or in the English language only.

(3) A manufacturer of radio equipment which the manufacturer has placed on the market shall—

(*a*) retain the technical documentation and a copy of the EU declaration of conformity for 10 years after the radio equipment has been placed on the market,

(*b*) when deemed appropriate with regard to a risk presented by radio equipment and to protect the health and safety of consumers, carry out sample testing of the radio equipment which has been made available on the market,

(*c*) investigate, and, if necessary, keep a register of complaints of non-conforming radio equipment and recalls of radio equipment,

(*d*) keep distributors informed of monitoring referred to in subparagraphs (*b*) and (*c*),

(*e*) in respect of radio equipment which the manufacturer considers or has reason to believe is not in conformity with the requirements of these Regulations—

(i) immediately take any corrective measures necessary to bring the radio equipment into conformity including the withdrawal or recall of the radio equipment if appropriate, and

(ii) where the radio equipment presents a risk, immediately inform the competent authority to that effect, giving details of—

(I) the non-compliance, and

(II) any corrective measures taken and the results of such measures,

(*f*) further to a request in a notice given to the manufacturer by the competent authority, giving reasons for the request, provide the competent authority with all the information and documentation in paper or electronic form, in both the Irish and English languages or the English language only, necessary to demonstrate the conformity of radio equipment with these regulations, and

(*g*) co-operate with the competent authority, on receipt of a request in that behalf from it, on any action taken to eliminate a risk posed by radio equipment which the manufacturer has placed on the market.

Authorised Representatives

10. (1) A manufacturer may, by a written mandate, appoint an authorised representative.

(2) Subject to paragraph (3), an authorised representative shall only perform the tasks specified in the mandate received from the manufacturer.

(3) The mandate referred to in paragraph (1) shall not include the obligations laid down in subparagraph (*a*) of Regulation 9(1) or subparagraph (*a*), (*b*) or (*c*) of Regulation 9(2).

(4) The mandate shall permit the authorised representative to perform the following tasks in respect of radio equipment placed on the market by the manufacturer which shall include, but are not limited to:

(*a*) retaining a copy of the EU declaration of conformity and the technical documentation at the disposal of the market surveillance authority for 10 years after the radio equipment has been placed on the market;

(*b*) further to a request in a notice given to the authorised representative by the competent authority, giving reasons for the request, provide the competent authority with all the information and documentation necessary to demonstrate the conformity of radio equipment;

(*c*) co-operating with the competent authority, at its request, on any action taken to eliminate the risks posed by radio equipment covered by the authorised representative's mandate.

Obligations of Importers

11. (1) An importer of radio equipment shall only place radio equipment on the market that complies with these Regulations.

(2) Before placing radio equipment on the market an importer shall ensure that—

(*a*) the conformity assessment procedure has been complied with by the manufacturer in accordance with Regulation 16,

(*b*) the radio equipment is so constructed that it can be operated in at least one Member State without infringing requirements applying in that State relating to the use of the radio spectrum,

(*c*) the manufacturer has drawn up the technical documentation,

(*d*) the radio equipment bears the CE marking,

(*e*) the radio equipment is accompanied by documents and information required under subparagraphs (*g*), (*h*) and (i) of Regulation 9(2),

(*f*) the manufacturer has complied with subparagraphs (*d*), (*f*) and (*j*) of Regulation 9(2),

(*g*) the radio equipment is accompanied by instructions and safety information,

(*h*) the importers name, registered trade name or registered trade mark and the postal address at which the importer can be contacted are indicated—

(i) on the radio equipment, or

(ii) if, for reasons including the size of the radio equipment or that it would require opening its packaging, compliance with clause (i) is not possible, on the packaging of, or in a document accompanying, the radio equipment,

and,

(*i*) the information required under paragraphs (*g*) and (*h*) is provided in both the Irish and English languages or in the English language only.

(3) Where, before placing radio equipment on the market, an importer considers or has reason to believe that radio equipment is not in conformity with the essential requirements, the importer—

(*a*) shall not place the radio equipment on the market until it has been brought into conformity, and

(*b*) where the radio equipment presents a risk, shall inform the manufacturer and the market surveillance authority of the risk.

(4) An importer shall ensure that, while radio equipment is under the responsibility of the importer, the storage of the radio equipment or the conditions under which it is transported do not jeopardise its compliance with the essential requirements.

(5) An importer of radio equipment who has placed radio equipment on the market shall—

(*a*) for a period of 10 years after the radio equipment has been placed on the market, retain a copy of the EU declaration of conformity and the technical documentation at the disposal of the market surveillance authority, and make it available upon request,

(*b*) carry out, as required, when deemed appropriate with regard to a risk presented by radio equipment and to protect the health and safety of consumers, sample testing of the radio equipment which has been made available on the market,

(*c*) investigate and, if necessary, keep a register of complaints of non-conforming radio equipment and recalls of radio equipment,

(*d*) keep distributors informed of monitoring referred to in subparagraphs (*b*) and (*c*),

(*e*) in respect of radio equipment which the importer considers or has reason to believe is not in conformity with the requirements of these Regulations—

(i) immediately take any corrective measures necessary to bring the radio equipment into conformity including withdrawal or recall of the radio equipment, if appropriate, and

(ii) where the radio equipment presents a risk, immediately inform the competent authority to that effect, giving details of—

(I) the non-compliance, and

(II) any corrective measures taken,

(*f*) further to a request in a notice given to the importer by the competent authority, giving reasons for the request, provide the competent authority with all the information and documentation, in paper or electronic form, in both the Irish and English languages or the English language only, necessary to demonstrate the conformity of radio equipment, and

(*g*) co-operate with the competent authority on receipt of a reasoned request from it on any action taken to eliminate a risk posed by radio equipment which the importer has placed on the market.

Obligations of Distributors

12. (1) A distributor shall not make radio equipment available on the market without acting with due care in relation to the requirements of these Regulations.

(2) Before making radio equipment available on the market a distributor shall verify that—

(*a*) the radio equipment bears the CE marking,

(*b*) the radio equipment is accompanied by the documents required by these Regulations,

(*c*) the radio equipment is accompanied by the instructions and safety information in both the Irish and English languages or the English language only, and

(*d*) the manufacturer and the importer have complied with the requirements set out in subparagraph (*b*) of Regulation 9(1), subparagraphs (*d*), (*f*), (*g*), (*h*), (i) and (*j*) of Regulation 9(2) and subparagraphs (*h*) and (i) of Regulation 11(2) respectively.

(3) Where, before making radio equipment available on the market a distributor considers or has reason to believe that the radio equipment is not in conformity with the essential requirements, the distributor—

(*a*) shall not make the radio equipment available on the market until it has been brought into conformity, and

(*b*) where the radio equipment presents a risk, shall inform the manufacturer or importer and the market surveillance authority.

(4) While radio equipment is under the responsibility of a distributor, that distributor shall ensure that the storage of the radio equipment or the conditions under which it is transported do not jeopardise its compliance with the essential requirements.

(5) A distributor who has made radio equipment available on the market shall—

(*a*) in respect of radio equipment which the distributor considers or has reason to believe is not in conformity with these Regulations—

(i) ensure that any corrective measures necessary to bring that radio equipment into conformity are taken, including withdrawal or recall of the radio equipment, if appropriate, and

(ii) where the radio equipment presents a risk, immediately inform the competent authority to that effect, giving details of—

(I) the non-compliance, and

(II) any corrective measures taken,

(*b*) further to a request in a notice given to the distributor by the competent authority, giving reasons for the request, provide the competent authority with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the radio equipment with these Regulations, and

(*c*) co-operate with the competent authority on receipt of a reasoned request from it on any action taken to eliminate a risk posed by radio equipment which the distributor has made available on the market.

Cases Where Obligations of Manufacturers Apply to Importer or Distributor

13. (1) An importer or a distributor shall be considered to be a manufacturer for the purposes of these Regulations and shall fulfil the obligations of the manufacturer under Regulation 9 where any of the following circumstances apply:

(*a*) the importer places radio equipment on the market under the importer's name or trade mark;

(*b*) the distributor places radio equipment on the market under the distributor's name or trademark;

(*c*) the importer or distributor modifies radio equipment already placed on the market in such a way that compliance with these Regulations may be affected.

