

SCHEDULE 1

Regulation 3(2)(b)

Radio equipment outside the scope of these Regulations

1.—(1) Radio equipment used by radio amateurs within the meaning of Article 1, definition 56, of the International Telecommunications Union (ITU) Radio Regulations ^{M1}, unless the equipment is made available on the market.

(2) The following must 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, and
- (c) equipment constructed by individual radio amateurs for experimental and scientific purposes related to amateur radio.

Marginal Citations

M1 See <http://www.itu.int/pub/R-REG-RR>.

[^{F1}2. Marine equipment falling within the Merchant Shipping (Marine Equipment) Regulations 2016.]

3. 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 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency ^{M2}.

Marginal Citations

M2 OJ L 79, 19.3.2008, p.1.

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

SCHEDULE 2

Regulation 41(4)(a)

Conformity assessment module A

Internal production control

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 2, 3 and 4 and ensures and declares on his sole responsibility that the radio equipment concerned satisfies the essential requirements.

Technical documentation

2. The manufacturer must establish the technical documentation in accordance with regulation 45 (technical documentation).

Status: Point in time view as at 31/12/2020.

Changes to legislation: The Radio Equipment Regulations 2017 is up to date with all changes known to be in force on or before 28 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

Manufacturing

3. The manufacturer must 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 paragraph 2 and with the essential requirements.

[^{F2}UK] marking and ^{F3}... declaration of conformity **E+W+S**

4.—(1) The manufacturer must affix the [^{F4}UK] marking in accordance with regulations 39 (prohibition on improper use of [^{F4}UK] marking) and 44 ([^{F4}UK] marking) to each item of radio equipment that satisfies the applicable requirements of these Regulations.

(2) The manufacturer must draw up a written ^{F5}... 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 ^{F5}... declaration of conformity must identify the radio equipment for which it has been drawn up.

(3) A copy of the ^{F6}... declaration of conformity must be made available to the relevant authorities upon request.

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

Textual Amendments

F2 Word in Sch. 2 para. 4 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. 47(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)

F3 Word in Sch. 2 para. 4 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. 47(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 Sch. 2 para. 4(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. 47(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)

F5 Word in Sch. 2 para. 4(2) 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. 47(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)

F6 Word in Sch. 2 para. 4(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. 47(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)

CE marking and EU declaration of conformity **N.I.**

4.—(1) The manufacturer must affix the CE marking in accordance with regulations 39 (prohibition on improper use of CE marking) and 44 (CE marking) to each item of radio equipment that satisfies the applicable requirements of these Regulations.

(2) The manufacturer must 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 must identify the radio equipment for which it has been drawn up.

(3) A copy of the EU declaration of conformity must be made available to the relevant authorities upon request.

Status: Point in time view as at 31/12/2020.

Changes to legislation: The Radio Equipment Regulations 2017 is up to date with all changes known to be in force on or before 28 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

Extent Information

- E45** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Authorised representatives

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

SCHEDULE 3

Regulation 41(4)(b)

Conformity assessment modules B and C

[^{F7}EU-type][^{F7}Type] examination and conformity
to type based on internal production control

Textual Amendments

- F7** Word in Sch. 3 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. 48(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)

When reference is made to this Schedule, the conformity assessment procedure must follow Modules B ([^{F7}EU-type][^{F7}Type] examination) and C (Conformity to type based on internal production control) of this Schedule.

Module B

[^{F7}Type] examination **E+W+S**

1. [^{F8}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.

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

Textual Amendments

- F7** Word in Sch. 3 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. 48(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)

Status: Point in time view as at 31/12/2020.

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F8 Word in Sch. 3 para. 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. 48\(a\)](#) (with [Sch. 29 para. 44](#)) (as amended by [S.I. 2020/676, regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

EU-type examination **N.I.**

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.

Extent Information

E46 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

2. [^{F9}Type] examination must 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 paragraph 3, without examination of a specimen (design type).

3.—(1) The manufacturer must lodge an application for [^{F10}Type] examination with a single [^{F11}approved] body of the manufacturer's choice.

(2) The application must include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, the representative's name and address as well;
- (b) a written declaration that the same application has not been lodged with any other [^{F12}approved] body;
- (c) the technical documentation. The technical documentation shall make it possible to assess the radio equipment's conformity with the applicable requirements of these Regulations and must include an adequate analysis and assessment of the risk(s). The technical documentation must 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 must contain, wherever applicable, the elements set out in Schedule 5 (contents of technical documentation);
- (d) the supporting evidence for the adequacy of the technical design solution. That supporting evidence must mention any documents that have been used, in particular where the relevant [^{F13}designated] standards have not been applied or have not been fully applied. The supporting evidence must 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 the manufacturer's behalf and under the manufacturer's responsibility.

4. The [^{F14}approved] body must examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the radio equipment.

5. The [^{F15}approved] body must draw up an evaluation report that records the activities undertaken in accordance with paragraph 4 and their outcomes. Without prejudice to its obligations as provided in paragraph 8, the [^{F15}approved] body must release the content of that report, in full or in part, only with the agreement of the manufacturer.

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6.—(1) Where the type meets the requirements of these Regulations that apply to the radio equipment concerned, the [^{F16}approved] body must issue [^{F17}a Type] examination certificate to the manufacturer. That certificate must contain—

- (a) the name and address of the manufacturer,
- (b) the conclusions of the examination,
- (c) the aspects of the essential requirements covered by the examination,
- (d) the conditions (if any) for its validity, and
- (e) the necessary data for identification of the assessed type.

(2) The [^{F18}Type] examination certificate may have one or more annexes attached.

