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## STATUTORY INSTRUMENTS

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# 2019 No. 837

## The Rail Safety (Amendment etc.) (EU Exit) Regulations 2019

### PART 1 U.K.

#### Introduction

#### Citation and commencement U.K.

1. These Regulations may be cited as the Rail Safety (Amendment etc.) (EU Exit) Regulations 2019 and come into force on exit day.

#### Commencement Information

**I1** Reg. 1 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

#### Extent U.K.

- 2.—(1) These Regulations extend as follows.
- (2) This Part and Part 3 extend to England and Wales, Scotland and Northern Ireland.
- (3) Parts 2 and 4 extend to England and Wales and Scotland.
- (4) Part 5 extends to Northern Ireland.

#### Commencement Information

**I2** Reg. 2 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

### PART 2 E+W+S

#### Amendments to subordinate legislation

#### Amendments to the Railways and Other Guided Transport Systems (Safety) Regulations 2006 E+W+S

3.—(1) The Railways and Other Guided Transport Systems (Safety) Regulations 2006<sup>M1</sup> are amended as follows.

- (2) In regulation 2 (interpretation and application)—
- (a) before the definition of “building operation”, insert—

[<sup>F1</sup>“2011 EU ECM Regulation” means [Commission Regulation \(EU\) No 445/2011](#) on a system of certification of entities in charge of maintenance for freight wagons and amending Regulation (EC) No 653/2007 as it had effect or as it has effect in EU law, as the context dictates;

“2019 EU ECM Regulation”, save in the expression “retained 2019 EU ECM Regulation”, means Commission Implementing Regulation (EU) 2019/779 laying down detailed provisions on a system of certification of entities in charge of maintenance of vehicles pursuant to [Directive \(EU\) 2016/798](#) of the European Parliament and of the Council and repealing [Commission Regulation \(EU\) No 445/2011](#) as it had effect or as it has effect in EU law, as the context dictates;]

“accident” means an unwanted or unintended sudden event or a specific chain of such events which have harmful consequences; accidents are divided into the following categories: collisions, derailments, level-crossing accidents, accidents to persons caused by rolling stock in motion, fires and others;”;

(b) in the definition of “certification body”, for “has the same meaning as in the ECM Regulation”, substitute “ means a body responsible for the certification of entities in charge of maintenance, on the basis of the criteria in Part 3 of Schedule 10 ”;

(c) for the definition of “common safety methods”, substitute—

““common safety methods” (“CSMs”) means—

(a) [Commission Regulation \(EU\) No 1158/2010](#) on a common safety method for assessing conformity with the requirements for obtaining railway safety certificates;

(b) [Commission Regulation \(EU\) No 1169/2010](#) on a common safety method for assessing conformity with the requirements for obtaining a railway safety authorisation;

[<sup>F2</sup>(c) [Commission Delegated Regulation \(EU\) 2018/761](#) establishing common safety methods for supervision by national safety authorities after the issue of a single safety certificate or a safety authorisation;]

(d) [Commission Regulation \(EU\) No 1078/2012](#) on a common safety method for monitoring to be applied by railway undertakings, infrastructure managers after receiving a safety certificate or safety authorisation and by entities in charge of maintenance; and

(e) [Commission Implementing Regulation \(EU\) No 402/2012](#) on a common safety method for risk evaluation and assessment,

as they have effect in Great Britain;”;

(d) for the definition of “common safety targets”, substitute—

““common safety targets” (“CSTs”) means the minimum safety levels that must be reached by the mainline railway system, or parts of the mainline railway system, expressed in risk categories as defined in paragraph 2 of Schedule 11;”;

[<sup>F3</sup>(dd) after the definition of “competent person”, insert—

““cross-border service” means a service for the carriage of passengers or goods by way of the tunnel system;

“cross-border UK-issued ECM certificate” means a certificate issued in the United Kingdom to an entity in charge of maintenance by an accredited or recognised body or by a safety authority in accordance with the retained 2019 EU ECM Regulation;”;

(e) for the definition of “ECM certificate”, substitute—

“EU ECM certificate” means a certificate issued to an entity in charge of maintenance in accordance with the [F<sup>4</sup>2011 EU ECM Regulation or the 2019 EU ECM Regulation as may be applicable];”;

- (f) omit the definition of “ECM Regulation”;
- [F<sup>5</sup>(g) after the definition of “responsible person”, insert—
- ““retained 2019 EU ECM Regulation” means [Commission Implementing Regulation \(EU\) 2019/779](#) laying down detailed provisions on a system of certification of entities in charge of maintenance of vehicles pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing [Commission Regulation \(EU\) No 445/2011](#), as it has effect in the UK after IP completion day;”;
- (h) for the definition of “safety authority”, substitute—
- ““safety authority”, save for in the expression “safety authority for the tunnel system”, means—
- (a) as regards Great Britain, the Office of Rail and Road <sup>M2</sup>; or
- (b) as regards Northern Ireland, the Department for Infrastructure established by article 3(1) of the Departments (Northern Ireland) Order 1999 <sup>M3</sup> and renamed by section 1(6) of the Departments Act (Northern Ireland) 2016 <sup>M4</sup>;”;
- (i) after the definition of “safety authority” insert—
- ““safety authority for the tunnel system” means the Intergovernmental Commission as defined in section 49(1) of the Channel Tunnel Act 1987 <sup>M5</sup>;”;
- (j) in the definition of “subsystem”, for “Directive”, substitute “Regulations”;
- [F<sup>6</sup>(ja) omit the definition of “technical specifications for interoperability;]
- (k) after the definition of “trolley vehicle system” insert—
- ““tunnel system” has the same meaning as in section 1(7) of the Channel Tunnel Act 1987;
- [F<sup>7</sup>“UK-issued ECM certificate”, save in the expression “cross-border UK-issued ECM certificate”, means a certificate issued in the United Kingdom to an entity in charge of maintenance by an accredited or recognised body or by a safety authority in accordance with Schedule 10;”];
- [F<sup>8</sup>(l) for paragraph 3 substitute—
- “(3) Parts 2 and 3 of these Regulations shall not apply to or in relation to the operation of a train or the management or use of infrastructure in the tunnel system, save for—
- (a) regulation 18(A1) for vehicles used to operate a cross-border service;
- (b) regulation 18B for the tunnel system.”.]
- [F<sup>9</sup>(2A) In regulation 7 (safety certificate)—
- (i) in paragraph (2), at the beginning, insert “ Subject to paragraph 2A, ”
- (ii) after paragraph (2), insert—
- “(2A) Where in accordance with paragraphs (1) and (2) of this regulation, the applicant has at any time before, on or after exit day submitted a copy of the certificate referred to in paragraph 1(b)(i)(bb) of Schedule 2, that certificate shall cease to be deemed to be Part A of the safety certificate after the second anniversary of exit day and no such certificate submitted after that anniversary shall be deemed to be Part A of the safety certificate.”
- (b) in paragraph (11), in the new paragraph 1(b)(i), in sub-paragraph (bb), after “member State” insert “ before exit day, ”.]

(3) After regulation 9 (further safety certificate), insert—

**“Format for safety certificates and applications**

**9A.** Schedule 8 has effect.”.

(4) In regulation 15 (revocation of safety certificate)—

(a) in paragraph (5)(b), omit “in another member State or”;

(b) after paragraph (5), insert—

“(6) Where—

(a) the Office of Rail and Road revokes Part B of a safety certificate; and

(b) Part A of that safety certificate is deemed to be Part A of a safety certificate pursuant to regulation 7(2) and was issued by an authority carrying out railway safety functions in a member State [<sup>F10</sup>or the European Union Agency for Railways],

the Office of Rail and Road must notify that authority or the [<sup>F11</sup>European Union Agency for Railways].

(7) For the purposes of paragraph (6), “authority carrying out railway safety functions” means an authority established in a member State in accordance with article 16.1 of the Directive [<sup>F12</sup>or Article 16.1 of the Recast Safety Directive].”.

(5) Omit regulation 18 (notification to the European Railway Agency regarding safety certificates and safety authorisations relating to the mainline railway).