(2) Regulation 9 applies where an importer or distributor is considered to be a manufacturer under paragraph (1), subject to the following:

(*a*) a reference in Regulation 9 to a manufacturer shall be construed as a reference, as the case may be, to an importer or distributor;

(*b*) any other necessary modifications.

Identification of Economic Operators

14. (1) Upon receipt of a request given in a notice by the market surveillance authority, an economic operator (the "first economic operator") shall identify the following to the market surveillance authority:

(*a*) any other economic operator who has supplied the first economic operator with radio equipment;

(*b*) any other economic operator to whom the first economic operator has supplied radio equipment.

(2) An economic operator is required to be able to present the information referred to in paragraph (1) for a period of 10 years after the economic operator has been supplied with, or has supplied, the radio equipment.

PART 4

CONFORMITY OF RADIO EQUIPMENT

Presumption of Compliance with Conformity Assessment Procedures

15. Radio equipment, which is in conformity with harmonised standards (or parts of harmonised standards) references to which standards have been published in the Official Journal of the European Union, shall be presumed to be

in conformity with the essential requirements to which the harmonised standards (or parts thereof) apply.

Conformity Assessment Procedures

16. (1) A manufacturer of radio equipment shall perform a conformity assessment of the radio equipment for the purpose of ensuring that the radio equipment complies with the essential requirements.

(2) The conformity assessment shall—

(*a*) take into account all operating conditions under which the radio equipment is intended to be operated, and,

(*b*) for the essential requirements referred to in Regulation 4(1)(*a*), also take into account reasonably foreseeable conditions under which the radio equipment could be operated.

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

(4) A manufacturer of radio equipment shall demonstrate compliance of the radio equipment with the essential requirements using any of the following conformity assessment procedures:

(*a*) Module A (internal production control) set out in Schedule 2;

(*b*) Module B (EU-type examination), followed by Module C (conformity to type based on internal production control) set out in Schedule 3;

(*c*) Module H (conformity based on full quality assurance) set out in Schedule 4.

(5) The manufacturer of radio equipment who has applied harmonised standards, the references of which have been published in the Official Journal of the European Union, in assessing the compliance of the radio equipment with the essential requirements referred to in subparagraph (*c*) of Regulation 4 (1) shall use any of the procedures referred to in subparagraph (*a*) (*b*) or (*c*) of paragraph (4).

(6) The manufacturer of radio equipment who has not applied or has partly applied harmonised standards the references of which have been published in the Official Journal of the European Union, or in respect of whose radio equipment no harmonised standard exists, in assessing the compliance of the radio equipment with the essential requirements referred to in subparagraph (*c*) of Regulation 4 (1), shall use the procedures referred to in subparagraph (*b*) or (*c*) of paragraph (4).

EU Declaration of Conformity

17. (1) A manufacturer of radio equipment, when drawing up an EU declaration of conformity or having one drawn up by an authorised representative, in respect of the radio equipment shall ensure that the declaration—

(*a*) states that the fulfilment of the essential requirements has been demonstrated,

(*b*) has the model structure set out in Schedule 6,

(*c*) contains the elements set out in Schedule 6,

(*d*) is continuously updated, and

(*e*) when the radio equipment is placed or made available on the market in the State, is translated into—

(i) both the Irish and English languages, or

(ii) the English language only.

(2) The manufacturer when drawing up a simplified EU declaration of conformity, or having one drawn up by an authorised representative, in respect of the radio equipment shall ensure that the simplified declaration—

(*a*) contains the elements set out in Schedule 7,

(*b*) is continuously updated,

(*c*) when the radio equipment is placed or made available on the market in the State, is translated into—

(i) both the Irish and English languages, or

(ii) the English language only,

and

(*d*) contains the exact internet address at which the full text of the EU declaration of conformity shall be available in both the Irish and English languages or the English language only.

(3) A manufacturer of radio equipment, when drawing up an EU declaration of conformity or having one drawn up by an authorised representative, in respect of the radio equipment which is subject to more than one Union act requiring an EU declaration of conformity, shall ensure that—

(*a*) a single EU declaration of conformity relating to the radio equipment shall be drawn up in respect of all such Union acts, and

(*b*) the EU declaration of conformity referred to in subparagraph (*a*) shall identify the Union acts concerned including their publication references.

(4) A manufacturer of radio equipment who has drawn up an EU declaration of conformity in accordance with this Regulation shall be responsible for compliance of the radio equipment in respect of which the declaration has been drawn up with these Regulations.

CE Marking

18. (1) A manufacturer of radio equipment or the authorised representative of that manufacturer shall affix the CE marking to the radio equipment before it is placed on the market.

(2) The CE marking referred to in paragraph (1) shall be the only marking which attests to the conformity of radio equipment with the applicable requirements of the relevant EU harmonisation legislation providing for its affixing.

(3) Unless it is not possible or warranted because of the nature of the radio equipment, the CE marking shall be affixed visibly, legibly and indelibly to the radio equipment or its data plate.

(4) The manufacturer of radio equipment or the authorised representative of that manufacturer shall also affix the CE marking visibly and legibly to the packaging of radio equipment.

(5) The CE marking affixed to radio equipment may be lower than 5 mm in height, provided that it remains visible and legible.

(6) The CE marking shall be followed by the identification number of the notified body, where the conformity assessment procedure set out in Schedule 4 is applied, which number shall have the same height as the CE marking.

(7) The identification number of the notified body shall be affixed—

(*a*) by the notified body itself or,

(*b*) where instructed to do so by the notified body, by—

(i) the manufacturer, or

(ii) the authorised representative of the manufacturer.

(8) The market surveillance authority shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

(9) A person shall not affix a sign, marking or inscription to radio equipment that is likely to mislead third parties as to the meaning or form of the CE marking.

(10) A person shall not affix a marking to radio equipment if it is likely to impair the visibility, legibility or meaning of the CE marking.

(11) A person who affixes a CE marking to radio equipment which is not in conformity with the requirements of these Regulations shall be guilty of an offence.

Technical Documentation

19. (1) The technical documentation shall contain—

(*a*) all relevant data or details of the means used by the manufacturer of radio equipment to ensure that the radio equipment complies with the essential requirements, and

(*b*) at a minimum, the elements set out in Schedule 5.

(2) The manufacturer shall continuously update the technical documentation drawn up by the manufacturer.

(3) The technical documentation and correspondence relating to any EU-type examination procedure concerning radio equipment shall be drawn up by the manufacturer of the radio equipment in—

(*a*) both the Irish and English languages, or

(*b*) the English language only.

(4) Where the technical documentation does not comply with paragraph (1), (2) or (3) and in so doing fails to present sufficient relevant data or means used to ensure compliance of radio equipment with the essential requirements, the market surveillance authority may give notice to the manufacturer or importer concerned requiring that manufacturer or importer to have a test performed by a body acceptable to the market surveillance authority at the expense of the manufacturer or importer, within a specified period, and to furnish the results of the test to the market surveillance authority in order that it may verify compliance of the radio equipment with the essential requirements.

(5) The manufacturer or importer shall have the test referred to in paragraph (4) performed and furnish the results of that test to the market surveillance authority as required by the authority under paragraph (4).

PART 5

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Notifying Authority

20. (1) The Commission for Communications Regulation is designated as the notifying authority in the State for the purposes of Article 23 of the Directive and these Regulations.

(2) The notifying authority shall—

(*a*) set up and carry out the necessary procedures for the assessment and notification of conformity assessment bodies, and

(*b*) carry out the monitoring of notified bodies, including compliance by a notified body with paragraphs 16, 17, 18 and 19 of Schedule 8.

(3) The notifying authority shall inform the European Commission of its procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies and any changes thereto.

(4) The notifying authority shall comply with the requirements of Article 24 of the Directive.

Application for Notification

21. (1) A conformity assessment body shall apply to the notifying authority for notification.

(2) The application under paragraph (1) shall be accompanied by—

(*a*) a description of—

(i) the conformity assessment activities,

(ii) the conformity assessment module or modules, and

(iii) the radio equipment,

in relation to which the conformity assessment body claims to have the competence to perform conformity assessment in accordance with these Regulations and relevant harmonised standards, and

(*b*) such other information and documentation as the notifying authority may require to satisfy itself that the conformity assessment body complies with the requirements specified in paragraphs 1 to 16 of Schedule 8 for the purposes of a notification.