(3) The [^{F19}Type] examination certificate and its annexes must 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.

(4) Where the type does not satisfy the applicable requirements of these Regulations, the [^{F20}approved] body must refuse to issue [^{F21}a Type] examination certificate and must inform the applicant accordingly, giving detailed reasons for its refusal.

7.—(1) The [^{F22}approved] body must keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of these Regulations, and must determine whether such changes require further investigation. If so, the [^{F22}approved] body must inform the manufacturer accordingly.

(2) The manufacturer must inform the [^{F22}approved] body that holds the technical documentation relating to the [^{F23}Type] examination certificate of all modifications to the approved type that may affect the conformity of the radio equipment with the essential requirements of these Regulations or the conditions for validity of that certificate. Such modifications require additional approval in the form of an addition to the original [^{F23}Type] examination certificate.

8.—(1) Each [^{F24}approved] body must inform [^{F25}the Secretary of State] concerning the [^{F26}Type] examination certificates and/or any additions thereto which it has issued or withdrawn, and must, periodically or upon request, make available to [^{F25}the Secretary of State] the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

(2) Each [^{F24}approved] body must inform the other [^{F24}approved] 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.

(3) Each [^{F24}approved] body must inform the [^{F27}Secretary of State and the other approved bodies] of [^{F28}Type] examination certificates it has issued and/or additions thereto in those cases where [^{F29}designated] standards ^{F30}... have not been applied or not been fully applied. The [^{F31}Secretary of State] and the other [^{F24}approved] bodies may, on request, obtain a copy of the [^{F28}Type] examination certificates and/or additions thereto. On request, the [^{F32}Secretary of State] may obtain a copy of the technical documentation and the results of the examinations carried out by the [^{F24}approved] body. The [^{F24}approved] body must keep a copy of the [^{F28}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.

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9. The manufacturer must keep a copy of the [^{F33}Type] examination certificate, its annexes and additions together with the technical documentation at the disposal of the [^{F34}enforcing] 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 paragraph 3 and fulfil the obligations set out in paragraphs 7 and 9, provided that they are specified in the mandate.

Module C

Conformity to type based on internal production control **E+W+S**

11. 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 paragraphs 2 and 3, and ensures and declares that the radio equipment concerned is in conformity with the type described in the [^{F35}Type] examination certificate and satisfies the requirements of these Regulations that apply to it.

Extent Information

E12 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F35 Word in [Sch. 3 para. 11](#) 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. 48\(c\)](#) (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 to type based on internal production control **N.I.**

11. 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 paragraphs 2 and 3, and ensures and declares that the radio equipment concerned is in conformity with the type described in the EU-type examination certificate and satisfies the requirements of these Regulations that apply to it.

Extent Information

E55 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Manufacturing **E+W+S**

12. The manufacturer must 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 [^{F36}Type] examination certificate and with the requirements of these Regulations that apply to it.

Extent Information

E13 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Status: Point in time view as at 31/12/2020.

Changes to legislation: The Radio Equipment Regulations 2017 is up to date with all changes known to be in force on or before 28 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

Textual Amendments

- F36** Word in Sch. 3 para. 12 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. 48(c) (with Sch. 29 para. 44) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Manufacturing **N.I.**

12. The manufacturer must 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 these Regulations that apply to it.

Extent Information

- E56** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F37}UK] marking and ^{F38}... declaration of conformity **E+W+S**

13.—(1) The manufacturer must affix the [^{F39}UK] marking in accordance with regulations 39 (prohibition on improper use of [^{F39}UK] marking) and 44 ([^{F39}UK] marking) to each item of radio equipment that is in conformity with the type described in the [^{F40}Type] examination certificate and satisfies the applicable requirements of these Regulations.

(2) The manufacturer must draw up a written ^{F41}... 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 ^{F41}...declaration of conformity must identify the radio equipment type for which it has been drawn up.

(3) A copy of the ^{F42}... declaration of conformity must be made available to the relevant authorities upon request.

Extent Information

- E14** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

- F37** Word in Sch. 3 para. 13 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. 48(i)(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)
- F38** Word in Sch. 3 para. 13 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. 48(i)(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)
- F39** Word in Sch. 3 para. 13(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. 48(i)(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)
- F40** Word in Sch. 3 para. 13(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. 48(c) (with Sch. 29 para. 44) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Status: Point in time view as at 31/12/2020.

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- F41** Word in Sch. 3 para. 13(2) 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. 48(i)(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)
- F42** Word in Sch. 3 para. 13(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. 48(i)(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)

CE marking and EU declaration of conformity **N.I.**

13.—(1) The manufacturer must affix the CE marking in accordance with regulations 39 (prohibition on improper use of CE marking) and 44 (CE marking) 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 these Regulations.

(2) The manufacturer must 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 must identify the radio equipment type for which it has been drawn up.

(3) A copy of the EU declaration of conformity must be made available to the relevant authorities upon request.

Extent Information

- E57** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Authorised representative

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

SCHEDULE 4

Regulation 41(4)(c)

Conformity assessment module H

Conformity based on full quality assurance

1. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 2 and 5 and ensures and declares the manufacturer's sole responsibility that the radio equipment concerned satisfies the requirements of these Regulations that apply to it.

Manufacturing

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

Quality system **E+W+S**

3.—(1) The manufacturer must lodge an application for assessment of the manufacturer's quality system with the [^{F43}approved] body of the manufacturer's choice, for the radio equipment concerned. The application must include—

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, the representative's name and address as well,
- (b) the technical documentation for each radio equipment type intended to be manufactured. The technical documentation must contain, wherever applicable, the elements set out in Schedule 5 (contents of technical documentation),
- (c) the documentation concerning the quality system, and
- (d) a written declaration that the same application has not been lodged with any other [^{F44}approved] body.