(6) In regulation 18A (maintenance of vehicles on the mainline railway)—

(a) for paragraph (1)(b), substitute—

“(b) where the vehicle is a freight wagon, holds either an EU ECM certificate valid on the terms of its original issue or a UK-issued ECM certificate.”;

[<sup>F13</sup>(aa) after paragraph (1), insert—

“(1A) No person may use a vehicle to operate a cross-border service unless that vehicle has an entity in charge of maintenance assigned to it, and that entity in charge of maintenance—

(a) is registered in relation to that vehicle in the National Vehicle Register; and

(b) holds either an EU ECM certificate valid on the terms of its original issue or a cross-border UK-issued ECM certificate, where it is required to do so in accordance with the retained 2019 EU ECM Regulation.”;]

(b) after paragraph (3), insert—

“(4) Schedule 9 (applications for UK-issued ECM certificates by entities in charge of maintenance) and Schedule 10 (system of certification of entities in charge of maintenance in respect of Great Britain) have effect.”.

(7) After regulation 18A, insert—

**“Common safety targets**

**18B.** The Office of Rail and Road must assess the achievement of common safety targets in accordance with Schedule 11 (common safety targets), which has effect.”.

(8) In regulation 20 (annual safety reports)—

(a) in paragraph (1)(c), omit “listed in Annex I (common safety indicators) to the Directive.”;

- (b) omit paragraphs (3), (4) and (5);
- (c) at the end, insert—

“(6) For the purposes of paragraph (1)(c), the common safety indicators are those laid down in paragraphs 1.1 to 6.2 of, and the Appendix to, Annex I to the Directive, save that the Appendix is to be read with the following modifications—

- (a) in paragraph 1.2, for “EUR 150 000” substitute “ £170,000 ”;
- (b) in paragraph 5.1, for “Member State” substitute “ United Kingdom ”; and
- (c) in paragraphs 7.3 and 7.4, for “railway network in Member States, whose scope is set out in Article 2” substitute “ mainline railway as defined in the Railways and Other Guided Transport Systems (Safety) Regulations 2006 ”.

(9) In regulation 21 (sending, issuing, and keeping of documents and making them available for public inspection), in paragraphs (3) and (8), omit “in Great Britain”.

(10) In regulation 27 (appeals)—

[<sup>F14</sup>(a) in paragraph (1)(a), for “an ECM certificate”, substitute “an EU ECM certificate, a cross-border UK-issued ECM certificate or a UK-issued ECM certificate”];

[<sup>F15</sup>(b) for sub-paragraph (b) substitute—

“(b) for paragraph (1)(d) substitute—

“(d) decision of the Office of Rail and Road, concerning his EU ECM Certificate taken pursuant to either—

- (i) Article 7(3), (4) or (7) of the 2011 EU ECM Regulation; or
- (ii) Article 7(5) or (8) or 8(2) of the 2019 EU ECM Regulation;”];

(c) after paragraph (1)(d), insert—

“(dd) decision of the Office of Rail and Road taken pursuant to paragraph 7(3), (4) or (7) of Schedule 10 concerning his UK-issued ECM certificate; <sup>F16</sup>...

[<sup>F17</sup>(de) decision of the Office of Rail and Road, concerning his cross-border UK-issued ECM certificate, taken pursuant to Article 7(5) or (8) or 8(2) of the retained 2019 EU ECM Regulation; or”];

(d) for paragraph (1A), substitute—

[<sup>F18</sup>(1A) A person who is aggrieved by—

(a) a decision taken either—

(i) to refuse an application for an EU ECM certificate or taken pursuant to Article 7(4) or (7) of the 2011 ECM Regulation by a certification body accredited or recognised in Great Britain for the purposes of the 2011 EU ECM Regulation; or

(ii) to refuse an application for an EU ECM certificate or taken pursuant to Article 7(8) or 8(2) of the 2019 EU ECM Regulation by a certification body accredited or recognised in Great Britain for the purposes of the 2019 EU ECM Regulation;

(b) a decision of a certification body accredited or recognised for the purposes of Schedule 10 either to refuse an application for a UK-issued ECM certificate or taken by that body pursuant to paragraph 7(3), (4) or (7) of Schedule 10; or

(c) a decision of a certification body accredited or recognised for the retained 2019 EU ECM Regulation, either to refuse an application for a cross-border UK-issued ECM certificate or taken by that body pursuant to Article 7(3), (4) or (7) of the retained 2019 EU ECM Regulation,

- may appeal to the Secretary of State.”];
- (e) after paragraph (1A), insert—
- “(1B) For the purposes of an appeal under paragraph (1A), references to the Office of Rail and Road in this regulation are to be construed as references to the relevant certification body (except for paragraph (7), which does not apply to such appeal).”.
- (11) In Schedule 2 (application for a safety certificate), for paragraph 1(b)(i), substitute—
- “(i) a copy of a current certificate issued to the applicant by—
- (aa) the Office of Rail and Road;
- [<sup>F19</sup>(bb) the European Union Agency for Railways or a safety authority in a member State before the end of the second anniversary of exit day, under provisions giving effect to Article 10(2)(a) of the Directive or Article 10 of the Recast Safety Directive;]
- (cc) the safety authority in Northern Ireland; or
- (dd) the safety authority for the tunnel system,
- which relates to an equivalent railway operation; or”.
- (12) The Schedule has effect.

#### Textual Amendments

- F1** Words in reg. 3(2)(a) inserted (31.12.2020 immediately before IP completion day) by [The Railways \(Miscellaneous Amendments, Revocations and Transitional Provisions\) \(EU Exit\) Regulations 2020 \(S.I. 2020/786\)](#), regs. 1(2)(b)(i), **7(2)(a)**
- F2** Words in reg. 3(2)(c) substituted (31.12.2020 immediately before IP completion day) by [The Railways \(Interoperability\) \(Miscellaneous Amendments and Revocations\) \(EU Exit\) Regulations 2020 \(S.I. 2020/318\)](#), regs. 1(2)(b), **6(a)**
- F3** Reg. 3(2)(dd) inserted (31.12.2020 immediately before IP completion day) by [The Railways \(Miscellaneous Amendments, Revocations and Transitional Provisions\) \(EU Exit\) Regulations 2020 \(S.I. 2020/786\)](#), regs. 1(2)(b)(i), **7(2)(b)**
- F4** Words in reg. 3(2)(e) substituted (31.12.2020 immediately before IP completion day) by [The Railways \(Miscellaneous Amendments, Revocations and Transitional Provisions\) \(EU Exit\) Regulations 2020 \(S.I. 2020/786\)](#), regs. 1(2)(b)(i), **7(2)(c)**
- F5** Reg. 3(2)(g) substituted (31.12.2020 immediately before IP completion day) by [The Railways \(Miscellaneous Amendments, Revocations and Transitional Provisions\) \(EU Exit\) Regulations 2020 \(S.I. 2020/786\)](#), regs. 1(2)(b)(i), **7(2)(d)**
- F6** Reg. 3(2)(ja) inserted (31.12.2020 immediately before IP completion day) by [The Railways \(Interoperability\) \(Miscellaneous Amendments and Revocations\) \(EU Exit\) Regulations 2020 \(S.I. 2020/318\)](#), regs. 1(2)(b), **6(b)**
- F7** Words in reg. 3(2)(k) substituted (31.12.2020 immediately before IP completion day) by [The Railways \(Miscellaneous Amendments, Revocations and Transitional Provisions\) \(EU Exit\) Regulations 2020 \(S.I. 2020/786\)](#), regs. 1(2)(b)(i), **7(2)(e)**
- F8** Reg. 3(2)(l) substituted (31.12.2020 immediately before IP completion day) by [The Railways \(Miscellaneous Amendments, Revocations and Transitional Provisions\) \(EU Exit\) Regulations 2020 \(S.I. 2020/786\)](#), regs. 1(2)(b)(i), **7(2)(f)**
- F9** Reg. 3(2A) inserted (31.12.2020 immediately before IP completion day) by [The Railways \(Safety, Access, Management and Interoperability\) \(Miscellaneous Amendments and Transitional Provision\) \(EU Exit\) Regulations 2019 \(S.I. 2019/1310\)](#), regs. 1(2)(c), **7(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F10** Words in reg. 3(4)(b) inserted (31.12.2020 immediately before IP completion day) by [The Railways \(Miscellaneous Amendments, Revocations and Transitional Provisions\) \(EU Exit\) Regulations 2020 \(S.I. 2020/786\)](#), regs. 1(2)(b)(i), **7(3)(a)(i)**