(3) The application under paragraph (1) shall also be accompanied by—

(*a*) where one exists, a certificate of accreditation,

(*b*) where no certificate of accreditation exists, all documentation attesting that the conformity assessment body meets the requirements specified in paragraphs 1 to 15 of Schedule 8.

(4) For the purposes of an application under paragraph (1), the certificate of accreditation referred to in paragraph (3) (*a*) may be issued by the national accreditation body.

(5) Without prejudice to any other enactment, the national accreditation body may issue a certificate of accreditation for the purposes of an application under this Regulation.

Presumption of Conformity of Notified Bodies

22. Where a conformity assessment body demonstrates conformity with the criteria laid down in the relevant harmonised standards (or part of such standards) the references of which have been published in the Official Journal of the European Union, the body shall be presumed to comply with the requirements set out in paragraphs 1 to 15 of Schedule 8, in so far as the applicable harmonised standards (or part of such standards) apply to those requirements.

Notification Procedure

23. (1) The notifying authority may notify only a conformity assessment body which has satisfied the requirements laid down in paragraphs 1 to 15 of Schedule 8.

(2) The notifying authority shall notify the European Commission and the other Member States using the electronic notification tool developed and managed by the European Commission.

(3) The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and the radio equipment concerned and the relevant attestation of competence.

(4) Where a notification is not based on an accreditation certificate referred to in Regulation 21(3) (*a*), the notifying authority shall provide the European Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in paragraphs 1 to 15 of Schedule 8.

(5) The conformity assessment body concerned may perform the activities of a notified body only where no objections are raised by the European Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

(6) Only a body which meets the criteria set out in paragraphs (1) to (5) shall be considered a notified body for the purposes of these Regulations.

(7) The notifying authority shall notify the European Commission and the other Member States of changes to the notification under this Regulation as it considers relevant.

Restriction, Suspension or Withdrawal of Notification

24. (1) Where the notifying authority has ascertained, or has been informed that a notified body—

(*a*) no longer meets the requirements specified in paragraphs 1 to 15 of Schedule 8, or

(*b*) that it is failing to fulfil its obligations under these Regulations, the notifying authority shall restrict, suspend or withdraw notification, as it considers appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations.

(2) The notifying authority shall immediately inform the European Commission and the other Member States of the matters referred to in paragraph (1).

(3) The notifying authority shall—

(*a*) give notice to the notified body advising the body of the restriction, suspension or withdrawal of a notification under paragraph (1) as soon as possible, and

(*b*) advise the notified body concerned that it may make representations to the authority in respect of the restriction, suspension or withdrawal, as the case may be, of a notification.

(4) Where—

(*a*) a restriction, suspension or withdrawal of a notification is made, or

(*b*) the notified body concerned has ceased its activity, the notifying authority shall take appropriate steps to ensure—

(i) that the files of that notified body are processed by another notified body, or

(ii) that those files are kept in a manner that will permit the notifying authority to have access to them for the performance by the authority of its functions under these Regulations.

Challenge of the Competence of Notified Bodies

25. (1) The notifying authority shall comply with paragraph 2 of Article 33 of the Directive.

(2) The notifying authority may give notice to the notified body concerned requesting the body to provide the authority with information or documents relating to or connected with the performance by the authority of its functions under paragraph (1).

(3) A notified body shall comply with a notice referred to in paragraph (2).

Operational Obligations of Notified Bodies

26. (1) A notified body shall carry out a conformity assessment in accordance with the conformity assessment procedures specified in Schedules 3 and 4.

(2) Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators.

(3) A 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.

(4) In performing its activities under paragraph (3), a notified body shall respect the degree of rigour and the level of protection required to ensure the compliance of the radio equipment with these Regulations.

(5) Where a notified body finds that the essential requirements or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue an EU-type examination certificate or a quality system approval.

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

(7) Where corrective measures referred to in paragraph (6) are not taken or do not have the required effect, the notified body shall, having considered any representations made to it by the manufacturer, restrict, suspend or withdraw any EU-type examination certificate or quality system approval, as appropriate.

(8) A notified body who has subcontracted specific tasks or has recourse to a subsidiary shall comply with paragraphs 17, 18, 19 and 20 of Schedule 8.

Appeal against decision of notified body

Appeal of Decision under Part 5

27. (1) Where—

(*a*) a manufacturer is aggrieved by a decision of a notified body under Regulation 26 which affects the manufacturer, or

(*b*) a notified body is aggrieved by a decision of the notifying authority under Regulation 24 to restrict, suspend or withdraw its notification,

the manufacturer, or as the case may be, notified body concerned may, within the period of 7 days beginning on the day on which the decision is taken or communicated to the manufacturer, or as the case may be, notified body, appeal to a judge of the District Court in the District Court District in which the manufacturer, or as the case may be, notified body, carries on business, against the decision and in determining the appeal the judge may—

(i) affirm the decision with or without modification, or

(ii) quash the decision.

(2) The judge of the District Court determining the appeal under paragraph (1) may make such order as to the payment of costs of the appeal as he or she considers appropriate.

Information Obligation of Notified Bodies

28. (1) A notified body shall inform the notifying authority of any 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 Schedules 3 and 4,

(*b*) any circumstances affecting the scope of or conditions for notification,

(*c*) any request for information which it has received in a notice given by the market surveillance authority or a market surveillance authority of a Member State other than the State regarding conformity assessment activities, or

(*d*) on receipt of a notice given by the notifying authority containing a request in that behalf, conformity assessment activities performed within the scope of the body's notification and any other conformity assessment activity performed, including cross-border activities and subcontracting.

(2) A notified body shall, in accordance with the requirements of Schedules 3 and 4, provide other bodies notified under the Directive or these Regulations which perform conformity assessment activities of a similar nature in respect of radio equipment of the same class or categories with relevant information on matters relating to negative and, on request, positive conformity assessment results.

(3) A notified body shall provide information required under Schedules 3 and 4.

Coordination of Notified Bodies

29. (1) A notified body shall participate in the work of a sectoral group of notified bodies established by the European Commission pursuant to Article 38 of the Directive.

(2) A notified body shall participate in the work of a sectoral group under paragraph (1) either directly or by means of a designated representative.

(3) A notified body shall, on receipt of a notice given by the notifying authority containing a request in that behalf, provide information to the notifying authority concerning compliance by the notified body with its obligations under this Regulation.

PART 6

UNION MARKET SURVEILLANCE, CONTROL OF RADIO EQUIPMENT ENTERING UNION MARKET AND SAFEGUARD PROCEDURE

Union Market Surveillance, Control of Radio Equipment Entering Union Market And Market Surveillance Authority

30. (1) For the purposes of these Regulations and the Directive the Commission for Communications Regulation is designated as the market surveillance authority in the State.

(2) For the purposes of Article 39 of the Directive and the application to radio equipment, of Articles 15(3) and 16 to 29 of Regulation (EC) No. 765/2008, the market surveillance authority shall—

(*a*) be the market surveillance authority, within the meaning of Regulation (EC) No. 765/2008, in the State for the purposes of those Articles and in relation to that application,

(*b*) perform the functions assigned to a market surveillance authority in those Articles of Regulation (EC) No. 765/2008 and in relation to that application, and

(*c*) perform the functions specified in Articles 20, 22 and 23(2) of Regulation (EC) No. 765/2008 in relation to that application.

(3) Without prejudice to paragraph (2)(*b*), for the purposes of Article 19 of Regulation (EC) No. 765/2008, where, pursuant to that Article, the market surveillance authority considers it is necessary to do so, the market surveillance authority may destroy or otherwise render inoperable radio equipment presenting a serious risk referred to in that Article.

Procedure for Dealing with Radio Equipment Presenting a Risk at National Level

31. (1) Where the market surveillance authority has sufficient reason to believe that radio equipment presents a risk to the health and safety of persons or to other aspects of protection of the public interest, the authority shall, without delay, carry out an evaluation in relation to the radio equipment concerned in respect of all relevant requirements of these Regulations.

(2) The relevant economic operators shall co-operate as necessary with the market surveillance authority for the purpose of an evaluation carried out under paragraph (1).

(3) Where, in the course of carrying out the evaluation under paragraph (1), the market surveillance authority finds that the radio equipment does not comply with the requirements of these Regulations, it shall give notice without delay to the economic operator concerned informing the operator of its finding.