(2) The quality system must ensure compliance of the radio equipment with the requirements of these Regulations that apply to it. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. That quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records. It must, 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 [^{F45}designated] standards will not be applied in full, the means that will be used to ensure that the essential requirements of these Regulations 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 [^{F46}approved] body must—

- (a) assess the quality system to determine whether it satisfies the requirements referred to in paragraph 3(2), and
- (b) presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant [^{F47}designated] standard.

(4) In addition to experience in quality management systems, the auditing team must—

- (a) 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 these Regulations, and

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- (b) review the technical documentation referred to in paragraph 3(1)(b) to verify the manufacturer's ability to identify the applicable requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the radio equipment with those requirements.
- (5) The audit must include an assessment visit to the manufacturer's premises.
- (6) The manufacturer or the manufacturer's authorised representative must be notified of the decision.
- (7) The notification must contain the conclusions of the audit and the reasoned assessment decision.
- (8) The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
- (9) The manufacturer must keep the [^{F48}approved] body that has approved the quality system informed of any intended change to the quality system. The [^{F48}approved] body must evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in paragraph 3(2) or whether a reassessment is necessary. The [^{F48}approved] body must notify the manufacturer of its decision. The notification must contain the conclusions of the examination and the reasoned assessment decision.

Extent Information

- E15** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

- F43** Word in Sch. 4 para. 3(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. 49(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)
- F44** Word in Sch. 4 para. 3(1)(d) 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. 49(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)
- F45** Word in Sch. 4 para. 3(2)(b) 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. 49(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)
- F46** Word in Sch. 4 para. 3(3) 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. 49(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)
- F47** Word in Sch. 4 para. 3(3)(b) 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. 49(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)
- F48** Word in Sch. 4 para. 3(9) 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. 49(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)

Quality system **N.I.**

3.—(1) The manufacturer must lodge an application for assessment of the manufacturer's quality system with the notified body of the manufacturer's choice, for the radio equipment concerned. The application must include—

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, the representative's name and address as well,

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- (b) the technical documentation for each radio equipment type intended to be manufactured. The technical documentation must contain, wherever applicable, the elements set out in Schedule 5 (contents of technical documentation),
 - (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 must ensure compliance of the radio equipment with the requirements of these Regulations that apply to it. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. That quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records. It must, in particular, contain an adequate description of—
- (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;
 - (b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards will not be applied in full, the means that will be used to ensure that the essential requirements of these Regulations 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 must—
- (a) assess the quality system to determine whether it satisfies the requirements referred to in paragraph 3(2), and
 - (b) 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.
- (4) In addition to experience in quality management systems, the auditing team must—
- (a) 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 these Regulations, and
 - (b) review the technical documentation referred to in paragraph 3(1)(b) to verify the manufacturer's ability to identify the applicable requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the radio equipment with those requirements.
- (5) The audit must include an assessment visit to the manufacturer's premises.
- (6) The manufacturer or the manufacturer's authorised representative must be notified of the decision.

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(7) The notification must contain the conclusions of the audit and the reasoned assessment decision.

(8) The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

(9) The manufacturer must keep the notified body that has approved the quality system informed of any intended change to the quality system. The notified body must evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in paragraph 3(2) or whether a reassessment is necessary. The notified body must notify the manufacturer of its decision. The notification must contain the conclusions of the examination and the reasoned assessment decision.

Extent Information

E58 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Surveillance under the responsibility of the [^{F49} approved] body **E+W+S**

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 must, for assessment purposes, allow the [^{F50} approved] body access to the design, manufacture, inspection, testing and storage sites, and must 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 [^{F51} approved] body must carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and must provide the manufacturer with an audit report.

(4) In addition, the [^{F52} approved] body may pay unexpected visits to the manufacturer. During such visits, the [^{F52} approved] 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 must provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

Extent Information

E16 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F49 Word in Sch. 4 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. 49(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)

F50 Word in Sch. 4 para. 4(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. 49(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)**

Status: Point in time view as at 31/12/2020.

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- F51** Word in Sch. 4 para. 4(3) 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. 49(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)**
- F52** Word in Sch. 4 para. 4(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. 49(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)**

Surveillance under the responsibility of the notified body **N.I.**

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 must, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and must 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 must carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and must 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 must provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

Extent Information

- E59** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F53}UK] marking and [^{F54}... declaration of conformity **E+W+S**

5.—(1) The manufacturer must affix the [^{F55}UK] marking in accordance with regulations 39 (prohibition on improper use of [^{F55}UK] marking) and 44 ([^{F55}UK] marking) and, under the responsibility of the [^{F56}approved] body referred to in paragraph 3(1), the latter's identification number to each item of radio equipment that satisfies the requirements of these Regulations.

(2) The manufacturer must draw up a written [^{F57}... declaration of conformity for each radio equipment type and keep it at the disposal of the [^{F58}enforcing] authorities for 10 years after the radio equipment has been placed on the market. The [^{F57}... declaration of conformity must identify the radio equipment type for which it has been drawn up. A copy of the [^{F57}... declaration of conformity must be made available to the [^{F58}enforcing] authorities upon request.