- F11** Words in reg. 3(4)(b) substituted (31.12.2020 immediately before IP completion day) by The Railways (Miscellaneous Amendments, Revocations and Transitional Provisions) (EU Exit) Regulations 2020 (S.I. 2020/786), regs. 1(2)(b)(i), **7(3)(a)(ii)**
- F12** Words in reg. 3(4)(b) inserted (31.12.2020 immediately before IP completion day) by The Railways (Miscellaneous Amendments, Revocations and Transitional Provisions) (EU Exit) Regulations 2020 (S.I. 2020/786), regs. 1(2)(b)(i), **7(3)(b)**
- F13** Reg. 3(6)(aa) inserted (31.12.2020 immediately before IP completion day) by The Railways (Miscellaneous Amendments, Revocations and Transitional Provisions) (EU Exit) Regulations 2020 (S.I. 2020/786), regs. 1(2)(b)(i), **7(4)**
- F14** Reg. 3(10)(a) substituted (31.12.2020 immediately before IP completion day) by The Railways (Miscellaneous Amendments, Revocations and Transitional Provisions) (EU Exit) Regulations 2020 (S.I. 2020/786), regs. 1(2)(b)(i), **7(5)(a)**
- F15** Reg. 3(10)(b) substituted (31.12.2020 immediately before IP completion day) by The Railways (Miscellaneous Amendments, Revocations and Transitional Provisions) (EU Exit) Regulations 2020 (S.I. 2020/786), regs. 1(2)(b)(i), **7(5)(b)**
- F16** Word in reg. 3(10)(c) omitted (31.12.2020 immediately before IP completion day) by virtue of The Railways (Miscellaneous Amendments, Revocations and Transitional Provisions) (EU Exit) Regulations 2020 (S.I. 2020/786), regs. 1(2)(b)(i), **7(5)(c)(i)**
- F17** Words in reg. 3(10)(c) inserted (31.12.2020 immediately before IP completion day) by The Railways (Miscellaneous Amendments, Revocations and Transitional Provisions) (EU Exit) Regulations 2020 (S.I. 2020/786), regs. 1(2)(b)(i), **7(5)(c)(ii)**
- F18** Words in reg. 3(10)(d) substituted (31.12.2020 immediately before IP completion day) by The Railways (Miscellaneous Amendments, Revocations and Transitional Provisions) (EU Exit) Regulations 2020 (S.I. 2020/786), regs. 1(2)(b)(i), **7(5)(d)**
- F19** Words in reg. 3(11) substituted (31.12.2020 immediately before IP completion day) by The Railways (Miscellaneous Amendments, Revocations and Transitional Provisions) (EU Exit) Regulations 2020 (S.I. 2020/786), regs. 1(2)(b)(i), **7(6)**

#### Commencement Information

- I3** Reg. 3 in force at 31.12.2020 in force on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

#### Marginal Citations

- M1** S.I. 2006/599; relevant amending instruments are S.I. 2007/950, 2011/1043, 2011/1860, 2011/3066, 2013/950, 2015/1682 and 2015/1917.
- M2** The Office of Rail and Road was established by section 15 of the Railways and Transport Safety Act 2003 (c. 20) as the Office of Rail Regulation and subsequently renamed by the Office of Rail Regulation (Change of Name) Regulations (S.I. 2015/1682).
- M3** S.I. 1999/283 (N.I. 1).
- M4** 2016 c. 5 (N.I.). The Department for Infrastructure was originally established as the Department for Regional Development by article 3(1) of the Departments (Northern Ireland) Order 1999) S.I. 1999/283) and subsequently renamed by subsection 1(6) of the Departments Act (Northern Ireland) 2016 (c. 5).
- M5** 1987 c. 53.

#### Amendments to the Railways (Access to Training Services) Regulations 2006 **E+W+S**

- 4.—(1) The Railways (Access to Training Services) Regulations 2006<sup>M6</sup> are amended as follows.
- (2) In regulation 2 (interpretation)—
- (a) omit the definition of “the Council Directive”;

*Status: This version of this Instrument contains provisions that are prospective.*  
*Changes to legislation: There are currently no known outstanding effects for the Rail Safety (Amendment etc.) (EU Exit) Regulations 2019. (See end of Document for details)*

(b) for “ “infrastructure manager”, “railway system” and “railway undertaking” have the meanings given by article 3 of the Council Directive;” substitute—

““infrastructure manager” means any body or undertaking that is responsible in particular for establishing and maintaining railway infrastructure, or a part thereof which may also include the management of infrastructure control and safety systems. The functions of the infrastructure manager on a network or part of a network may be allocated to different bodies or undertakings;

“railway system” means the totality of the subsystems for structural and operational areas, as defined in paragraph 2.1 to 2.7 of Annex II to Directive [2008/57/EC](#)<sup>M7</sup>, as well as the management and operation of the system as a whole;

“railway undertaking” means a public or private undertaking, licensed according to applicable legislation, the activity of which is to provide transport of goods and/or passengers by rail on the basis that the undertaking must ensure traction; this also includes undertakings which provide traction only;”;

(c) omit paragraph 2.

#### Commencement Information

**I4** Reg. 4 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

#### Marginal Citations

**M6** [S.I. 2006/598](#), to which there are amendments not relevant to these Regulations.

**M7** OJ No. L 191 18.07.2008, p. 1-45.

## PART 3 **U.K.**

### Revocation of EU retained legislation and amendment to Annex XIII of the Agreement on the European Economic Area

#### Revocation of Commission Regulation (EC) No 653/2007 **U.K.**

**5.** Commission Regulation (EC) No 653/2007 on the use of a common European format for safety certificates and application documents in accordance with Article 10 of Directive [2004/49/EC](#) of the European Parliament and of the Council and on the validity of safety certificates delivered under Directive [2001/14/EC](#) is revoked, save in respect of the tunnel system.

#### Commencement Information

**I5** Reg. 5 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

#### Revocation of Commission Decision 2009/460/EC **U.K.**

**6.** Commission Decision [2009/460/EC](#) on the adoption of a common safety method for assessment of achievement of safety targets as referred to in Article 6 of Directive [2004/49/EC](#) of the European Parliament and of the Council (notified under document number C(2009) 4246) is revoked.



*Status: This version of this Instrument contains provisions that are prospective.*  
*Changes to legislation: There are currently no known outstanding effects for the The Rail Safety (Amendment etc.) (EU Exit) Regulations 2019. (See end of Document for details)*

#### Commencement Information

- I6** Reg. 6 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

#### Revocation of Commission Regulation (EU) No 445/2011 **U.K.**

**7.** Commission Regulation (EU) No 445/2011 on a system of certification of entities in charge of maintenance for freight wagons and amending Regulation (EC) No 653/2007 is revoked.

#### Commencement Information

- I7** Reg. 7 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

#### Revocation of Commission Decision 2012/226/EU **U.K.**

**8.** Commission Decision 2012/226/EU on the second set of common safety targets (notified under document C(2012) 2084) as regards the rail system is revoked.

#### Commencement Information

- I8** Reg. 8 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

#### Revocation of Commission Implementing Decision 2013/753/EU **U.K.**

**9.** Commission Implementing Decision 2013/753/EU amending Decision 2012/226/EU on the second set of common safety targets for the rail system (notified under document C(2013) 8780) is revoked.

#### Commencement Information

- I9** Reg. 9 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

PROSPECTIVE

#### Revocation of Commission Implementing Regulation (EU) 2018/763 **U.K.**

- 10.** <sup>F20F21</sup> ...

#### Textual Amendments

- F20** Reg. 10 omitted (N.I.) (30.12.2020) by virtue of [The Railways \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/277\)](#), regs. 1(2), **2(2)**

*Status: This version of this Instrument contains provisions that are prospective.*  
*Changes to legislation: There are currently no known outstanding effects for the Rail Safety (Amendment etc.) (EU Exit) Regulations 2019. (See end of Document for details)*

**F21** Reg. 10 omitted (E.W.S.) (31.12.2020 immediately before IP completion day) by virtue of [The Railways \(Miscellaneous Amendments, Revocations and Transitional Provisions\) \(EU Exit\) Regulations 2020 \(S.I. 2020/786\)](#), regs. 1(2)(b)(i), 7(7)

## Amendment to Annex XIII to the Agreement on the European Economic Area **U.K.**

**11.** Points 42ea, 42eb and 42ed of Annex XIII to the Agreement on the European Economic Area signed at Oporto on 2nd May 1992, so far as that Annex forms part of domestic law by virtue of section 3(2)(b) of the European Union (Withdrawal) Act 2018, are omitted.