(4) Where, in the course of the evaluation under paragraph (1) the market surveillance authority has reason to believe that action is required to prevent a

risk to the health and safety of persons or protection of the public interest, it may, having regard to the nature of the risk, give a direction, giving the reasons for the direction, to the economic operator requiring the economic operator to, within such period specified in the direction as the market surveillance authority considers reasonable—

(*a*) take all appropriate corrective action to bring the radio equipment into compliance with the requirements of these Regulations,

(*b*) withdraw the radio equipment from the market or from service, or

(*c*) recall the radio equipment.

(5) The market surveillance authority shall give notice to the notified body which carried out the conformity assessment of the product informing the body of the giving of the direction under paragraph (4).

(6) Where a direction is given under paragraph (4)—

(*a*) without prejudice to Regulation 36, Article 21 of Regulation (EC) No. 765/2008 shall apply to the measures specified in the direction, and

(*b*) the market surveillance authority shall ensure that any measure specified in that direction complies with Article 21 of Regulation (EC) No. 765/2008 and without prejudice to the generality of the foregoing, for the purposes of making representations, the market surveillance authority shall have regard to the period specified in Article 21 of Regulation (EC) No. 765/2008 in respect of the making of those representations.

(7) Where the market surveillance authority considers that non-compliance is not restricted to the State, the authority shall inform the European Commission and the other Member States of the results of the evaluation and of the giving of the direction to take action.

(8) The economic operator shall, within the time specified in the direction, comply with a direction given to the operator under paragraph (4).

Procedures Where Radio Equipment Continues to Present a Risk at National Level

32. (1) Where the relevant economic operator does not take adequate corrective action within the period specified in a direction given under Regulation 31(4), the market surveillance authority shall, without delay, take all appropriate provisional measures it considers necessary.

(2) The provisional measures which the market surveillance authority may take under paragraph (1) are—

(*a*) the prohibition or restriction of the radio equipment from being made available on the market,

(*b*) the withdrawal of the radio equipment from the market in the State, or

(*c*) the recall of the radio equipment from the market in the State.

(3) Where the market surveillance authority takes a measure specified in paragraph (2)—

(*a*) the authority shall give notice to the economic operator informing the operator of the measure concerned, and

(*b*) paragraph (6) of Regulation 31 shall apply to a notice under this paragraph as it applies to a direction under Regulation 31 subject to any other necessary modifications.

(4) An economic operator shall comply with a measure taken under paragraph (2) and a notice given under paragraph (3).

(5) The market surveillance authority shall inform the European Commission and other Member States, without delay, of a measure which the authority has taken under paragraph (2).

(6) The information provided under paragraph (5) shall—

(*a*) include all available details,

(*b*) without prejudice to the generality of subparagraph (*a*), include details of—

(i) the data necessary for the identification of the non-compliant radio equipment,

(ii) the origin of the radio equipment,

(iii) the nature of the non-compliance alleged and the risk involved,

(iv) the nature and duration of the measure taken, and

(v) the arguments put forward by the relevant economic operator,

and

(*c*) indicate, in the information, whether the non-compliance is due to either—

(i) the failure of the radio equipment to meet the relevant essential requirements or

(ii) shortcomings in the harmonised standards referred to in Regulation 15 conferring a presumption of conformity.

(7) Where another Member State initiates the procedure under Article 40 of the Directive—

(*a*) the market surveillance authority shall without delay inform the European Commission and the other Member States of—

(i) any measures adopted, and

(ii) any additional information at the disposal of the market surveillance authority relating to the non-compliance of the radio equipment concerned,

and

(*b*) where the market surveillance authority disagrees with the adopted national measure, the objections of the market surveillance authority.

(8) Where, within 3 months of the market surveillance authority informing, under paragraph (5), the European Commission and other Member States of a provisional measure taken, no objection has been raised by the European Commission or a Member State in respect of the measure, the provisional measure shall be deemed to be justified.

Union Safeguard Procedure

33. (1) Where, pursuant to Article 41 of the Directive, a national measure of a Member State other than the State is considered to be justified, the market surveillance authority shall—

(*a*) take the necessary measures to ensure that the non-compliant radio equipment is withdrawn or recalled from the market in the State, and

(*b*) inform the European Commission accordingly.

(2) Where, pursuant to Article 41 of the Directive a national measure of a Member State other than the State is considered to be unjustified, the market surveillance authority shall withdraw the measure.

Compliant Radio Equipment Presenting Risk

34. (1) Where having carried out an evaluation under Regulation 31(1), the market surveillance authority is of the opinion that radio equipment that is in compliance with these Regulations nonetheless presents a risk to the health or safety of persons or to the protection of the public interest, it shall give a direction to the economic operator requiring the economic operator to do any of the following within such period specified in the direction as the market surveillance authority considers reasonable:

(*a*) to take all appropriate measures to ensure that the radio equipment concerned, when placed on the market, no longer presents that risk;

(*b*) to withdraw the radio equipment from the market in the State;

(*c*) to recall the radio equipment from the market in the State;

(*d*) to do or refrain from doing anything in order to comply with these Regulations and the Directive.

(2) The economic operator shall, within the time specified in the direction, comply with a direction given to the operator under paragraph (1).

(3) The market surveillance authority shall give notice to the European Commission and the other Member States of a direction given under paragraph (1) which shall include all available details, in particular—

(*a*) the data necessary for the identification of the non-compliant radio equipment,

(*b*) the origin and supply chain of the radio equipment,

(*c*) the nature of the non-compliance alleged and the risk involved, and

(*d*) the nature and duration of the national measures taken.

Formal Non-Compliance

35. (1) (*a*) Without prejudice to Regulation 31 or 32, where the market surveillance authority makes one of the findings specified in paragraph (*b*), the authority shall give a direction to the relevant economic operator to take specified measures to end the non-compliance concerned.

(*b*) The findings referred to in paragraph (*a*) are:

(i) the CE marking has been affixed in violation of—

(I) Article 30 of Regulation (EC) No. 765/2008, or

(II) Regulation 18;

(ii) the CE marking has not been affixed;

(iii) the identification number of the notified body, where the conformity assessment procedure set out in Schedule 4 is applied, has been affixed in contravention of Regulation 18 or has not been affixed;

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

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

(vi) the technical documentation is either not available or not complete;

(vii) the information referred to in subparagraphs (*d*) and (*f*) of Regulation 9(2) or subparagraph (*h*) of Regulation 11(2) is absent, false or incomplete;

(viii) information on the intended use of radio equipment, the EU declaration of conformity or usage restrictions as set out in subparagraphs (*g*), (*h*) and (i) of Regulation 9(2) does not accompany the radio equipment;

(ix) an economic operator has not complied with Regulation 14.

(2) The economic operator shall, within the time specified in the direction, comply with a direction given to the operator under paragraph (1).

(3) Where the relevant economic operator does not take adequate corrective action within the period specified in a direction given under paragraph (1) the market surveillance authority may, in respect of the non-compliance, take all appropriate measures to—

(*a*) restrict or prohibit the radio equipment from being made available on the market,

(*b*) withdraw the radio equipment from the market in the State, or

(*c*) recall the radio equipment from the market in the State.

(4) Where the market surveillance authority takes a measure specified in paragraph (3)—

(*a*) the authority shall give notice to the economic operator informing the economic operator of the measure concerned, and

(*b*) paragraph (6) of Regulation 31 shall apply to a notice under this paragraph as it applies to a direction under Regulation 31 subject to any other necessary modifications.

(5) An economic operator shall comply with a measure taken under paragraph (3) and a notice under paragraph (4).

PART 7

ENFORCEMENT

Directions

36. (1) Subject to paragraph (7), where the market surveillance authority proposes to give a direction, the authority shall, before giving the direction, give notice of the proposal to the person and that notice shall contain a statement in summary form of the opinion of the market surveillance authority and a statement that the person may, within 14 days of receipt of the notice, make representations in writing to the authority in relation to the proposal, and any such representations made by a person to the authority within that period shall be

considered by the authority in deciding whether to give the direction to the person.

(2) A direction under paragraph (1) may be given to one or more than one economic operator to whom the notice relates.