Extent Information

- E17** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

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Textual Amendments

- F53** Word in Sch. 4 para. 5 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. 49(c)(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)
- F54** Word in Sch. 4 para. 5 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. 49(c)(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)
- F55** Word in Sch. 4 para. 5(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. 49(c)(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)
- F56** Word in Sch. 4 para. 5(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. 49(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)
- F57** Word in Sch. 4 para. 5(2) 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. 49(c)(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)
- F58** Word in Sch. 4 para. 5(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. 49(c)(iii)** (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 and EU declaration of conformity **N.I.**

5.—(1) The manufacturer must affix the CE marking in accordance with regulations 39 (prohibition on improper use of CE marking) and 44 (CE marking) and, under the responsibility of the notified body referred to in paragraph 3(1), the latter's identification number to each item of radio equipment that satisfies the requirements of these Regulations.

(2) The manufacturer must 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 must identify the radio equipment type for which it has been drawn up. A copy of the EU declaration of conformity must be made available to the relevant authorities upon request.

Extent Information

- E60** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

6. The manufacturer must, for a period ending 10 years after the radio equipment has been placed on the market, keep at the disposal of the ^[F59]enforcing] authorities—

- (a) the technical documentation referred to in paragraph 3(1);
- (b) the documentation concerning the quality system referred to in paragraph 3(1);
- (c) the change referred to in paragraph 3(9), as approved;
- (d) the decisions and reports of the ^[F60]approved] body referred to in paragraphs 3(9), 4(3) and 4(4).

7.—(1) Each ^[F61]approved] body must inform ^[F62]the Secretary of State] of quality system approvals which it has issued or withdrawn, and must, periodically or upon request, make available to ^[F62]the Secretary of State] the list of quality system approvals refused, suspended or otherwise restricted.

(2) Each [F63 approved] body must inform the other [F63 approved] bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

Authorised representative

8. The manufacturer's obligations set out in paragraphs 3(1) and (9), 5 and 6 may be fulfilled by the manufacturer's authorised representative, on the manufacturer's behalf and under the manufacturer's responsibility, provided that they are specified in the mandate.

SCHEDULE 5

Regulation 45(2)(a)

Contents of technical documentation

1. The technical documentation must, 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 conformity with the 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 [F64 designated] standards applied in full or in part F65..., and, where those [F64 designated] standards have not been applied, descriptions of the solutions adopted to meet the essential requirements, including a list of other relevant technical specifications applied. In the event of partly applied [F64 designated] standards, the technical documentation must specify the parts which have been applied;
- (e) copy of the F66... declaration of conformity;
- (f) where the conformity assessment module in Schedule 3 ([F67 Type] examination and conformity to type based on internal production control) has been applied, copy of the [F67 Type] examination certificate and its annexes as delivered by the [F68 approved] 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 regulation 8 (construction must allow operation [F69 without infringement of requirements]) and of the inclusion or not of information on the packaging in accordance with regulation 14 (information to be included where there are restrictions on putting into service or requirements for authorisation of use).

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SCHEDULE 6

Regulation 42(b)

[^{F70}EU][^{F71}declaration][^{F71}Declaration] of conformity

Textual Amendments

- F70** Word in Sch. 6 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. 51(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)
- F71** Word in Sch. 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. 51(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 [^{F71}declaration][^{F71}Declaration] of conformity (No XXX) ^{M3}

Marginal Citations

M3 It is optional for the manufacturer to assign a number to the EU declaration of conformity.

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 [^{F72}statutory requirements]
6. References to the relevant [^{F73}designated] 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 [^{F74}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 [^{F75}EU] declaration of conformity:
 - Additional information:
 - Signed for and on behalf of:
 - (place and date of issue):
 - (name, function) (signature):

Textual Amendments

- F75** Word in Sch. 6 para. 8 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. 51(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)

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SCHEDULE 7

Regulation 43(1)

Simplified [F76EU] declaration of conformity

Textual Amendments

F76 Word in Sch. 7 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. 52(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)

1. The simplified [F77EU] declaration of conformity referred to in regulation 13(3) (instructions and information to be included with the radio equipment) must be provided as follows—

Textual Amendments

F77 Word in Sch. 7 para. 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. 52(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)

2. Hereby, [Name of manufacturer] declares that the radio equipment type [designation of type of radio equipment] is in compliance with [F78the relevant statutory requirements].

3. The full text of the [F79EU] declaration of conformity is available at the following internet address:

Textual Amendments

F79 Word in Sch. 7 para. 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. 52(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)

SCHEDULE 8

Regulation 2(1)

[F80Notified][F80Approved] body requirements

Textual Amendments

F80 Word in Sch. 8 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. 53(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)

1. A conformity assessment body must be established in the United Kingdom and have legal personality.

2.—(1) A conformity assessment body must be a third-party body independent of the organisation or the radio equipment it assesses.

(2) A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of

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radio equipment which it assesses may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered to satisfy sub-paragraph (1).

3.—(1) A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment activities must not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the radio equipment it assesses nor the representative of any of those parties.

(2) Sub-paragraph (1) does 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.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment activities must not be directly involved in the design, manufacture or construction, marketing, installation, use or maintenance of the radio equipment it assesses nor represent parties engaged in those activities.

5. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment activities must not engage in any activity, including consultancy services, that may conflict with their independence of judgment or integrity in relation to conformity assessment activities for which they are [^{F81}approved].

6. A conformity assessment body must ensure that the activities of its subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

7. A conformity assessment body and its personnel must carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and must be free from all pressures and inducements, particularly financial, which might influence their judgment 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.