### Commencement Information

**110** Reg. 11 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

## PART 4 **E+W+S**

### Amendments to retained direct EU legislation in respect of Great Britain

#### CHAPTER 1 **E+W+S**

##### Safety certificates and authorisations

### Amendments to Commission Regulation (EU) No 1158/2010 on a common safety method for assessing conformity with the requirements for obtaining railway safety certificates **E+W+S**

**12.—(1)** Commission Regulation (EU) No 1158/2010 on a common safety method for assessing conformity with the requirements for obtaining railway safety certificates is amended as follows.

(2) Omit Article 1 (subject matter).

(3) In Article 2 (definitions)—

(a) for “definition” substitute “ definitions ”;

(b) at the end of the definition of “supervision”, insert—

“;

“Intergovernmental Commission” has the meaning provided in section 49(1) of the Channel Tunnel Act 1987;

“national safety authority” means one or both of—

(a) a safety authority; and

(b) the safety authority for the tunnel system as defined in the Railways and Other Guided Transport Systems (Safety) Regulations 2006;

“Part A safety certificate” and “Part B safety certificate” have the meanings provided by the Railways and Other Guided Transport Systems (Safety) Regulations 2006 for “Part A of a safety certificate” and “Part B of a safety certificate” respectively.”

(4) In Article 3 (procedures for assessing applications)—

(a) for paragraph 1, substitute—

“1. When examining applications for both Part A safety certificates and Part B safety certificates, national safety authorities shall apply the procedure set out in Annex I to this Regulation for assessing their conformity with requirements for safety certificates issued in accordance with regulations 7, 8 and 9 of the Railways and Other Guided Transport Systems (Safety) Regulations 2006. National safety authorities shall use the assessment criteria set out in Annex II to this Regulation for Part A safety certificates and those contained in Annex III to this Regulation for Part B safety certificates. These criteria shall also be used in case of renewal of safety certificates in accordance with regulation 9 of the Railways and Other Guided Transport Systems (Safety) Regulations 2006 or where the national safety authority is the Intergovernmental Commission.”;

- (b) in paragraph 3—
  - (i) for “Union legislation”, substitute “legislation in Great Britain”;
  - (ii) after the final sentence, insert “Products or services provided by contractors or suppliers to railway undertakings shall be presumed to conform to safety requirements if the contractors, suppliers or products are certified in accordance with relevant certification schemes established under European Union legislation for the provision of such products and services, unless there are reasonable grounds for believing that they do not so conform.”.
- (5) In Article 4 (supervision), after “Part A”, insert “safety certificates”.
- (6) Omit the words following Article 5 (entry into force), up to but not including “Annex I”.
- (7) In Annex I (procedure for assessing conformity with requirements for obtaining safety certificates to be issued in accordance with Article 10(2)(a) and (b) of Directive 2004/49/EC)—
  - (a) in the heading, for “Article 10(2)(a) and (b) of Directive 2004/49/EC”, substitute “regulations 7, 8 and 9 of the Railways and Other Guided Transport Systems (Safety) Regulations 2006 or by the Intergovernmental Commission”;
  - (b) in paragraph 2, for “complies with Commission Regulation (EC) No 653/2007”, substitute “is in the format specified in Part 4 of Schedule 8 to the Railways and Other Guided Transport Systems (Safety) Regulations 2006”;
  - (c) in paragraph 6—
    - (i) after “Part A” in the first place it occurs, insert “safety certificates”;
    - (ii) after “Part A”, in the second place it occurs, insert “safety”;
    - (iii) omit “as provided for in Regulation (EC) No 653/2007”;
  - (d) in paragraph 7, for “Article 10(2)(b) of Directive 2004/49/EC”, substitute “regulation 7(4)(b)(ii) of the Railways and Other Guided Transport Systems (Safety) Regulations 2006 and to applications to the Intergovernmental Commission for Part B safety certificates”;
  - (e) in paragraph 8—
    - (i) omit “as referred to in Article 10(2)(b) of Directive 2004/49/EC”;
    - (ii) after “Part A”, insert “safety”;
  - (f) for paragraph 10, substitute—

“10. National safety authorities shall cooperate to address issues of non-compliance with the Part B safety certificate assessment criteria or to deal with queries on the application for a Part B safety certificate. A national safety authority assessing an application for a Part B safety certificate shall liaise with the national safety authority that

*Status: This version of this Instrument contains provisions that are prospective.*  
*Changes to legislation: There are currently no known outstanding effects for the Rail Safety (Amendment etc.) (EU Exit) Regulations 2019. (See end of Document for details)*

issued the Part A safety certificate to discuss and agree what action, if any, each one will take to ensure compliance with the Part B safety certificate assessment criteria.”.

(8) In Annex II (criteria for assessing conformity with the requirements for obtaining safety certificates to be issued in accordance with Article 10(2)(b) of Directive 2004/49/EC)—

- (a) for the heading, substitute “ Criteria for assessing conformity with the requirements for obtaining Part A safety certificates ”;
- (b) in point A.4, for “in accordance with Article 4(3) of Directive 2004/49/EC”, substitute “ for the safe operation of the railway ”;
- (c) in point E.3, for “Article 9 and Annex III of Directive 2004/49/EC”, substitute “ regulations 5 and 6 of the Railways and Other Guided Transport Systems (Safety) Regulations 2006 or paragraph 22 of the Schedule to the Channel Tunnel (Safety) (Amendment) Order 2013 <sup>M8</sup> ”;
- (d) in point K.3, for “member state level”, substitute “ a national level ”;
- (e) in point M.2, for “Commission Regulation (EC) No 352/2009”, substitute “ Commission Implementing Regulation (EU) No 402/2013 as it has effect in Great Britain ”;
- (f) in point Q.2, for “national investigating body” substitute “ Rail Accident Investigation Branch <sup>M9</sup> ”.

(9) In Annex III (criteria for assessing conformity with the requirements for obtaining safety certificates to be issued in accordance with Article 10(2)(b) of Directive 2004/49/EC)—

- (a) for the heading, substitute “ Criteria for assessing conformity with the requirements for obtaining Part B safety certificates ”;
- (b) in the paragraph headed “GENERAL”—
  - (i) after “Part B”, insert “ safety ”;
  - (ii) for “Article 10(2)(a) of Directive 2004/49/EC”, substitute “ Regulation 7(4)(b)(ii) of the Railways and Other Guided Transport Systems (Safety) Regulations 2006 or paragraphs 39 to 55 of the Schedule to the Channel Tunnel (Safety) (Amendment) Order 2013 ”.

(10) In Annex IV (principles for supervision after the award of a Part A or Part B certificate)—

- (a) in the heading, for “Part A or Part B”, substitute “ Part A safety certificate or Part B safety certificate ”;
- (b) in paragraph 1, omit “as referred to in Article 4(1) and 16(2)(e) of Directive 2004/49/EC”;
- (c) in paragraph 7, for “National safety authorities shall be accountable for their decisions in accordance with Article 17(3) of Directive 2004/49/EC”, substitute “ The decisions of national safety authorities shall be subject to judicial review. ”.

#### Commencement Information

- I11** Reg. 12 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1
- I12** Reg. 12 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

#### Marginal Citations

- M8** S.I. 2013/407.
- M9** The Rail Accident Investigation Branch was established by section 3 of the Railways and Transport Safety Act 2003 (c. 20).

### **Amendments to Commission Regulation (EU) No 1169/2010 on a common safety method for assessing conformity with the requirements for obtaining a railway safety authorisation E +W+S**

**13.**—(1) Commission Regulation (EU) No 1169/2010 on a common safety method for assessing conformity with the requirements for obtaining a railway safety authorisation is amended as follows.

(2) Omit Article 1 (subject matter).

(3) In Article 2 (definition)—

(a) in the heading and in the first paragraph, for “definition” substitute “ definitions ”;

(b) after the definition of “supervision”, insert—

“national safety authority” means one or both of—

(a) a safety authority; and

(b) the safety authority for the tunnel system, as defined in the Railways and Other Guided Transport Systems (Safety) Regulations 2006.”.

(4) In Article 3 (procedures for assessing applications)—

(a) in paragraph 1, omit “for assessing their conformity with requirements in Directive [2004/49/EC](#)”;

(b) in paragraph 3—

(i) for “Union” substitute “ domestic ”;

(ii) after the final sentence, insert “ Products or services provided by contractors or suppliers to railway undertakings shall be presumed to conform to safety requirements if the contractors, suppliers or products are certified in accordance with relevant certification schemes established under European Union legislation for the provision of such products and services, unless there are reasonable grounds for believing that they do not so conform. ”.

(5) Omit the words following Article 5 (entry into force), up to but not including “Annex I”.