(3) A direction under paragraph (1) shall—

(*a*) state the reason for the opinion referred to in paragraph (1),

(*b*) identify the provision of these Regulations in respect of which the opinion is held,

(*c*) specify the action to be taken in respect of the radio equipment by the person to whom the direction is given and the period specified in the direction within which the action shall be taken,

(*d*) inform the person of the requirement to confirm compliance with the direction in accordance with paragraph (9),

(*e*) inform the person of the right to appeal the direction under Regulation 37,

(*f*) include an address for service of an appeal,

(*g*) be signed and dated by the market surveillance authority, and

(*h*) state that if the person to whom it is given fails to comply with the direction the person shall be guilty of an offence and liable on conviction to the penalty referred to in paragraph (15).

(4) A direction may require that the action required be undertaken—

(*a*) immediately because of the urgency of the matter,

(*b*) from a specified date,

(*c*) by a specified date, or

(*d*) between specified dates.

(5) A direction may include—

(*a*) the action to be taken to bring radio equipment into compliance with the requirements of these Regulations,

(*b*) a requirement to bring to the attention of any person who may be affected by the non-compliance or to the notice of the public generally.

(6) A person to whom a direction has been given may appeal the direction under Regulation 37.

(7) Where, in the opinion of the market surveillance authority—

(*a*) urgent action is required which is justified in particular by public health or safety requirements, and

(*b*) it is necessary because of the gravity of the non-compliance with the requirements of these Regulations, to immediately give the person a direction,

the authority may, notwithstanding paragraphs (1) and (2), give the person a direction.

(8) Where paragraph (7) applies, the market surveillance authority shall give the person to whom the direction is given the opportunity to make representations to it in writing as soon as may be after the giving of the direction.

(9) As soon as practicable after complying, and in any case not later than 7 days after the date specified in the direction by which it is to be complied with, a person to whom a direction has been given shall notify the market surveillance authority in writing that the direction has been complied with.

(10) Within one month of receiving a notification under paragraph (9), where the market surveillance authority is satisfied that the direction has been complied with, the authority shall give notice to the to the person concerned confirming that compliance.

(11) The market surveillance authority may, where it considers it appropriate to do so, by notice in writing to the person to whom a direction was given, withdraw a direction.

(12) A direction shall, subject to paragraphs (4) and (5) of Regulation 37, take effect on the date specified in the direction.

(13) Where a person fails to comply with a direction the market surveillance authority may apply to the judge of the District Court in whose District Court district the person resides or carries on business for an order requiring the person to comply with the direction and the Court may make an order directing the person to comply with the direction.

(14) A person to whom a direction has been given shall not—

(*a*) pending the determination of any appeal under Regulation 37, deal with radio equipment or other matter to which the direction relates, other than in accordance with the terms of the direction, or

(*b*) if the direction is confirmed or varied on appeal under Regulation 37, deal with radio equipment or any other matter to which the direction relates other than in accordance with the terms of the direction as confirmed or varied.

(15) A person who fails to comply with paragraph (14) shall be guilty of an offence and shall be liable on summary conviction to a class A fine.

(16) This Regulation shall not operate to prevent or restrict—

(*a*) the entitlement of any person to bring proceedings for the purpose of securing compliance with these Regulations or Regulation (EC) No. 765/2008, or

(*b*) the bringing or prosecuting of any proceedings for an offence under these Regulations.

Right of Appeal Against a Direction, Notice or Measure of Market Surveillance Authority

37. (1) A person aggrieved by—

(*a*) a direction given by the market surveillance authority,

(*b*) a notice given by the market surveillance authority under Regulation 32(3) or 35(4), or

(*c*) a measure taken under Regulation 32(1) or 35(3) by the market surveillance authority,

may appeal to the appropriate court against the direction or notice given or the measure taken.

(2) A notice of an appeal shall contain a statement of the grounds on which the appeal is made and be made by written notice, which shall be lodged with the appropriate office of the court by the appellant not later than 14 days from the date upon which the direction or notice concerned was given to him or her or the measure was taken.

(3) A copy of the notice by which a person makes an appeal under this Regulation shall be given by him or her to the market surveillance authority not less than 48 hours before the hearing of the appeal and the authority shall be entitled to appear, be heard and adduce evidence on the hearing of the appeal and at the hearing of any application referred to it under paragraph (4).

(4) The bringing of an appeal shall not have the effect of suspending the operation of the direction, notice or measure as the case may be, but the appropriate court to which the appeal has been made, may, on application to it by the appellant, suspend its operation until the appeal is determined or withdrawn.

(5) On the hearing of an appeal the appropriate court may confirm, vary or revoke the direction, notice or measure as the case may be.

(6) In this Regulation "the appropriate court" means—

(*a*) in case the estimated value of the radio equipment to which the direction or notice given or measure taken relates does not exceed €15,000

or such amount as may stand specified for the time being by law as that Court's jurisdiction in tort, the District Court,

(*b*) in case the estimated value of the radio equipment to which the direction or notice given or measure taken relates does not exceed €75,000 or such amount as may stand specified for the time being by law as that Court's jurisdiction in tort, the Circuit Court, and

(*c*) in any other case, the High Court.

(7) If, in relation to an appeal under this Regulation to the District Court, that court becomes of the opinion during the hearing of the appeal that the value of the radio equipment, the subject of the appeal, exceeds that court's jurisdiction in tort, it may, if it so thinks fit, transfer the appeal to the Circuit Court or the High Court, whichever it considers appropriate having regard to its opinion of the value of the radio equipment.

(8) If, in relation to an appeal under this Regulation to the Circuit Court, that court becomes of the opinion during the hearing of the appeal that the value of the radio equipment, the subject of the appeal, exceeds that courts' jurisdiction in tort, it may, if it so thinks fit, transfer the appeal to the High Court.

(9) Paragraphs (7) and (8) are without prejudice to the jurisdiction of a court (being either the District Court or the Circuit Court) to determine an appeal under this Regulation in relation to which it was, at the time of the hearing of the appeal, the appropriate court.

(10) An appeal under this Regulation to the District Court shall be determined by the judge of the District Court for the District Court district in which the radio equipment concerned was placed on the market or the appellant ordinarily resides.

(11) An appeal under this Regulation to the Circuit Court shall be determined by the judge of the Circuit Court for the circuit in which the radio equipment concerned was placed on the market or the appellant ordinarily resides.

Power to Make Applications to High Court.

38. (1) If, of the opinion that radio equipment to which these Regulations apply—

(*a*) is being or may be placed on the market, and

(*b*) is likely to cause serious injury or damage to property or harmful interference,

the market surveillance authority may apply to the High Court for an order under paragraph (5).

(2) An application under paragraph (1) shall be made by way of motion.

(3) The High Court may hear the application only if it is satisfied that a copy of the application has been served on the person alleged to be responsible for placing or proposing to place the radio equipment on the market and on being served with such a copy, the person becomes the respondent to the application.

(4) The High Court may make such interim or interlocutory order as it considers appropriate pending determination of an application made under paragraph (1) and the Court may not refuse interim or interlocutory relief merely because the market surveillance authority may not suffer damage if relief were not granted pending determination of the application.

(5) On hearing an application under paragraph (1), the High Court may, if it considers it appropriate to do so, make either or both of the following orders:

(*a*) if it appears to the Court that the respondent has placed the radio equipment on the market, an order requiring the respondent to withdraw the radio equipment from the market;

(*b*) if it appears to the Court that the respondent is proposing or continuing to place the radio equipment on the market, an order prohibiting the respondent from doing or continuing to do so.

(6) If the High Court makes an order under paragraph (5), it may make such ancillary orders as it considers appropriate.

Inspections and Surveillance

39. (1) The market surveillance authority shall carry out inspections of radio equipment to which these Regulations apply where appropriate—

(*a*) on its entry into the State (where the State is their place of entry into the Union), or

(*b*) at the storage or manufacturing site of such radio equipment.

(2) Without prejudice to the generality of paragraph (1), the market surveillance authority shall organise and perform appropriate surveillance of radio equipment made available on the market or put into service, taking due account of the presumption of the conformity of radio equipment bearing a CE marking, including the requirements arising from Regulation 30 and paragraph (6) of Regulation 31 and the performance of functions in respect of an Article of Regulation (EC) No. 765/2008 referred to in these Regulations.

Appointment of Authorised Officers

40. (1) The market surveillance authority may appoint such and so many members of staff of the authority, or other person whom the authority considers to be suitably qualified, to be authorised officers for the purpose of these Regulations and the Directive.