8. A conformity assessment body must be capable of carrying out all of the conformity assessment activities in relation to which it has been, or is to be, [^{F82}approved], whether those activities are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

9. A conformity assessment body must have at its disposal—

- (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment activities;
- (b) descriptions of procedures in accordance with which conformity assessment is carried out ensuring the transparency and ability of reproduction of those procedures;
- (c) policies and procedures in place to distinguish between activities that it carries out as a [^{F83}approved] body and other activities;
- (d) 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 must have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and must have access to the necessary equipment and facilities to perform these activities.

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

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- (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been [^{F84}approved];
- (b) satisfactory knowledge of the requirements of the assessments that they carry out and adequate authority to carry out those assessments;
- (c) appropriate knowledge and understanding of the essential requirements, the applicable [^{F85}designated] standards ^{F86}... and these Regulations;
- (d) the ability to draw up [^{F87}Type] examination certificates or quality system approvals, records and reports demonstrating that assessments have been carried out.

12. A conformity assessment body must be able to demonstrate the impartiality of its top level management and the personnel responsible for carrying out the conformity assessment activities.

13. The remuneration of the top level management and the personnel responsible for carrying out the conformity assessment activities must not depend on the number of assessments carried out or on the results of those assessments.

14. A conformity assessment body must have, [^{F88}and must satisfy the Secretary of State that it has], adequate civil liability insurance in respect of its activities.

Textual Amendments

F88 Words in Sch. 8 para. 14 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. 53(d)** (with Sch. 29 para. 44) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

15. A conformity assessment body must ensure that its personnel observe professional secrecy with regard to all information obtained in carrying out their tasks in accordance with these Regulations and that proprietary rights are protected.

16. Paragraph 15 does not prevent the personnel from providing information to the Secretary of State or an enforcing authority.

17. A conformity assessment body must participate in, or ensure that its personnel who are responsible for carrying out the conformity assessment activities are informed of, the relevant standardisation activities and the activities of any [^{F89}approved] body coordination group established [^{F90}by the Secretary of State] and must apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

SCHEDULE 9

Regulation 53

Operational obligations of [^{F91}notified][^{F91}approved] bodies

Textual Amendments

F91 Word in Sch. 9 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. 54(a)(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)

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1. [F92 An approved] body must carry out conformity assessments in accordance with the relevant conformity assessment procedures in Schedule 3 (conformity assessment concerning EU-type examination) or Schedule 4 (conformity assessment concerning quality system approval).
2. [F93 An approved] body must carry out conformity assessments in a proportionate manner, avoiding unnecessary burdens on economic operators.
3. A conformity assessment body must 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. A conformity assessment body must respect the degree of rigour and the level of protection required to ensure that the radio equipment is in conformity with the requirements of these Regulations.
5. Where [F94 an approved] body finds that the essential requirements or the corresponding [F95 designated] standards have not been met by the manufacturer, that body must require that manufacturer to take appropriate corrective measures and must not issue [F96 a Type] examination certificate or quality system approval until the appropriate corrective measures have been taken.
6. Where, in the course of the monitoring of conformity following the issue of [F97 a Type] examination certificate or a quality system approval, [F98 an approved] body finds that the radio equipment is no longer in conformity with the essential requirements, it must require the manufacturer to take appropriate corrective measures and must suspend or withdraw the [F99 Type] examination certificate or quality system approval (if necessary).
7. Where the [F100 approved] body has required a manufacturer to take corrective measures and the manufacturer has failed to take such measures, or those measures have not had the required effect, the [F100 approved] body must restrict, suspend or withdraw any [F101 Type] examination certificates or quality system approvals as appropriate.
8. Paragraph 9 applies where [F102 an approved] body is minded to—
 - (a) refuse to issue [F103 a Type] examination certificate,
 - (b) refuse to grant a quality system approval, or
 - (c) restrict, suspend or withdraw [F103 a Type] examination certificate or quality system approval.
9. Where this paragraph applies, the [F104 approved] body must—
 - (a) give the person applying for the [F105 Type] examination certificate or quality system approval, or the person to whom the [F105 Type] examination certificate or quality system approval was given—
 - (i) a notice in writing giving reasons and specifying the date on which the refusal, restriction, suspension or withdrawal is intended to take effect, and
 - (ii) an opportunity to make representations within a reasonable period from the date of the notice, and
 - (b) take account of any representations made under sub-paragraph (a)(ii) before taking its decision.
10. [F106 An approved] body must inform the Secretary of State of—
 - (a) any refusal, restriction, suspension or withdrawal of [F107 a Type] examination certificate or quality system approval in accordance with the requirements of Schedule 3 or Schedule 4 as appropriate,

Status: Point in time view as at 31/12/2020.

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- (b) any circumstances affecting the scope of, or conditions for, [F108approval] under regulation 47 ([F109approval of conformity assessment bodies]),
 - (c) any request for information which it has received from an enforcing authority F110... regarding conformity assessment activities, and
 - (d) on request, conformity assessment activities performed within the scope of its notification under regulation 47 and any other activity performed, including cross-border activities and subcontracting.
11. [F111An approved] body must make provision in its contracts with its clients enabling such clients to appeal against a decision—
- (a) to refuse to issue [F112a Type] examination certificate or quality system approval decision, or
 - (b) to restrict, suspend or withdraw [F112a Type] examination certificate or quality system approval decision.
12. [F113An approved] body must, in accordance with the requirements in Schedule 3 and Schedule 4, provide other bodies [F114approved] under [F115these Regulations] carrying out similar conformity assessment activities covering the same type of radio equipment with relevant information on issues relating to negative and, on request, positive conformity assessment results.
13. [F116An approved] body must participate in the work of any [F117approved] body coordination group established [F118by the Secretary of State], directly or by means of its designated representatives.
14. [F119An approved] body must fulfil any information obligations under Schedules 3 and 4.