(6) In Annex I (procedure for assessing conformity with requirements for obtaining safety authorisations), in the heading, for “Article 11(1)(a) and (b) of Directive [2004/49/EC](#)”, substitute “ regulations 10, 11 and 12 of the Railways and Other Guided Transport Systems (Safety) Regulations 2006 or paragraphs 27 to 38 of the Schedule to the Channel Tunnel (Safety) (Amendment) Order 2013 ”.

(7) In Annex II (criteria for assessing conformity with the requirements for obtaining safety authorisations)—

(a) in the heading, for “Article 11(1)(a) and (b) of Directive [2004/49/EC](#)”, substitute “ regulations 10, 11 and 12 of the Railways and Other Guided Transport Systems (Safety) Regulations 2006 or paragraphs 27 to 38 of the Schedule to the Channel Tunnel (Safety) (Amendment) Order 2013 ”;

(b) in point A.4, for “in accordance with Article 4(3) of Directive [2004/49/EC](#)”, substitute “ for the safe operation of the railway ”;

(c) in point E.3, for “Article 9 and Annex III of Directive [2004/49/EC](#)”, substitute “ regulations 5 and 6 of the Railways and Other Guided Transport Systems (Safety) Regulations 2006 or paragraph 22 of the Schedule to the Channel Tunnel (Safety) (Amendment) Order 2013 ”;

(d) in point K.3 for “member state level”, substitute “ a national level ”;

(e) in point M.2, for “Commission Regulation ([EC](#)) No 352/2009”, substitute “ Commission Implementing Regulation (EU) No 402/2013 as it has effect in Great Britain ”;

*Status: This version of this Instrument contains provisions that are prospective.*  
**Changes to legislation:** There are currently no known outstanding effects for the The Rail Safety (Amendment etc.) (EU Exit) Regulations 2019. (See end of Document for details)

- (f) in point Q.1, for “national bodies”, substitute “ the Rail Accident Investigation Branch ”.
- (8) In Annex III (principles for supervision after the award of an authorisation)—
  - (a) in paragraph 1, omit “as referred to in Article 4(1) and 16(2)(e) of Directive 2004/49/EC”;
  - (b) in paragraph 7, for “National safety authorities shall be accountable for their decisions in accordance with Article 17(3) of Directive 2004/49/EC”, substitute “ The decisions of national safety authorities shall be subject to judicial review. ”.

**Commencement Information**

**I13** Reg. 13 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

CHAPTER 2 **E+W+S**

Supervision and monitoring

PROSPECTIVE

**Amendments to Commission Regulation (EU) No 1077/2012 on a common safety method for supervision by national safety authorities after issuing a safety certificate or safety authorisation **E+W+S****

<sup>F22</sup>**14.** . . . . .

**Textual Amendments**

**F22** Reg. 14 omitted (31.12.2020 immediately before IP completion day) by virtue of The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), 7(3); 2020 c. 1, Sch. 5 para. 1(1)

**Amendments to Commission Regulation (EU) No 1078/2012 on a common safety method for monitoring to be applied by railway undertakings, infrastructure managers after receiving a safety certificate or safety authorisation and by entities in charge of maintenance **E+W+S****

**15.**—(1) Commission Regulation (EU) No 1078/2012 on a common safety method for monitoring to be applied by railway undertakings, infrastructure managers after receiving a safety certificate or safety authorisation and by entities in charge of maintenance is amended as follows.

(2) In Article 1 (subject matter and scope), in paragraph 2(a), for “Article 10(2)(a) and 11(1)(a) and the provisions adopted to obtain the certification/authorisation specified in Article 10(2)(b) and 11(1)(b) of Directive 2004/49/EC”, substitute “ regulations 7(4) and 10(3) of the Railways and Other Guided Transport Systems (Safety) Regulations 2006 or Chapter 3 of the Schedule to the Channel Tunnel (Safety) (Amendment) Order 2013 ”.

(3) For Article 2 (definitions) substitute—

“Article 2

Definitions

For the purposes of this Regulation the following definitions apply.

‘accident’ means an unwanted or unintended sudden event or a specific chain of such events which have harmful consequences; accidents are divided into the following categories: collisions, derailments, level-crossing accidents, accidents to persons caused by rolling stock in motion, fires and others;

‘entity in charge of maintenance’ means an entity in charge of maintenance of a vehicle, and registered as such in the National Vehicle Register;

‘incident’ means any occurrence, other than an accident, associated with the operation of trains and affecting the safety of operation;

‘infrastructure manager’ means any body or undertaking that is responsible in particular for establishing and maintaining railway infrastructure, or a part thereof, as defined in Article 3 of Directive 91/440/EEC<sup>M10</sup>, which may also include the management of infrastructure control and safety systems. The functions of the infrastructure manager on a network or part of a network may be allocated to different bodies or undertakings.

‘interfaces’ means all points of interaction during a system or subsystem life-cycle, including operation and maintenance where different actors of the rail sector will work together in order to manage the risks;

‘management system’ means either a safety management system as defined in the Railways and Other Guided Transport Systems (Safety) Regulations 2006, or the system of maintenance of entities in charge of maintenance complying with requirements laid down in paragraph 3 of Regulation 18A of the Railways and Other Guided Transport Systems (Safety) Regulations 2006 or paragraph 55B of the Schedule to the Channel Tunnel (Safety) (Amendment) Order 2013;

‘monitoring’ means the arrangements put in place by railway undertakings, infrastructure managers or entities in charge of maintenance to check their management system is correctly applied and effective;

‘national safety authority’ means one or both of—

- (a) a safety authority; and
- (b) the safety authority for the tunnel system

as defined in the Railways and Other Guided Transport Systems (Safety) Regulations 2006;

‘railway system’ means the totality of the subsystems in Great Britain for structural and operational areas, as defined in paragraph 2(1) to 2(7) of Annex II to Directive 2008/57/EC, as well as the management and operation of the system as a whole;

‘railway undertaking’ means a public or private undertaking, licensed according to applicable legislation, the activity of which is to provide transport of goods and/or passengers by rail on the basis that the undertaking must ensure traction; this also includes undertakings which provide traction only.”.

(4) In Article 5 (reporting)—

- (a) in paragraph 1, omit “in accordance with Article 9(4) of Directive 2004/49/EC”;
- (b) omit paragraph 2;
- (c) in paragraph 3—
  - (i) for “point I.7.4(k) of Annex III to Regulation (EU) No 445/2011”, substitute “paragraph 27(4)(k) of Schedule 10 to the Railways and Other Guided Systems (Safety) Regulations 2006”;
  - (ii) omit the final sentence;
- (d) omit paragraphs 4 to 7.

(5) Omit the words following Article 6 (entry into force), up to but not including “Annex”.

*Status: This version of this Instrument contains provisions that are prospective.*  
*Changes to legislation: There are currently no known outstanding effects for the Rail Safety (Amendment etc.) (EU Exit) Regulations 2019. (See end of Document for details)*

#### Commencement Information

**I14** Reg. 15 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see **reg. 1**

#### Marginal Citations

**M10** OJ No. L 237, 24.08.1991, p. 25-28.

## CHAPTER 3 **E+W+S**

### Risk evaluation and assessment

#### **Amendments to Commission Implementing Regulation (EU) No 402/2013 on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009 **E+W+S****

**16.**—(1) Commission Implementing Regulation (EU) No 402/2013 on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009 is amended as follows.

(2) Omit Article 1 (subject matter).

(3) In Article 2 (scope)—

(a) in paragraph 1, for “a Member State”, substitute “ Great Britain ”;

(b) in paragraph 3—

(i) in the first place that it occurs, for “Directive 2008/58/EC applies” substitute “ the Railways (Interoperability) Regulations 2011 <sup>M11</sup> apply ”;

(ii) omit paragraph (a);

(iii) in paragraph (b), omit “, by virtue of Article 15(1) of Directive 2008/57/EC”;

<sup>F23</sup>(c) in paragraph 4—

(i) for “TSIs” substitute “ NTSNs ”;

(ii) for the second sentence substitute “ If such contradictions occur, the proposer shall inform the Secretary of State who may then decide to publish a variation of the NTSN in accordance with paragraphs (3) and (4) of regulation 3B of the Railways (Interoperability) Regulations 2011 or issue an exemption in accordance with regulation 14 of those Regulations. ”]

(d) omit paragraphs 5 and 6.

