STATUTORY INSTRUMENTS

2017 No. 1206

The Radio Equipment Regulations 2017

PART 3

Conformity assessment

Presumption of conformity **E+W+S**

40.—(1) Radio equipment which is in conformity with a [^{F1}designated] standard (or part of such a standard), ^{F2}... must be presumed to be in conformity with the essential requirements covered by that standard (or that part of that standard).

(2) The presumption in paragraph (1) is rebuttable.

Extent Information

- E1 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only
- **F1** Word in reg. 40(1) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 29 para. 30(a) (with Sch. 29 para. 44) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F2 Words in reg. 40(1) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 29 para. 30(b) (with Sch. 29 para. 44) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Presumption of conformity N.I.

40.—(1) Radio equipment which is in conformity with a harmonised standard (or part of such a standard), the reference to which has been published in the Official Journal, must be presumed to be in conformity with the essential requirements covered by that standard (or that part of that standard).

(2) The presumption in paragraph (1) is rebuttable.

Extent Information

E7 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Conformity assessment procedures E+W+S

41.—(1) The manufacturer must perform a conformity assessment of the radio equipment, in all its possible configurations, with a view to meeting the essential requirements.

(2) The conformity assessment must take into account all intended operating conditions.

(3) In relation to the assessment of compliance with regulation 6(1)(a), the conformity assessment must also take into account all reasonably foreseeable conditions.

(4) In relation to the assessment of compliance with regulation 6(1)(a) or (b), one of the following procedures must be used—

- (a) internal production control set out in Schedule 2 (conformity assessment module A),
- (b) ^{F3}...type examination that is followed by the conformity to type based on internal production control set out in Schedule 3 (conformity assessment modules B and C),
- (c) conformity based on full quality assurance set out in Schedule 4 (conformity assessment module H).

(5) In relation to the assessment of compliance with regulation 6(2), where the manufacturer has applied [^{F4}designated] standards, ^{F5}... the manufacturer must use one of the procedures in paragraph (4) for the conformity assessment.

(6) In relation to the assessment of compliance with regulation 6(2), where the manufacturer has not applied or has only partly applied [^{F6}designated] standards, ^{F7}... or where [^{F6}designated] standards do not exist, the manufacturer must use the procedure in either paragraph (4)(b) or paragraph (4)(c).

Extent Information

- E2 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only
- **F3** Word in reg. 41(4)(b) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 29 para. 31(a) (with Sch. 29 para. 44) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F4 Word in reg. 41(5) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 29 para. 31(b)(i) (with Sch. 29 para. 44) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- Words in reg. 41(5) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 29 para. 31(b)(ii) (with Sch. 29 para. 44) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F6 Word in reg. 41(6) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 29 para. 31(b)(i) (with Sch. 29 para. 44) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- Words in reg. 41(6) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 29 para. 31(b)(ii) (with Sch. 29 para. 44) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Conformity assessment procedures N.I.

41.—(1) The manufacturer must perform a conformity assessment of the radio equipment, in all its possible configurations, with a view to meeting the essential requirements.

(2) The conformity assessment must take into account all intended operating conditions.

(3) In relation to the assessment of compliance with regulation 6(1)(a), the conformity assessment must also take into account all reasonably foreseeable conditions.

(4) In relation to the assessment of compliance with regulation 6(1)(a) or (b), one of the following procedures must be used—

- (a) internal production control set out in Schedule 2 (conformity assessment module A),
- (b) EU-type examination that is followed by the conformity to type based on internal production control set out in Schedule 3 (conformity assessment modules B and C),

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

(5) In relation to the assessment of compliance with regulation 6(2) [^{F25} or (3)], where the manufacturer has applied harmonised standards, the references of which have been published in the Official Journal, the manufacturer must use one of the procedures in paragraph (4) for the conformity assessment.