SCHEDULE 10

Regulation 55(3), 57(1)

Enforcement and investigatory powers conferred on the enforcing authority and the market surveillance authority

PART 1

Powers

Enforcement powers under the 1987 Act

1. For the purposes of enforcing these Regulations, the following sections of the 1987 Act apply subject to the modifications in paragraph 2—

- (a) section 13 (prohibition notices and notices to warn),
- (b) section 14 (suspension notices),
- (c) section 16 (forfeiture: England, Wales and Northern Ireland),
- (d) section 17 (forfeiture: Scotland),
- (e) section 18 (power to obtain information),
- (f) section 29 (powers of search etc),
- (g) section 30 (provisions supplemental to s 29),

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- (h) section 31 (power of customs officer to detain goods),
- (i) section 33 (appeals against detention of goods),
- (j) section 34 (compensation for seizure and detention),
- (k) section 35 (recovery of expenses of enforcement),
- (l) section 37 (power of Commissioners for Revenue and Customs to disclose information)),
- (m) section 45 (interpretation),
- (n) section 46(1) (meaning of “supply”), and
- (o) Schedule 2 (prohibition notices and notices to warn).

Modifications to the 1987 Act

2. The sections of the 1987 Act referred to in paragraph 1 are to apply as if—
 - (a) in section 13—
 - (i) in subsection (1), “relevant” were omitted on each occasion that it appears,
 - (ii) for “unsafe”, on each occasion that it appears, there were substituted “ non-compliant ”,
 - (iii) in subsection (2), the words from “; and the Secretary of State may” to the end were omitted, and
 - (iv) subsections (4) to (7) were omitted;
 - (b) in section 14—
 - (i) in subsection (1), after “any safety provision has been contravened in relation to any goods”, there were inserted “ or that such goods present a risk ”,
 - (ii) in subsection 2(b), after “a safety provision has been contravened in relation to the goods”, there were inserted “ or that such goods present a risk ”,
 - (iii) in subsection (2)(c), “under section 15 below” were omitted, and
 - (iv) subsections (6) to (8) were omitted;
 - (c) in section 16—
 - (i) in subsection (1), after “a contravention in relation to the goods of a safety provision”, there were inserted “ or that such goods present a risk ”,
 - (ii) for subsection 2(b) there were substituted—
 - “(b) where an application with respect to some or all of the goods has been made to a magistrates' court under regulation 73 (appeals against notices) of the 2017 Regulations or section 33, to that court; and”,
 - (iii) in subsection (3), after “a contravention in relation to the goods of a safety provision”, there were inserted “ or that such goods present a risk ”,
 - (iv) after subsection (4), there were inserted—
 - “(4A) A court may infer for the purposes of this section that any goods present a risk, if it is satisfied that such a risk is presented by goods which are representative of those goods (whether by reason of being of the same design or part of the same consignment or batch or otherwise).”,
 - (v) in subsection (6), the words “Subject to subsection (7) below,” were omitted, and
 - (vi) subsection (7) were omitted;
 - (d) in section 17—

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- (i) in subsection (1), after “a contravention of a safety provision”, there were inserted “ or where the goods present a risk ”,
- (ii) in subsection (6), after “a contravention in relation to those goods of a safety provision”, there were inserted “ or that those goods present a risk ”, and
- (iii) after subsection (7), there were inserted—
 - “(7A) The sheriff may infer for the purposes of this section that any goods present a risk, if the sheriff is satisfied that such a risk is presented by goods which are representative of those goods (whether by reason of being of the same design or part of the same consignment or batch or otherwise).”;
- (e) in section 18, subsections (3) and (4) were omitted;
- (f) in section 29—
 - (i) in subsection 4(a), after “any contravention of any safety provision in relation to the goods”, there were inserted “ or whether the goods present a risk ”; and
 - (ii) in subsection 4(b), after “any such contravention”, there were inserted “ or whether the goods present a risk ”;
- (g) in section 30—
 - (i) at the end of subsection (2)(a)(ii), for “and” there were substituted “ or ”,
 - (ii) after subsection (2)(a)(ii), there were inserted—
 - “(iii) that any goods which any officer has power to inspect under section 29 are on any premises and their inspection is likely to demonstrate that they present a risk; and”, and
 - (iii) subsections (5), (7) and (8) were omitted;
- (h) in section 31(1), for “Part II of this Act”, there were substituted “ the 2017 Regulations ”,
- (i) in section 34—
 - (i) omit the word “and” at the end of subsection (1)(a), and
 - (ii) after that subsection, insert—
 - “(aa) the goods do not present a risk; and”,
- (j) in section 37(1), for “Part II of this Act”, there were substituted “ the 2017 Regulations ”,
- (k) in section 45(1)—
 - (i) the definitions of “conditional sale agreement”, “gas”, “motor vehicle”, “personal injury”, “subordinate legislation” and “substance” were omitted,
 - (ii) before the definition of “aircraft”, there were inserted—
 - ““the 2017 Regulations” means the Radio Equipment Regulations 2017;”,
 - (iii) for the definition of “enforcement authority” there were substituted—
 - ““enforcement authority” means an enforcing authority as defined in regulation 2(1) of the 2017 Regulations;”,
 - (iv) for the definition of “goods” there were substituted—
 - ““goods” means radio equipment within the scope of the 2017 Regulations;”,
 - (v) after the definition of “motor vehicle”, there were inserted—
 - ““non-compliant” in relation to any goods means that—
 - (a) a safety provision has been contravened in relation to the goods; or
 - (b) the goods present a risk”,

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- (vi) after the definition of “premises” there were inserted—
 - ““present a risk” means present a risk where “risk” has the meaning set out in regulation 2(5) of the 2017 Regulations;”,
- (vii) for the definition of “safety provision” there were substituted—
 - ““safety provision” means any provision of the 2017 Regulations;”, and
- (viii) for the definition of “safety regulations” there were inserted—
 - ““safety regulations” means the 2017 Regulations;”,
- (l) in section 46(1), there were omitted from “and, in relation to gas or water” to the end; and
- (m) in Schedule 2—
 - (i) for “unsafe”, on each occasion that it appears, there were substituted “ non-compliant ”, and
 - (ii) for “safe”, on each occasion that it appears, there were substituted “ not non-compliant ”.