(4) For Article 3 (definitions) substitute—

#### *“Article 3*

#### *Definitions*

For the purposes of this Regulation the following definitions shall apply.

‘accident’ means an unwanted or unintended sudden event or a specific chain of such events which have harmful consequences; accidents are divided into the following categories: collisions, derailments, level-crossing accidents, accidents to persons caused by rolling stock in motion, fires and others;

‘accreditation’ means an attestation by a national accreditation body that a conformity assessment body meets the requirements set by designated standards and, where applicable,



any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity;

‘actors’ means all parties which are, directly or through contractual arrangements, involved in the application of this Regulation;

[<sup>F24</sup>‘approved body’ has the meaning provided in regulation 2 of the Railways (Interoperability) Regulations 2011;]

‘assessment body’ means the independent and competent external or internal individual, organisation or entity which undertakes investigation to provide a judgement, based on evidence, of the suitability of a system to fulfil its safety requirements;

‘barrier’ means a technical, operational or organisational risk control measure outside the system under assessment that either reduces the frequency of occurrence of a hazard or mitigates the severity of the potential consequence of that hazard;

‘catastrophic accident’ means an accident typically affecting a large number of people and resulting in multiple fatalities;

‘certification body’ has the meaning provided in regulation 2 of the Railways and Other Guided Transport (Safety) Regulations 2006;

‘code of practice’ means a written set of rules that, when correctly applied, can be used to control one or more specific hazards;

‘conformity assessment body’ means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

‘critical accident’ means an accident typically affecting a very small number of people and resulting in at least one fatality;

[<sup>F25</sup>‘designated body’ has the meaning provided in regulation 2 of the Railways (Interoperability) Regulations 2011;]

‘designated standard’ has the meaning provided in Article 3A;

‘entity in charge of maintenance’ means an entity in charge of maintenance of a vehicle, and registered as such in the National Vehicle Register;

[<sup>F26</sup>‘EU notified body’ has the meaning provided in regulation 2 of the Railways (Interoperability) Regulations 2011;]

‘hazard’ means a condition that could lead to an accident;

‘hazard identification’ means the process of finding, listing and characterising hazards;

‘hazard record’ means the document in which identified hazards, their related measures, their origin and the reference to the organisation which has to manage them are recorded and referenced;

‘highly improbable’ means an occurrence of failure at a frequency less than or equal to  $10^{-9}$  per operating hour;

‘improbable’ means an occurrence of failure at a frequency less than or equal to  $10^{-7}$  per operating hour.

‘incident’ means any occurrence, other than an accident, associated with the operation of trains and affecting the safety of operation;

‘infrastructure manager’ means any body or undertaking that is responsible in particular for establishing and maintaining railway infrastructure, or a part thereof, as defined in Article 3 of Directive [91/440/EEC](#), which may also include the management of infrastructure control and safety systems. The functions of the infrastructure manager on a network or part of a network may be allocated to different bodies or undertakings;

‘interfaces’ means all points of interaction during a system or subsystem life cycle, including operation and maintenance where different actors of the rail sector will work together in order to manage the risks;

‘investigation’ means a process conducted for the purpose of accident and incident prevention which includes the gathering and analysis of information, the drawing of conclusions, including the determination of causes and, when appropriate, the making of safety recommendations;

‘national accreditation body’ means the sole body in the United Kingdom that performs accreditation in accordance with Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9th July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93;

[<sup>F27</sup>‘national rule’ means NTRs as defined in regulation 2 of the Railways (Interoperability) Regulations 2011 and national safety rules as defined in regulation 2 of the Railways and Other Guided Transport Systems (Safety) Regulations 2006;

‘NTSN’ has the meaning provided in regulation 2 of the Railways (Interoperability) Regulations 2011;]

‘national safety authority’ means one or both of—

- (a) a safety authority; and
- (b) the safety authority for the tunnel system; as defined in the Railways and Other Guided Transport Systems (Safety) Regulations 2006;

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‘proposer’ means one of the following—

- (a) a railway undertaking or an infrastructure manager;
- (b) an entity in charge of maintenance;
- (c) [<sup>F30</sup>a contracting entity or manufacturer which invites—
  - (i) an approved body or a designated body to apply the UK verification assessment procedure in accordance with regulation 17 of and Schedule 4 to the Railways (Interoperability) Regulations 2011; or
  - (ii) an EU notified body to apply the EC verification procedure in accordance with Directive 2008/57/EC or a designated body according to Article 17(3) of that Directive;]

‘railway system’ means the totality of the subsystems in Great Britain for structural and operational areas, as defined in paragraph 2(1) to 2(7) of Annex II to Directive 2008/57/EC, as well as the management and operation of the system as a whole;

‘railway undertaking’ means a public or private undertaking, licensed according to applicable legislation, the activity of which is to provide transport of goods and/or passengers by rail on the basis that the undertaking must ensure traction; this also includes undertakings which provide traction only;

‘recognition’ means an attestation by a national body other than the national accreditation body that the assessment body meets the requirements set out in Annex II to this Regulation to carry out the independent assessment activity specified in Article 6(1) and (2);

‘reference system’ means a system proven in use to have an acceptable safety level and against which the acceptability of the risks from a system under assessment can be evaluated by comparison;

‘risk’ means the frequency of occurrence of accidents and incidents resulting in harm caused by a hazard and the degree of severity of that harm;

‘risk acceptance criteria’ means the terms of reference by which the acceptability of a specific risk is assessed; these criteria are used to determine that the level of a risk is sufficiently low that it is not necessary to take any immediate action to reduce it further;

‘risk acceptance principle’ means the rules used in order to arrive at the conclusion whether or not the risk related to one or more specific hazards is acceptable;

‘risk analysis’ means systematic use of all available information to identify hazards and to estimate the risk;

‘risk assessment’ means the overall process comprising a risk analysis and a risk evaluation;

‘risk estimation’ means the process used to produce a measure of the level of risks being analysed, consisting of the following steps: estimation of frequency, consequence analysis and their integration;

‘risk evaluation’ means a procedure based on the risk analysis to determine whether an acceptable level of risk has been achieved;

‘risk management’ means the systematic application of management policies, procedures and practices to the tasks of analysing, evaluating and controlling risks;

‘safety’ means freedom from unacceptable risk of harm;

‘safety acceptance’ means the status given to the change by the proposer based on the safety assessment report provided by the assessment body;

‘safety assessment report’ means the document containing the conclusions of the assessment performed by an assessment body on the system under assessment;

‘safety management system’ means the organisation and arrangements established by an infrastructure manager or a railway undertaking to ensure the safe management of its operations;

‘safety measures’ means a set of actions either reducing the frequency of occurrence of a hazard or mitigating its consequences in order to achieve and/or maintain an acceptable level of risk;

‘safety requirements’ means the safety characteristics (qualitative or quantitative, or when needed both qualitative and quantitative) necessary for the design, operation (including operational rules) and maintenance of a system in order to meet legal or company safety targets;

‘system’ means any part of the railway system which is subjected to a change whereby the change may be of a technical, operational or organisational nature;

‘systematic failure’ means a failure that occurs repeatedly under some particular combination of inputs or under some particular environmental or application conditions;

‘systematic fault’ means an inherent fault in the specification, design, manufacturing, installation, operation or maintenance of the system under assessment;

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...

‘technical system’ means a product or an assembly of products including the design, implementation and support documentation; the development of a technical system starts with its requirements specification and ends with its acceptance; although the design of relevant interfaces with human behaviour is considered, human operators and their actions are not included in a technical system; the maintenance process is described in the maintenance manuals but is not itself part of the technical system;

‘vehicle’ means a railway vehicle suitable for circulation on its own wheels on railway lines, with or without traction. A vehicle is composed of one or more structural and functional subsystems or parts of such subsystems.”

(5) After Article 3 (definitions), insert—

*“Article 3A*

*Designated standards*

1. Subject to paragraphs 6 and 7, in this Regulation a “designated standard” means a technical specification which is—

- (a) adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory; and
- (b) designated by the Secretary of State by publishing the reference to the standard and maintaining that publication in a manner the Secretary of State considers appropriate.

2. For the purposes of paragraph 1, a “technical specification” means a document that prescribes technical requirements to be fulfilled by a product, process, service or system and which lays down one or more of the following—

- (a) the characteristics required of a product, including—
  - (i) levels of quality, performance, interoperability, environmental protection, health, safety or dimensions; and
  - (ii) the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures; and
- (b) production methods and processes relating to the product, where these have an effect on the characteristics of the product.