(2) An authorised officer shall be furnished with a certificate of his or her appointment and shall, when exercising a power conferred on him or her under

these Regulations, if requested by a person affected, produce to the person the certificate or a copy of it.

(3) The market surveillance authority may terminate the appointment of an authorised officer appointed by the authority whether or not the appointment was for a fixed period.

(4) An appointment of an authorised officer ceases—

(*a*) if it is terminated under paragraph (3),

(*b*) if it is for a fixed period, on the expiry of that period, or

(*c*) if the person appointed is a member of staff of the market surveillance authority, upon the person ceasing to be such a member of staff.

Powers of Authorised Officers

41. (1) An authorised officer shall, for the purposes of all or any of these Regulations and of ensuring compliance with their requirements, have power to do any or all of the following:

(*a*) subject to paragraph (4) or (5), at all reasonable times enter and examine any place at which there are reasonable grounds to believe that radio equipment is being kept or has been manufactured, stored, distributed, supplied, placed on the market, made available on the market or put into service or that records relating to the radio equipment are kept, and search and inspect the place, any process being carried out and any radio equipment or records found at that place;

(*b*) secure for later inspection a place referred to in subparagraph (*a*) or part of that place, or radio equipment or records kept at that place and require that the place, part thereof, radio equipment or records or any other thing kept at that place as the authorised officer considers appropriate having regard to his or her functions is or are left undisturbed for so long as is reasonably necessary for the purpose of any search, examination, investigation, inspection or inquiry;

(*c*) require any person in charge of, or employed in, a place referred to in subparagraph (*a*) to produce to the authorised officer such books, documents or records (and in the case of such information in a non-legible form to reproduce it in a permanent legible form) that are in the person's power, possession or control or to give to the authorised officer such information as the officer may reasonably require in relation to any entries in such records;

(*d*) inspect and take copies of or extracts from any such books, documents or records (including in the case of information in non-legible form a copy of or extract from such information in a permanent legible form) or require that such a copy be provided;

(*e*) require a person at a place referred to in subparagraph (*a*) by whom or on whose behalf a computer is or has been used to produce or store records or any person having control of, or otherwise concerned with the operation of the computer, to afford the authorised officer access thereto and such reasonable assistance as the authorised officer may require;

(*f*) remove and detain, where the officer has reasonable cause to suspect that there has been a contravention of these Regulations, radio equipment or records (including documents stored in a non-legible form) and any copies taken for such period as the authorised officer considers reasonably to be necessary for further examination or until the conclusion of any legal proceedings;

(*g*) require that records at a place referred to in subparagraph (*a*) be maintained for such period as the authorised officer considers reasonably to be necessary;

(*h*) require any person to give the authorised officer such information in relation to radio equipment or part thereof or any article or substance or process used in the manufacture of radio equipment as the authorised officer may reasonably require for the purposes of any search, examination, investigation, inspection or inquiry under these Regulations;

(*i*) require by notice, at a time and place specified in the notice, any person (including the person in charge) to give the authorised officer any information that the authorised officer may reasonably require in relation to such place, any radio equipment or part of the place, activity, installation or procedure at such place, and to produce to the authorised officer any records that are in that person's power, possession or control;

(*j*) examine any person whom the authorised officer reasonably believes to be able to give to the authorised officer information relevant to any search, examination, investigation, inspection or inquiry under these Regulations and require the person to answer such questions as the authorised officer may ask relative to the search, examination, investigation, inspection or inquiry and to sign a declaration of the truth of the answers;

(*k*) where appropriate, install, use and maintain at a place referred to in subparagraph (*a*) monitoring instruments or systems or take any measurements or photographs or make any tape, electronic or other recordings that the authorised officer considers necessary for the purposes of any search, examination, investigation, inspection or inquiry under these Regulations;

(*l*) as regards any radio equipment or any article or substance used in the manufacture of radio equipment the authorised officer finds at a place

referred to in subparagraph (*a*), require any person in charge of the place, or any person who appears to the authorised officer to be in possession of the radio equipment or the article or substance, to supply without charge or payment, for test, examination or analysis sufficient samples thereof;

(*m*) take possession of and detain any radio equipment or part thereof or any article or substance used in the manufacture of radio equipment kept at a place referred to in subparagraph (*a*) which appears to the authorised officer to be in contravention of these Regulations for so long as is necessary for all or any of the following purposes, namely:

(i) to examine or arrange for the examination, testing or analysis of it under subparagraph (*o*);

(ii) to ensure that it is not tampered with before the examination, testing or analysis of it is completed;

(iii) to ensure that it is available for use as evidence in any proceedings;

(*n*) cause any radio equipment or part thereof or any article or substance used in the manufacture of radio equipment found at a place referred to in subparagraph (*a*) which appears to the authorised officer to be in contravention of these Regulations to be dismantled or subjected to any process, test or analysis (but not so as to damage or destroy it unless this is in the circumstances necessary for the purposes of these Regulations) and where an authorised officer proposes to exercise this power in the case of radio equipment or an article or substance used in the manufacture of radio equipment found at a place referred to in subparagraph (*a*), the authorised officer shall, if so requested by a person who at the time is present at or in, and has responsibilities in relation to, that place, and if it is practicable and safe to do so, cause anything which is to be done by virtue of that power to be done in the presence of that person;

(*o*) require any person to afford the authorised officer such facilities and assistance within the person's power, control or responsibilities as are reasonably necessary to enable the authorised officer to exercise any of the powers conferred on him or her by these Regulations.

(2) Before exercising the power conferred by subparagraph (*m*) or (*n*) of paragraph (1) in respect of any radio equipment, article or substance, an authorised officer shall, in so far as it is reasonably practicable to do so, consult such persons as appear to him or her to be appropriate for the purpose of ascertaining what dangers, if any, there may be in doing anything which he or she proposes to do under that power.

(3) Where, under the power conferred by subparagraph (*m*) or (*n*) of paragraph (1) an authorised officer takes possession of any radio equipment, article

or substance found at or in any place, the authorised officer shall, if it is practicable for him or her to do so, take a sample thereof and give to a responsible person at the place a portion of the sample marked by the authorised officer in a manner sufficient to identify it.

(4) An authorised officer shall not, other than with the consent of the occupier, enter a private dwelling unless he or she has obtained a warrant from the District Court under Regulation 42 authorising such entry.

(5) Where an authorised officer in the exercise of his or her powers under this Regulation is prevented from entering any place, an application may be made to the District Court under Regulation 42 for a warrant authorising such entry.

(6) A statement or admission made by a person pursuant to a requirement under subparagraph (*h*), (i) or (*j*) of paragraph (1) shall not be admissible in proceedings brought against that person for an offence (other than an offence under paragraph (2) of Regulation 44).

(7) Where any measure has been taken or notice given by the market surveillance authority under this Regulation or Regulation 32, 33, or 35, the costs of any removal, detention, seizure, destruction, rendering inoperable or disposal for the purposes of these Regulations may be charged to the economic operator, the manager of the place where the product was found or the private importer, where known.

(8) (*a*) In this Regulation "place" means any structure, premises, land or other location or part thereof and includes any container, railway wagon, vessel, aircraft or other vehicle.

(*b*) In this Regulation—

"person in charge" means, in relation to a place—

(i) the person under whose direction and control the activities at that place are being conducted, or

(ii) the person whom the authorised officer has reasonable grounds for believing is in control of that place.

(*c*) In this Regulation—

"record" includes any memorandum, book, report, statement, register, plan, chart, map, drawing, specification, diagram, pictorial or graphic work or other document, any photograph, film or recording (whether of sound or images or both), any form in which data (within the meaning of the Data Protection Acts 1988 and 2003) are held, any form (including machine-readable form) or thing in which information is held or stored manually, mechanically or electronically, and anything that is a part or copy, in any form, of any of, or any combination of, the foregoing.

Search Warrant

42. (1) Without prejudice to the powers conferred on an authorised officer by any provision of these Regulations, an authorised officer may, for the purposes of an investigation into an offence under these Regulation, apply to a judge of the District Court for a warrant in relation to any place.