(6) In relation to the assessment of compliance with regulation 6(2) [^{F26}or (3)], where the manufacturer has not applied or has only partly applied harmonised standards, the references of which have been published in the Official Journal, or where harmonised standards do not exist, the manufacturer must use the procedure in either paragraph (4)(b) or paragraph (4)(c).

Extent Information

- **E8** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only
- F25 Words in reg. 41(5) inserted (N.I.) (3.4.2023) by The Radio Equipment (Amendment) (Northern Ireland) Regulations 2023 (S.I. 2023/328), regs. 1(1), 2(3)(a)
- **F26** Words in reg. 41(6) inserted (N.I.) (3.4.2023) by The Radio Equipment (Amendment) (Northern Ireland) Regulations 2023 (S.I. 2023/328), regs. 1(1), **2(3)(b)**

[^{F8}Declaration] of conformity E+W+S

42. The ^{F9}... declaration of conformity for radio equipment must—

- (a) state that the fulfilment of the essential requirements has been demonstrated in respect of that radio equipment,
- (b) contain the elements specified and have the model structure set out in Schedule 6 (^{F10}... declaration of conformity) for the relevant conformity assessment procedure followed in respect of that radio equipment.

Extent Information

- E3 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only
- F8 Word in reg. 42 heading substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 29 para. 32(a) (with Sch. 29 para. 44) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F9 Word in reg. 42 omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 29 para. 32(b) (with Sch. 29 para. 44) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F10** Word in reg. 42(b) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 29 para. 32(b) (with Sch. 29 para. 44) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

EU declaration of conformity N.I.

- 42. The EU declaration of conformity for radio equipment must—
 - (a) state that the fulfilment of the essential requirements has been demonstrated in respect of that radio equipment,

(b) contain the elements specified and have the model structure set out in Schedule 6 (EU declaration of conformity) for the relevant conformity assessment procedure followed in respect of that radio equipment.

Extent Information

E9 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Simplified ^{F11}... declaration of conformity **E+W+S**

43.—(1) Where only a simplified F12 ... declaration of conformity is provided pursuant to regulation 13(3), it must contain the elements specified and have the model structure set out in Schedule 7 (simplified F12 ... declaration of conformity).

(2) The full text of the F12 ... declaration of conformity must be made available at the internet address referred to in the simplified F12 ... declaration of conformity.

Extent Information

- E4 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only
- F11 Word in reg. 43 heading omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 29 para. 33 (with Sch. 29 para. 44) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F12 Word in reg. 43 omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 29 para. 33 (with Sch. 29 para. 44) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Simplified EU declaration of conformity N.I.

43.—(1) Where only a simplified EU declaration of conformity is provided pursuant to regulation 13(3), it must contain the elements specified and have the model structure set out in Schedule 7 (simplified EU declaration of conformity).

(2) The full text of the EU declaration of conformity must be made available at the internet address referred to in the simplified EU declaration of conformity.

Extent Information

E10 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F13}UK] marking E+W+S

44.—[^{F14}(1) The UK marking must be affixed visibly, legibly and indelibly—

- (a) to the radio equipment or to its data plate, unless that is not possible or not warranted on account of the radio equipment; or
- (b) where paragraph (1A) applies—

(i) to a label affixed to the radio equipment or its data plate; or

(ii) to a document accompanying the radio equipment.]

 $[^{F15}(1A)$ For a period of $[^{F16}$ seven years] beginning with IP completion day, the UK marking may be affixed to—

- (a) a label affixed to the radio equipment or its data plate; or
- (b) a document accompanying the radio equipment.]
- [^{F17}(2) The UK marking must be affixed visibly and legibly—
 - (a) to the radio equipment packaging; or
 - (b) where paragraph (2A) applies—
 - (i) to a label affixed to the radio equipment packaging; or
 - (ii) a document accompanying the radio equipment packaging.]

 $[^{F18}(2A)$ For a period of $[^{F19}$ seven years] beginning with IP completion day, the UK marking may be affixed to—

- (a) a label affixed to the radio equipment packaging; or
- (b) a document accompanying the radio equipment packaging.]