3. For the purposes of this article, a “recognised standardisation body” means any one of the following organisations—

- (a) the European Committee for Standardisation (CEN);
- (b) the European Committee for Electrotechnical Standardisation (Cenelec);
- (c) the European Telecommunications Standards Institute (ETSI);
- (d) the British Standards Institution (BSI).

4. When considering whether the manner of publication of a reference is appropriate in accordance with paragraph 1(b), the Secretary of State must have regard to whether the publication will draw the standard to the attention of any person who may have an interest in the standard.

5. Before publishing the reference to a technical specification adopted by the British Standards Institution, the Secretary of State must have regard to whether the technical specification is consistent with technical specifications adopted by the other recognised standardisation bodies.

6. The Secretary of State may remove from publication the reference to a standard which has been published in accordance with paragraph 1(b).

7. Where the Secretary of State removes the reference to a standard from publication, that standard is no longer a designated standard.”
- (6) In Article 4 (significant changes), for the first sentence of paragraph 1, substitute “ The proposer shall consider the potential impact of a change on the safety of the railway system. ”.
- (7) In Article 6 (independent assessment)—
- (a) in paragraph 1, omit “Union or”;
  - (b) in paragraph 3(a), for “Directive 2004/49/EC”, substitute “ regulation 18A of the Railways and Other Guided Transport Systems (Safety) Regulations 2006 or paragraph 55A of the Schedule to the Channel Tunnel (Safety) (Amendment) Order 2013 ”;
  - [<sup>F32</sup>(c) in paragraph 3(b), for “a notified body as defined by Article 2(j) of Directive 2008/57/EC or a body designated in accordance with Article 17 of that Directive” substitute “ an EU notified body or an approved body ”;]
  - (d) in paragraph 4, for “Without prejudice to Union legislation, the” substitute “ The ”;
  - (e) in paragraph 4(a) and (b), omit the words following “service”;
  - (f) in paragraph 4(c), omit the words following “operation”;
  - (g) in paragraph 4(d), omit the words following “framework”;
  - (h) in paragraph 4(e), omit the words following “maintenance”;
  - (i) in paragraph 4(f), omit the words following “framework”;
  - [<sup>F33</sup>(j) in the final paragraph—
    - (i) omit “as referred to in Article 15(1) or Article 20 of Directive 2008/57/EC”;
    - (ii) for “a notified body in accordance with Article 18(2) of that Directive”, substitute “ an approved body ”.]
- (8) In Article 7 (accreditation/recognition of the assessment body)—
- (a) omit “referred to in Article 13(1)” in both places where it occurs;
  - (b) for “under the requirement of Article 9(2)” substitute “ where it fulfils the requirements set out in Annex II and the accreditation functions of the national safety authority are demonstrably independent of its other functions ”.
- (9) In Article 8 (acceptance of accreditation/recognition)—
- [<sup>F34</sup>(a) in paragraph 1—
    - (i) for “Commission Regulation (EU) No 1158/2010 or Commission Regulation (EU) No 1169” substitute “ regulation 7 or 10 of the Railways and Other Guided Transport Systems (Safety) Regulations 2006, or Chapter 3 of the Schedule to the Channel Tunnel (Safety) (Amendment) Order 2013 ”;
    - (ii) for “by a Member State in accordance with Article 7” substitute “ in Northern Ireland ”;]
  - (b) in paragraph 2—
    - (i) for “Regulation (EU) No 445/2011”, substitute “ Schedule 10 to the Railways and Other Guided Transport Systems (Safety) Regulations 2006 ”;
    - [<sup>F35</sup>(ii) for “by a Member State”, substitute “ in Northern Ireland ”;]
- (10) In Article 9 (types of recognition of the assessment body)—
- (a) in paragraph 1(a), after “Member State” insert “ of the European Union ”;
  - (b) in paragraph 1(c), omit “in conformity with Article 10 of Regulation (EU) No 445/2011”;
  - (c) in paragraph 1(d), for “by the Member State” substitute “ in the United Kingdom ”;

- (d) omit paragraph 2.
- (11) In Article 10 (validity of recognition)—
- (a) in paragraph 1, for “Article 9(2)”, substitute “ where the national safety authority is recognised as an assessment body ”;
  - (b) in paragraph 2(a), for “harmonised format of safety certificates provided in Annex I to Commission Regulation (EC) No 653/2007”, substitute “ safety certificates in the form provided in Part 2 of Schedule 8 to the Railways and Other Guided Transport Systems (Safety) Regulations 2006 ”;
  - (c) in paragraph 3(a), for “harmonised format of certificates for entities in charge of maintenance provided in Annex V, or Annex VI where relevant, of Regulation (EU) No 445/2011”, substitute “ certificates in the forms provided in Part 1 or Part 4 of Schedule 9 to the Railways and Other Guided Transport Systems (Safety) Regulations 2006, as appropriate ”.
- (12) Omit Article 12 (relaxed criteria where a significant change is not to be mutually recognised), Article 13 (provision of information to the Agency) and Article 14 (support from the Agency to accreditation or recognition of the assessment body).
- [<sup>F36</sup>(13) In Article 15 (safety assessment reports)—
- (a) in paragraph 3, for “Without prejudice to Article 16 of Directive 2008/57/EC, the” substitute “ The ”;
  - (b) in paragraph 4—
    - (i) for “In the case referred to in point (a) of Article 2(3)” substitute “ Where the application of this Regulation or part of this Regulation is required by a relevant NTSN ”;
    - (ii) for “notified body” substitute “ approved body ”;
- (14) In Article 17 (risk control management and audits)—
- (a) in paragraph 1, for “Article 9 of Directive 2004/49/EC”, substitute “ regulations 5 and 6 of the Railways and Other Guided Transport Systems (Safety) Regulations 2006 or paragraphs 22 to 26 of the Schedule to the Channel Tunnel (Safety) (Amendment) Order 2013 ”;
  - (b) in paragraph 2, for “Article 14a(3) of Directive 2004/49/EC”, substitute “ regulation 18A of the Railways and Other Guided Transport Systems (Safety) Regulations 2006 or paragraphs 55A and 55B of the Schedule to the Channel Tunnel (Safety) (Amendment) Order 2013 ”;
  - (c) in paragraph 3—
    - (i) for “As part of the tasks defined in Article 16(2)(e) of Directive 2004/49/EC, the” substitute “ The ”;
    - (ii) for “Regulation (EU) No 445/2011”, substitute “ Schedule 10 to the Railways and Other Guided Transport Systems (Safety) Regulations 2006 ”;
  - (d) in paragraph 4, for “Article 7(1) of Regulation (EU) No 445/2011”, substitute “ paragraph 7(1) of Schedule 10 to the Railways and Other Guided Transport Systems (Safety) Regulations 2006 ”.
- (15) In Article 18 (feedback and technical progress)—
- (a) in paragraph 1, for “referred to in Article 9(4) of Directive 2004/49/EC”, substitute “ pursuant to regulation 20(1) of the Railways and Other Guided Transport Systems (Safety) Regulations 2006 or paragraph 16 of the Schedule to the Channel Tunnel (Safety) (Amendment) Order 2013 ”;