(2) Where, on the hearing of an application under paragraph (5) of Regulation 42 or paragraph (1), a judge of the District Court is satisfied on sworn information of the authorised officer that he or she—

(*a*) has been prevented from entering any place that is not a private dwelling,

(*b*) has reasonable grounds for believing that relevant records are kept at a place that comprises, of forms part of, a private dwelling, or

(*c*) has reasonable grounds for suspecting that evidence of, or relating to the commission of an offence under these Regulations is to be found in any place,

that judge may issue to the authorised officer a warrant under this Regulation authorising one or more than one authorised officer accompanied, if the judge considers it appropriate to so provide, by such number of members of te Garda Síochána as may be specified in the warrant, at any time within 4 weeks from the date of issue of the warrant, to enter, if necessary by force, the place or private dwelling and exercise any of the powers referred to in Regulation 42.

(3) An application under paragraph (1) in the case of a place shall be made to the judge of the District Court in whose District Court district the place is situated.

(4) In this Regulation "place" has the meaning assigned to it by Regulation 41(8)(*a*).

PART 8

MISCELLANEOUS

Giving of Direction, Notice or Other Document

43. (1) Subject to paragraphs (2) and (3), a direction, notice or other document that is required to be given to a person by these Regulations shall be addressed to the person concerned by name and may be given to the person in one of the following ways:

(*a*) by delivering it to the person;

(*b*) by leaving it at the address at which the person carries on business or ordinarily resides or, in the case in which an address for service has been furnished, at that address;

(*c*) by sending it by post in a prepaid registered letter to the address at which the person carries on business or ordinarily resides or, in a case in which an address for service has been furnished, to that address;

(*d*) where there is a facility for receiving the text of the notice by electronic means at the address at which the person carries on business or ordinarily resides, by transmitting the text of the notice by such means to such address, provided that the notice is also delivered in any of the other ways referred to in this paragraph;

(*e*) if the address at which the person ordinarily resides cannot be ascertained by reasonable inquiry and the notice relates to a premises, by delivering to the premises or by affixing it in a conspicuous position on or near the premises.

(2) Where a direction is to be given to a person who is the owner or occupier of land or property and the name of the person cannot be ascertained by reasonable inquiry, it may be addressed to the person by using the words "the owner" or, as the case may require, "the occupier".

(3) For the purposes of this Regulation, a company within the meaning of the Companies Act 2014 or an existing company within the meaning of that Act shall be deemed to be ordinarily resident at its registered office, and every other body corporate and every unincorporated body shall be deemed to be ordinarily resident at its principal office or place of business.

(4) Where an opinion, finding, statement or decision of the competent authority or market surveillance authority is contained in a document which—

(*a*) purports to have been made by or at the direction of the competent authority or market surveillance authority, as the case may be, and

(*b*) is produced in evidence by an officer of the competent authority or market surveillance authority, as the case may be, or by an authorised officer in any proceedings,

such document shall be admissible in evidence and shall be evidence of any such opinion, finding, statement or decision in such proceedings without further proof.

Offences and Penalties

44. (1) A person who contravenes or fails to comply with any of the following shall be guilty of an offence:

(*a*) paragraph (2) or (3) of Regulation 4;

(*b*) subparagraph (*a*), (*b*) or (*c*) of Regulation 5 (3);

(*c*) Regulation 9;

(*d*) paragraph (2) of Regulation 10;

(*e*) Regulation 11, 12, 14, 16, or 17;

(*f*) paragraph (1), (3) or (4) of Regulation 18;

(*g*) paragraph (2) or (5) of Regulation 19;

(*h*) paragraph (6) of Regulation 23;

(*i*) paragraph (3) of Regulation 25;

(*j*) paragraph (1), (5), (6) or (7) of Regulation 26;

(*j*) Regulation 28;

(*k*) paragraph (2) or (8) of Regulation 31;

(*l*) paragraph (4) of Regulation 32;

(*m*) paragraph (2) or (5) of Regulation 35;

(*n*) paragraph (2) of Regulation 34.

(2) A person shall be guilty of an offence who—

(*a*) obstructs or impedes an authorised officer in the exercise of his or her powers under these Regulations,

(*b*) refuses to produce any radio equipment, article, substance, book, record or other document or to answer any question that an authorised officer lawfully requires him or her to produce or to answer,

(*c*) produces or causes to be produced any book, record or other document to an authorised officer which is false or misleading in any material respect knowing it to be so false or misleading, or

(*d*) gives to an authorised officer any information, which is false or misleading in any material respect knowing it to be so false or misleading.

(3) A person who falsely represents himself or herself to be an authorised officer shall be guilty of an offence.

(4) A person guilty of an offence under this Regulation shall be liable on summary conviction to a class A fine.

(5) Summary proceedings for an offence under this Regulation may be brought and prosecuted by the market surveillance authority.

(6) Where an offence under these Regulations is committed by a body corporate and is proved to have been so committed with the consent or connivance of or to be attributable to any neglect on the part of any person, being a director, manager, secretary, or other officer of the body corporate, or a person who was

purporting to act in such capacity, that person shall, as well as the body corporate, be guilty of an offence and shall be liable to be proceeded against and punished as if he or she were guilty of the first-mentioned offence.

(7) Where the affairs of a body corporate are managed by its members, paragraph (6) applies in relation to the acts and defaults of a member in connection with his or her functions of management as if he or she were a director or manager of the body corporate.

(8) In this Regulation "record" has the meaning assigned to it by Regulation 41 (8) (*c*).

Review and Reporting

45. (1) The market surveillance authority shall submit to the European Commission regular reports on the application of the Directive by 12 June 2017 and at least every two years thereafter.

(2) The reports prepared and submitted in accordance with paragraph (1) shall contain a presentation of the market surveillance activities performed by the market surveillance authority and provide information on whether and to what extent compliance with the requirements of the Directive has been attained, including in particular requirements on identification of economic operators.

Application of the Wireless Telegraphy Act, 1926

46. (1) Notwithstanding section 3 (1) of the Wireless Telegraphy Act, 1926, a person shall not be required to hold a licence under that Act to keep or have in his or her possession any apparatus for wireless telegraphy solely for the purpose of placing that apparatus on the market, within the meaning of the Directive.

(2) Nothing in the Wireless Telegraphy Acts, 1926 to 1988, shall operate to restrict or prevent any person from working or using an apparatus for wireless telegraphy, which is lawfully in their possession, or which is otherwise in compliance with the licensing requirements of those Acts for its intended purpose where it complies with the provisions of the Directive, save where such restriction or prevention is related to the effective and appropriate use of the radio frequency spectrum, avoidance of harmful interference or matters relating to public health.

Revocation

47. The Regulations of 2001 are revoked.

Transitional Provisions and Continuation of Regulations of 2001

48. (1) A person may, before 13 June 2017, place on the market or put into service radio equipment to which the Regulations of 2001 apply.

(2) A person may, at any time, make available on the market radio equipment referred to in paragraph (1).

(3) Notwithstanding their revocation under Regulation 47, the Regulations of 2001 shall continue to apply to a product specified in the Regulations of 2001 which is—

(*a*) placed on the market or put into service in accordance with paragraph (1), or

(*b*) made available on the market in accordance with paragraph (2).

(4) A person who, immediately before the coming into operation of these Regulations, was an authorised officer under the Regulations of 2001 shall be deemed to be an authorised officer appointed under these Regulations and, accordingly, paragraph (4) of Regulation 41 shall apply in respect of that person.

SCHEDULE 1

Equipment to Which These Regulations Do Not Apply

1. Radio equipment used by radio amateurs within the meaning of Article 1, definition 56, of the International Telecommunications Union (ITU) 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) equipment constructed by individual radio amateurs for experimental and scientific purposes related to amateur radio.

2. Marine equipment falling within the scope of Council Directive the European Union (Marine Equipment) Regulations 2014 (S.I. No. 540 of 2014). Airborne products, parts and appliances falling within the scope of Article 3 of Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 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.

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

SCHEDULE 2

Conformity Assessment Module A

Module A (Internal Production Control)

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

2. The manufacturer shall establish the technical documentation in accordance with Article 21 of the Directive.

3. 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 Schedule and with the relevant essential requirements set out in Article 3 of the Directive.

4. (a) The manufacturer shall affix the CE marking in accordance with Articles 19 and 20 of the Directive to each item of radio equipment that satisfies the applicable requirements of the Directive.

(b) 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 the national 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 relevant authorities upon request.