(3) On account of the nature of the radio equipment, the height of the $[^{F20}UK]$ marking affixed to radio equipment may be lower than 5 mm, provided that the marking remains visible and legible.

(4) When the conformity assessment procedure in Schedule 4 (conformity assessment module H) has been applied, the [^{F20}UK] marking must be followed by the identification number of the [^{F21}approved body] which carried out the relevant conformity assessment procedure for the radio equipment.

(5) The identification number in paragraph (4) must have the same height as the $[^{F20}UK]$ marking and be affixed—

- (a) by the [^{F21}approved body] itself, or
- (b) under the instructions of the [^{F21}approved body], by the manufacturer or the manufacturer's authorised representative.

Extent Information

- E5 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only
- F13 Word in reg. 44 heading substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 29 para. 34(ad) (with Sch. 29 para. 44) (as amended by S.I. 2020/676, regs. 1(1), 2; S.I. 2020/1460, reg. 1(4), Sch. 3 para. 21(4)(b)); 2020 c. 1, Sch. 5 para. 1(1)
- F14 Reg. 44(1) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 29 para. 34(a) (with Sch. 29 para. 44) (as amended by S.I. 2020/676, regs. 1(1), 2; S.I. 2020/1460, reg. 1(4), Sch. 3 para. 21(4)(a)); 2020 c. 1, Sch. 5 para. 1(1)
- F15 Reg. 44(1A) inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 29 para. 34(aa) (with Sch. 29 para. 44) (as amended by S.I. 2020/676, regs. 1(1), 2; S.I. 2020/1460, reg. 1(4), Sch. 3 para. 21(4)(b)); 2020 c. 1, Sch. 5 para. 1(1)
- F16 Words in reg. 44(1A) substituted (E.W.S.) (31.12.2022) by The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (S.I. 2022/1393), regs. 1(1), 3, Sch. 2 (r)
- F17 Reg. 44(2) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 29 para. 34(ab) (with Sch. 29 para. 44)

(as amended by S.I. 2020/676, regs. 1(1), 2; S.I. 2020/1460, reg. 1(4), Sch. 3 para. 21(4)(b)); 2020 c. 1, Sch. 5 para. 1(1)

- **F18** Reg. 44(2A) inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 29 para. 34(ac) (with Sch. 29 para. 44) (as amended by S.I. 2020/676, regs. 1(1), 2; S.I. 2020/1460, reg. 1(4), Sch. 3 para. 21(4)(b)); 2020 c. 1, Sch. 5 para. 1(1)
- F19 Words in reg. 44(2A) substituted (E.W.S.) (31.12.2022) by The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (S.I. 2022/1393), regs. 1(1), 3, Sch. 2 (r)
- **F20** Word in reg. 44(3)-(5) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 29 para. 34(ad)** (with Sch. 29 para. 44) (as amended by S.I. 2020/676, regs. 1(1), 2; S.I. 2020/1460, reg. 1(4), Sch. 3 para. 21(4)(b)); 2020 c. 1, Sch. 5 para. 1(1)
- F21 Words in reg. 44 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 29 para. 34(b) (with Sch. 29 para. 44) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

CE marking N.I.

44.—(1) The CE marking must be affixed visibly, legibly and indelibly to the radio equipment or to its data plate, unless that is not possible or not warranted on account of the nature of the radio equipment.

(2) The CE marking must be affixed visibly and legibly to the radio equipment packaging.

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

(4) When the conformity assessment procedure in Schedule 4 (conformity assessment module H) has been applied, the CE marking must be followed by the identification number of the notified body which carried out the relevant conformity assessment procedure for the radio equipment.

(5) The identification number in paragraph (4) must have the same height as the CE marking and be affixed—

- (a) by the notified body itself, or
- (b) under the instructions of the notified body, by the manufacturer or the manufacturer's authorised representative.