Application of Schedule 5 to the Consumer Rights Act 2015

3. Schedule 5 to the Consumer Rights Act 2015 (investigatory powers etc) ^{M4} applies to OFCOM as if—

- (a) OFCOM were a domestic enforcer within the meaning of that Schedule, and
- (b) the enforcer's legislation within the meaning of that Schedule, in relation to OFCOM, were the legislation and notices which, by virtue of regulation 56(1)(a)(i) or (b)(i), OFCOM has a duty or power to enforce.

Marginal Citations

M4 2015 c.15.

PART 2

Notices

Compliance notice

4.—(1) An enforcing authority may serve a compliance notice on a relevant economic operator in respect of radio equipment if the authority has reasonable grounds for believing that there is non-compliance.

- (2) A compliance notice must—
 - (a) require the relevant economic operator on which it is served to—
 - (i) end the non-compliance within such period as may be specified in the notice, or
 - (ii) provide evidence, within such period as may be specified in the notice, demonstrating to the satisfaction of the enforcing authority that the non-compliance has not in fact occurred, and
 - (b) warn the economic operator that, if the non-compliance persists beyond, or if satisfactory evidence has not been produced within, the period specified in the notice, further action

may be taken in respect of the radio equipment or any radio equipment of the same type made available on the market by that relevant economic operator.

(3) A compliance notice may include directions as to the measures to be taken by the economic operator to secure compliance, including different ways of securing compliance.

(4) Subject to sub-paragraph (5), an enforcing authority may revoke or vary a compliance notice by serving a notification on the economic operator.

(5) An enforcing authority may not vary a compliance notice so as to make it more restrictive for the economic operator or more onerous for the economic operator to comply.

Withdrawal notice **E+W+S**

5.—(1) An enforcing authority may serve a withdrawal notice on a relevant economic operator in respect of radio equipment if the authority has reasonable grounds for believing that—

- (a) the radio equipment has been made available on the market, and
- (b) there is non-compliance.

(2) A withdrawal notice must prohibit the relevant economic operator from making the radio equipment available on the market without the consent of the enforcing authority.

(3) A withdrawal notice may require the relevant economic operator to take action to alert end-users to any risk presented by the radio equipment.

(4) A withdrawal notice may require the relevant economic operator to keep the enforcing authority informed of the whereabouts of any radio equipment referred to in the notice.

(5) A consent given by the enforcing authority pursuant to a withdrawal notice may impose such conditions on the making available on the market of the radio equipment as the enforcing authority considers appropriate.

(6) Subject to sub-paragraph (7), an enforcing authority may revoke or vary a withdrawal notice by serving a notification on the economic operator.

(7) An enforcing authority may not vary a withdrawal notice so as to make it more restrictive for the economic operator or more onerous for the economic operator to comply.

(8) A withdrawal notice has effect throughout the United Kingdom.

Extent Information

E42 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Withdrawal notice **N.I.**

5.—(1) An enforcing authority may serve a withdrawal notice on a relevant economic operator in respect of radio equipment if the authority has reasonable grounds for believing that—

- (a) the radio equipment has been made available on the market, and
- (b) there is non-compliance.

(2) A withdrawal notice must prohibit the relevant economic operator from making the radio equipment available on the market without the consent of the enforcing authority.

(3) A withdrawal notice may require the relevant economic operator to take action to alert end-users to any risk presented by the radio equipment.

(4) A withdrawal notice may require the relevant economic operator to keep the enforcing authority informed of the whereabouts of any radio equipment referred to in the notice.

Status: Point in time view as at 31/12/2020.

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(5) A consent given by the enforcing authority pursuant to a withdrawal notice may impose such conditions on the making available on the market of the radio equipment as the enforcing authority considers appropriate.

(6) Subject to sub-paragraph (7), an enforcing authority may revoke or vary a withdrawal notice by serving a notification on the economic operator.

(7) An enforcing authority may not vary a withdrawal notice so as to make it more restrictive for the economic operator or more onerous for the economic operator to comply.

(8) A withdrawal notice has effect throughout [^{F124}Northern Ireland].

Extent Information

E85 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F124 Words in [Sch. 10 para. 5\(8\)](#) 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. 8\(4\)](#)

Recall notice **E+W+S**

6.—(1) The enforcing authority may serve a recall notice on a relevant economic operator in respect of radio equipment if the authority has reasonable grounds for believing that—

- (a) the radio equipment has been made available to end-users, and
- (b) there is non-compliance.

(2) A recall notice must require the relevant economic operator to use reasonable endeavours to organise the return of the radio equipment from end-users to the relevant economic operator or another person specified in the notice.