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

SCHEDULE 3

Conformity Assessment Modules B and C

EU-Type Examination And Conformity to Type Based on Internal Production Control

When reference is made to this Schedule the conformity assessment procedure shall follow Modules B (EU-type examination) and C (Conformity to type based on internal production control) of this Schedule.

Module B

EU-type examination

1. EU-type examination is the 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 Article 3 of the Directive.

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 evidence referred to in point 3 of this Module B Schedule, 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 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) the technical documentation. The technical documentation shall make it possible to assess the radio equipment's conformity with the applicable requirements of the 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, the design, manufacture and operation of the radio equipment. The technical documentation shall contain, wherever applicable, the elements set out in Schedule 5;

(d) the supporting evidence for the adequacy of the technical design solution. That supporting evidence shall mention 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.

4. The notified body shall examine the technical documentation and supporting evidence 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 of this Schedule and their outcomes. Without prejudice to its obligations as provided in point 8 of this Module B Schedule, 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 the 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 the 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 the 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 its notifying authority 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 EU-type examination certificates it has issued and/or additions thereto in those cases where harmonised standards the references of which have been published in the Official Journal of the European Union have not been applied or not been fully applied. The Member States, the Commission and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Member States and the European Commission 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 the national authorities for 10 years after the radio equipment has been placed on the market.

10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9 of this Module B Schedule, 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 the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3 of this Module C Schedule, 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 the Directive that apply to it.

2. 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 the Directive that apply to it.

3. (1) The manufacturer shall affix the CE marking in accordance with Articles 19 and 20 of the Directive 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 the Directive.

(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 national 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 relevant authorities upon request.

4. The manufacturer's obligations set out in point 3 of this Module C Schedule may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

SCHEDULE 4

Conformity Assessment Module

MODULE H

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 5 of this Schedule, and ensures and declares on his sole responsibility that the radio equipment concerned satisfies the requirements of the Directive that apply to it.

2. 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 of this Schedule and shall be subject to surveillance as specified in point 4 of this Schedule.

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 the authorised representative, his name and address as well;

(b) the technical documentation for each radio equipment type intended to be manufactured. The technical documentation shall contain, wherever applicable, the elements set out in Schedule 5;

(c) the documentation concerning the quality system; and

(d) a written declaration that the same application has not been lodged with any other notified body.

(2) The quality system shall ensure compliance of the radio equipment with the requirements of the 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 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 this Directive that apply to the radio equipment 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.

(3) The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3(2) of this Schedule.

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.

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 the Directive. 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)(b) of this Schedule to verify the manufacturer's ability to identify the applicable requirements of the Directive and to carry out the necessary examinations with a view to ensuring compliance of the radio equipment with those requirements.

The manufacturer or his authorised representative shall be notified of the decision.

The notification shall contain the conclusions of the audit and the reasoned assessment decision.

(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.

(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) of this Schedule 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. (1) The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

(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) 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.

(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) 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. (1) The manufacturer shall affix the CE marking in accordance with Articles 19 and 20 of the Directive and, under the responsibility of the notified body referred to in point 3(1) if this Schedule, the latter's identification number to each item of radio equipment that satisfies the applicable requirements set out in Article 3 of the Directive.

(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 national 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 relevant authorities upon request.

6. (1) 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 national authorities:

(a) the technical documentation referred to in point 3(1) of this Schedule;

(b) the documentation concerning the quality system referred to in point 3(1) of this Schedule;

(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) of this Schedule.

7. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority 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. The manufacturer's obligations set out in points 3(1), 3(5), 5 and 6 of this Schedule may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

SCHEDULE 5

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 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 of the Directive, 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 in Schedule 3 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 Article 10(2) of the Directive and of the inclusion or not of information on the packaging in accordance with Article 10(10) of the Directive.

SCHEDULE 6

EU Declaration of Conformity (No.)

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:

(a) Directive 2014/53/EU

(b) Other Union harmonisation legislation 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):

SCHEDULE 7

Simplified EU Declaration of Conformity

The simplified EU declaration of conformity referred to in Article 10(9) 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:

SCHEDULE 8

Minimum Criteria for Notification as a Notified Body in the State

1. A conformity assessment body shall be a third-party body independent of the organisation or the product it assesses. A body 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, may, on condition that it can demonstrate independence and the absence of any conflict of interest, be considered such a body.

2. A conformity assessment body, its 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 person undertaking maintenance 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.

3. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture, marketing, installation, use or maintenance of that radio equipment, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall also apply to consultancy services provided by the conformity assessment body.

4. A conformity assessment body shall ensure that the activities of a subsidiary of the body or a subcontractor undertaking activities under the responsibility of the body, if any, do not affect the confidentiality, objectivity or impartiality of its conformity assessment activities.

5. A conformity assessment body and its 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, including 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.

6. A conformity assessment body shall be capable of carrying out the conformity assessment tasks required of it under Schedule 3 or 4, and in relation to which it has been notified under Part 5, whether those tasks are carried out by the conformity assessment body itself or on its behalf or under its responsibility.

7. A conformity assessment body shall have at its disposal, at all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, the necessary—

(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks, and

(b) descriptions of procedures in accordance with which conformity assessment is carried out ensuring the transparency and ability of reproduction of those procedures.

8. A conformity assessment body shall have appropriate policies and procedures in place that distinguish between the tasks carried out as a notified body and other activities.

9. A conformity assessment body shall have at its disposal, at all times and for each conformity assessment procedure and each kind or category of radio equipment in relation to which it has been notified, the necessary 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 the technology of the radio equipment in question and the mass or serial nature of the production process.

10. A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

11. The personnel responsible for carrying out the conformity assessment activities shall have—

(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, the applicable harmonised standards, the relevant Union harmonisation legislation and enactments within the meaning of section 2 of the Interpretation Act, implementing those requirements, and

(d) the ability to draw up EU-type certificates, or quality system approvals, records and reports demonstrating that assessments have been carried out.

12. A conformity assessment body shall ensure that it is impartial and shall ensure the impartiality of its top level management and assessment personnel. The remuneration of the top level management and assessment personnel of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

13. A conformity assessment body shall take out a contract of, or make another arrangement in respect of, insurance against liability for damages or costs that

may be incurred in respect of any act done or omitted to be done in the performance or purported performance of conformity assessment activities by it.

14. The personnel of a conformity assessment body shall be bound to observe professional secrecy with regard to all information obtained in carrying out tasks required of it under Schedule 3 or 4, and in relation to which it has been notified under Part 5, except as regards information provided to the competent authority or the competent authorities of other Member States in which it carries out its activities and proprietary rights shall be protected.

15. A conformity assessment body shall participate in, or ensure that their assessment personnel are informed of, the relevant standardisation activities, the regulatory activities in the area of radio equipment and frequency planning, and the activities of any notified body coordination group established by the Commission under the relevant harmonisation legislation and shall apply, as general guidance, the administrative decisions and documents produced as a result of the work of that group.

16. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary for the purpose of carrying out conformity assessment tasks, it shall ensure that the subcontractor or the subsidiary, as the case may be, meets the requirements specified in paragraphs 1 to 15, and shall inform the notifying authority accordingly.

17. A notified body shall take full responsibility for the tasks connected with conformity assessment performed by a subcontractor or a subsidiary, as the case may be, wherever such a subcontractor or subsidiary is established.

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

19. A notified body shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of a subcontractor or a subsidiary and the work carried out by such entity under Regulations 19 to 24.

L.S.

GIVEN under my official Seal,
6 June 2017.

DENIS NAUGHTEN,
Minister for Communications, Climate Action and Environment.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to a legal interpretation.)

The purpose of these Regulations is to give legal effect to Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and of giving full effect to Regulation (EC) No 765/2008 of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products.

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52 FAICHE STIABHNA, BAILE ÁTHA CLIATH 2
(Teil: 01 - 6476834 nó 1890 213434; Fax: 01 - 6476843)
nó trí aon díoltóir leabhar.

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DUBLIN
PUBLISHED BY THE STATIONERY OFFICE
To be purchased from
GOVERNMENT PUBLICATIONS,
52 ST. STEPHEN'S GREEN, DUBLIN 2.
(Tel: 01 - 6476834 or 1890 213434; Fax: 01 - 6476843)
or through any bookseller.

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ISBN 978-1-4064-5980-7

€12.70

9 781406 459807

Wt. (B32848). 285. 6/17. Essentra. Gr 30-15.