Extent Information

E11 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F22}UK(NI) indication

44A.—(1) Where the CE marking is affixed on the basis of an assessment or a certificate issued by a notified body established in the United Kingdom, a UK(NI) indication must be affixed in relation to the radio equipment, in accordance with this regulation.

- (2) The UK(NI) indication must be affixed—
 - (a) visibly, legibly and indelibly; and
 - (b) before the radio equipment is placed on the market in Northern Ireland.

(3) The UK(NI) indication must accompany the CE marking, wherever that is affixed in accordance with regulation 44.

- (4) The UK(NI) indication must be affixed by-
 - (a) the manufacturer; or
 - (b) the manufacturer's authorised representative.

(5) When placing radio equipment on the market in Northern Ireland, an importer must ensure that the manufacturer has complied with their obligations under this regulation.]

F22 Regs. 44A, 44B inserted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(2), Sch. 2 para. 14(4)

[^{F22}Register of notified bodies established in the United Kingdom

44B.—(1) The Secretary of State must ensure that—

- (a) each notified body established in the United Kingdom is assigned an identification number; and
- (b) there is a register of—
 - (i) notified bodies established in the United Kingdom;
 - (ii) their notified body identification number;
 - (iii) the activities for which they have been notified;
 - (iv) any restrictions on those activities.

(2) The Secretary of State must ensure that the register referred to in paragraph (1) is maintained and made publicly available.

(3) The Secretary of State may authorise the United Kingdom Accreditation Service to compile and maintain the register in accordance with paragraph (1)(b).]

F22 Regs. 44A, 44B inserted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(2), Sch. 2 para. 14(4)

Technical documentation E+W+S

45.—(1) The technical documentation produced by the manufacturer for the radio equipment must contain all the relevant data or details of the means used by the manufacturer to ensure that the radio equipment complies with the essential requirements.

- (2) The technical documentation in paragraph (1) must—
 - (a) contain, at least, the elements set out in Schedule 5 (contents of technical documentation),
 - (b) be drawn up before the radio equipment is placed on the market, and
 - (c) be continuously updated.
- $F^{23}(3)$

(4) Where the technical documentation does not comply with the requirements in [F24 paragraphs (1) and (2)] and in doing so fails to present sufficient relevant data or details of the means used to ensure compliance of radio equipment with the essential requirements, the market surveillance authority may ask the manufacturer or importer to have a test performed, within a specified period, by a body acceptable to the market surveillance authority, at the expense of the manufacturer or the importer to verify conformity with the essential requirements.

Extent Information

- **E6** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only
- **F23** Reg. 45(3) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 29 para. 35(a) (with Sch. 29 para. 44) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F24** Words in reg. 45(4) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 29 para. 35(b) (with Sch. 29 para. 44) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Technical documentation N.I.

45.—(1) The technical documentation produced by the manufacturer for the radio equipment must contain all the relevant data or details of the means used by the manufacturer to ensure that the radio equipment complies with the essential requirements.

- (2) The technical documentation in paragraph (1) must—
 - (a) contain, at least, the elements set out in Schedule 5 (contents of technical documentation),
 - (b) be drawn up before the radio equipment is placed on the market, and
 - (c) be continuously updated.

(3) The technical documentation in paragraph (1) and correspondence relating to any EU-type examination procedure must be drawn up in an official language of the [F27 relevant state] in which the notified body is established or in a language acceptable to that body.

(4) Where the technical documentation does not comply with the requirements in paragraphs (1), (2) or (3) and in doing so fails to present sufficient relevant data or details of the means used to ensure compliance of radio equipment with the essential requirements, the market surveillance authority may ask the manufacturer or importer to have a test performed, within a specified period, by a body acceptable to the market surveillance authority, at the expense of the manufacturer or the importer to verify conformity with the essential requirements.

Extent Information

- E12 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only
- F27 Words in reg. 45 substituted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), Sch. 16 para. 4

Changes to legislation: There are currently no known outstanding effects for the The Radio Equipment Regulations 2017, PART 3.