(3) A recall notice may—

- (a) require the relevant economic operator to—
 - (i) contact end-users in order to inform them of the recall, to the extent that it is practicable to do so,
 - (ii) publish a notice in such form and such manner as is likely to bring to the attention of end-users any risk the radio equipment poses and the fact of the recall, or
 - (iii) make arrangements for the collection or return of the radio equipment from end-users or its disposal, or
- (b) impose such additional requirements on the relevant economic operator as are reasonable and practicable with a view to achieving the return of the radio equipment.

(4) In determining what requirements to include in a recall notice, the enforcing authority must take into consideration the need to encourage distributors and end-users to contribute to its implementation.

(5) A recall notice may only be issued by the enforcing authority where—

- (a) other action which it may require under these Regulations would not suffice to address the non-compliance,
- (b) the action being undertaken by the relevant economic operator is unsatisfactory or insufficient to address the non-compliance,

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- (c) the enforcing authority has given not less than 10 days' notice to the relevant economic operator of its intention to serve such a notice, and
 - (d) the enforcing authority has taken account of any advice obtained under sub-paragraph (6).
- (6) A relevant economic operator which has received notice from the enforcing authority of an intention to serve a recall notice may at any time prior to the service of the recall notice require the authority to seek the advice of such person as the Institute determines on the questions of—
- (a) whether there is non-compliance, and
 - (b) whether the issue of a recall notice would be proportionate.
- (7) Sub-paragraph (5)(b), (c) and (d) do not apply in the case of radio equipment presenting a serious risk requiring, in the view of the enforcing authority, urgent action.
- (8) Where a relevant economic operator requires the enforcing authority to seek advice under sub-paragraph (6), that relevant economic operator is to be responsible for the fees, costs and expenses of the Institute and of the person appointed by the Institute to advise the enforcing authority.
- (9) In this paragraph, “Institute” means the charitable organisation with registered number 803725 and known as the Chartered Institute of Arbitrators.
- (10) A recall notice served by the enforcing authority may require the relevant economic operator to keep the authority informed of the whereabouts of radio equipment to which the recall notice relates, so far as the relevant economic operator is able to do so.
- (11) Subject to sub-paragraph (12), an enforcing authority may revoke or vary a recall notice by serving a notification on the economic operator.
- (12) An enforcing authority may not vary a recall notice so as to make it more restrictive for the economic operator or more onerous for the economic operator to comply.
- (13) A recall notice has effect throughout the United Kingdom.

Extent Information

E43 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Recall notice **N.I.**

- 6.—(1) The enforcing authority may serve a recall notice on a relevant economic operator in respect of radio equipment if the authority has reasonable grounds for believing that—
- (a) the radio equipment has been made available to end-users, and
 - (b) there is non-compliance.
- (2) A recall notice must require the relevant economic operator to use reasonable endeavours to organise the return of the radio equipment from end-users to the relevant economic operator or another person specified in the notice.
- (3) A recall notice may—
- (a) require the relevant economic operator to—
 - (i) contact end-users in order to inform them of the recall, to the extent that it is practicable to do so,
 - (ii) publish a notice in such form and such manner as is likely to bring to the attention of end-users any risk the radio equipment poses and the fact of the recall, or
 - (iii) make arrangements for the collection or return of the radio equipment from end-users or its disposal, or

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- (b) impose such additional requirements on the relevant economic operator as are reasonable and practicable with a view to achieving the return of the radio equipment.
- (4) In determining what requirements to include in a recall notice, the enforcing authority must take into consideration the need to encourage distributors and end-users to contribute to its implementation.
- (5) A recall notice may only be issued by the enforcing authority where—
- other action which it may require under these Regulations would not suffice to address the non-compliance,
 - the action being undertaken by the relevant economic operator is unsatisfactory or insufficient to address the non-compliance,
 - the enforcing authority has given not less than 10 days' notice to the relevant economic operator of its intention to serve such a notice, and
 - the enforcing authority has taken account of any advice obtained under sub-paragraph (6).
- (6) A relevant economic operator which has received notice from the enforcing authority of an intention to serve a recall notice may at any time prior to the service of the recall notice require the authority to seek the advice of such person as the Institute determines on the questions of—
- whether there is non-compliance, and
 - whether the issue of a recall notice would be proportionate.
- (7) Sub-paragraph (5)(b), (c) and (d) do not apply in the case of radio equipment presenting a serious risk requiring, in the view of the enforcing authority, urgent action.
- (8) Where a relevant economic operator requires the enforcing authority to seek advice under sub-paragraph (6), that relevant economic operator is to be responsible for the fees, costs and expenses of the Institute and of the person appointed by the Institute to advise the enforcing authority.
- (9) In this paragraph, “Institute” means the charitable organisation with registered number 803725 and known as the Chartered Institute of Arbitrators.
- (10) A recall notice served by the enforcing authority may require the relevant economic operator to keep the authority informed of the whereabouts of radio equipment to which the recall notice relates, so far as the relevant economic operator is able to do so.
- (11) Subject to sub-paragraph (12), an enforcing authority may revoke or vary a recall notice by serving a notification on the economic operator.
- (12) An enforcing authority may not vary a recall notice so as to make it more restrictive for the economic operator or more onerous for the economic operator to comply.
- (13) A recall notice has effect throughout [^{F125}Northern Ireland].

Extent Information

E86 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F125 Words in [Sch. 10 para. 6\(13\)](#) 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. 8\(4\)](#)

Interpretation

7. In this Schedule, “non-compliance” means that the radio equipment—

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- (a) presents a risk, or
- (b) is not in conformity with Part 2 or RAMS (in its application to radio equipment).

Status:

Point in time view as at 31/12/2020.

Changes to legislation:

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