- (b) omit paragraph 2;
- (c) in paragraph 3—
  - (i) for “point I(7)(4)(k) of Annex III to Regulation (EU) No 445/2011”, substitute “ paragraph 7(4)(k) of Part 4 of Schedule 10 to the Railways and Other Guided Transport Systems (Safety) Regulations 2006 ”;
  - (ii) omit the final sentence;
- (d) omit paragraphs 4, 5 and 6.
- (16) Omit Article 19 (repeal).
- (17) In Article 20 (entry into force and application), omit the <sup>F37</sup>last sentence] .
- (18) In Annex I (general principles applicable to the risk management process)—
  - (a) in point 1.1.4(a), for “Article 10(2)(a) or Article 11(1)(a) of Directive [2004/49/EC](#)”, substitute “ regulation 7(4)(b)(i) or regulation 10(1)(b)(ii) of the Railways and Other Guided Transport Systems (Safety) Regulations 2006 or paragraphs 22 to 26 of the Schedule to the Channel Tunnel (Safety) (Amendment) Order 2013 ”;
  - <sup>F38</sup>(aa) in point 1.1.4(b)—
    - (i) for “a TSI” substitute “ an NTSN ”;
    - (ii) for “notified national rules” substitute “ national rules ”;]
  - (b) in point 1.1.5, for “Member States”, substitute “ United Kingdom ”;
  - <sup>F39</sup>(bb) in point 1.2.1, for “TSIs” substitute “ NTSNs ”;
  - (bc) in point 1.2.6, for “notified national rule” substitute “ national rule ”;]
  - <sup>F40</sup>(c) in point 2.3.3—
    - (i) for “TSIs”, in both places it occurs, substitute “ NTSNs ”;
    - (ii) omit “by Directive [2008/57/EC](#)”;
    - (iii) for “TSI” substitute “ NTSN ”;]
  - <sup>F41</sup>(cc) in point 2.3.4, omit “notified in accordance with Article 8 of Directive [2004/49/EC](#) and Article 17(3) of Directive [2008/57/EC](#)”;
  - (d) in point 2.4.2(a), for “and would therefore still qualify for approval in the Member State where the change is to be introduced”, substitute “ in the United Kingdom ”;
  - <sup>F42</sup>(e) in point 2.5.2, for—
    - (i) for “Union legislation” substitute “ legislation applying in Great Britain ”;
    - (ii) “notified national rules”, substitute “national rules”;
  - (f) in points 2.5.5 to 2.5.8, omit “harmonised” in each place it occurs;
  - <sup>F43</sup>(ff) in point 2.5.5, for “definition (23) and definition (35)” substitute “ catastrophic accident or critical accident ”.]
  - (g) in point 2.5.6—
    - (i) omit “They shall be the most demanding design targets that can be required for mutual recognition.”;
    - (ii) omit “of a Member State”;
  - (h) omit point 2.5.10;
  - (i) in point 2.5.11—
    - (i) for “Member State where the system is being used” substitute “ United Kingdom ”;
    - (ii) for “harmonised design target”, substitute “ design target ”;

(iii) omit “of the harmonised one”.

(19) In Annex II (criteria for accreditation or recognition of the assessment body), in paragraph 2, for “By analogy to Article 28 of Directive 2008/57/EC concerning the notification of notified bodies, the”, substitute “The”.

#### Textual Amendments

- F23** Reg. 16(3)(c) substituted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F24** Words in reg. 16(4) inserted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(4)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F25** Words in reg. 16(4) inserted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(4)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F26** Words in reg. 16(4) inserted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(4)(b)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F27** Words in reg. 16(4) inserted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(4)(b)(iv)**; 2020 c. 1, Sch. 5 para. 1(1)
- F28** Words in reg. 16(4) omitted (31.12.2020 immediately before IP completion day) by virtue of The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(4)(b)(v)**; 2020 c. 1, Sch. 5 para. 1(1)
- F29** Words in reg. 16(4) omitted (31.12.2020 immediately before IP completion day) by virtue of The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(4)(b)(vi)**; 2020 c. 1, Sch. 5 para. 1(1)
- F30** Words in reg. 16(4) substituted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(4)(b)(vii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F31** Words in reg. 16(4) omitted (31.12.2020 immediately before IP completion day) by virtue of The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(4)(b)(viii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F32** Reg. 16(7)(c) substituted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(4)(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F33** Reg. 16(7)(j) substituted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(4)(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F34** Reg. 16(9)(a) substituted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional



- Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(4)(d)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F35** Reg. 16(9)(b)(ii) substituted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(4)(d)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F36** Reg. 16(13) substituted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(4)(e)**; 2020 c. 1, Sch. 5 para. 1(1)
- F37** Words in reg. 16(17) substituted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(4)(f)**; 2020 c. 1, Sch. 5 para. 1(1)
- F38** Reg. 16(18)(aa) inserted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(4)(g)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F39** Reg. 16(18)(bb)(bc) inserted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(4)(g)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F40** Reg. 16(18)(c) substituted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(4)(g)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F41** Reg. 16(18)(cc) inserted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(4)(g)(iv)**; 2020 c. 1, Sch. 5 para. 1(1)
- F42** Reg. 16(18)(e) substituted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(4)(g)(v)**; 2020 c. 1, Sch. 5 para. 1(1)
- F43** Reg. 16(18)(ff) inserted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(4)(g)(vi)**; 2020 c. 1, Sch. 5 para. 1(1)

#### **Commencement Information**

- I15** Reg. 16 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

#### **Marginal Citations**

- M11** S.I. 2011/3066; relevant amending instruments are S.I. 2011/3066 and 2015/2022.

## PART 5 N.I.

### Amendments to EU retained direct legislation in respect of Northern Ireland

#### CHAPTER 1 N.I.

##### Safety certificates and authorisations

#### **Amendments to Commission Regulation (EU) No 1158/2010 on a common safety method for assessing conformity with the requirements for obtaining railway safety certificates N.I.**

17.—(1) Commission Regulation (EU) No 1158/2010 on a common safety method for assessing conformity with the requirements for obtaining railway safety certificates is amended as follows.

(2) Omit Article 1 (subject matter).

(3) In Article 2 (definitions)—

(a) for “definition” substitute “ definitions ”; and

(b) at the end of the definition of “supervision”, insert—

“,

“national safety authority” has the meaning provided for “safety authority” in regulation 2 of the Railways (Safety Management) Regulations (Northern Ireland) 2006<sup>M12</sup>;

“Part A safety certificate” and “Part B safety certificate” have the meanings provided in regulation 2 of the Railways (Safety Management) Regulations (Northern Ireland) 2006 for “Part A of a safety certificate” and “Part B of a safety certificate” respectively”.

(4) In Article 3 (procedures for assessing applications)—

(a) for paragraph 1, substitute—

“1. When examining applications for both Part A safety certificates and Part B safety certificates, national safety authorities shall apply the procedure set out in Annex I to this Regulation for assessing their conformity with requirements for safety certificates issued in accordance with regulations 5, 6 and 7 of the Railways (Safety Management) Regulations (Northern Ireland) 2006. National safety authorities shall use the assessment criteria set out in Annex II to this Regulation for Part A safety certificates and those contained in Annex III to this Regulation for Part B safety certificates. These criteria shall also be used in case of renewal of safety certificates in accordance with regulation 7 of the Railways (Safety Management) Regulations (Northern Ireland) 2006.”;

(b) in paragraph 3—

(i) for “Union legislation” substitute “ legislation in Northern Ireland ”;

(ii) after the final sentence, insert “ Products or services provided by contractors or suppliers to railway undertakings shall be presumed to conform to safety requirements if the contractors, suppliers or products are certified in accordance with relevant certification schemes established under European Union legislation for the provision of such products and services, unless there are reasonable grounds for believing that they do not so conform. ”.

(5) In Article 4 (supervision), after “Part A”, insert “ safety certificates ”.

(6) Omit the words following Article 5 (entry into force), up to but not including “Annex I”.

(7) In Annex I (procedure for assessing conformity with requirements for obtaining safety certificates to be issued in accordance with Article 10(2)(a) and (b) of Directive [2004/49/EC](#))—

- (a) in the heading, for “Article 10(2)(a) and (b) of Directive 2004/49/EC” substitute “regulations 5, 6 and 7 of the Railways (Safety Management) Regulations (Northern Ireland) 2006”;
  - (b) in paragraph (2), for “complies with Commission Regulation (EC) No 653/2007” substitute “is in the format specified in Part 4 of [F44Schedule 6] to the Railways (Safety Management) Regulations (Northern Ireland) 2006”;
  - (c) in paragraph 6—
    - (i) after “Part A” in the first place it occurs, insert “safety certificates”;
    - (ii) after “Part A” in the second place it occurs, insert “safety”;
    - (iii) omit “as provided for in Regulation (EC) No 653/2007”;
  - (d) in paragraph 7, for “Article 10(2)(b) of Directive 2004/49/EC”, substitute “regulation 5(4)(b)(ii) of the Railways (Safety Management) Regulations (Northern Ireland) 2006.”;
  - (e) in paragraph 8—
    - (i) omit “as referred to in Article 10(2)(b) of Directive 2004/49/EC”;
    - (ii) after “Part A”, insert “safety”;
  - (f) omit paragraph 10.
- (8) In Annex II (criteria for assessing conformity with the requirements for obtaining safety certificates to be issued in accordance with Article 10(2)(a) of Directive 2004/49/EC related to the railway undertaking's safety management system as described in Article 9 and Annex III of that Directive)—
- (a) for the heading, substitute “Criteria for assessing conformity with the requirements for obtaining Part A safety certificates”;
  - (b) in point A.4, for “in accordance with Article 4(3) of Directive 2004/49/EC”, substitute “for the safe operation of the railway”;
  - (c) in point E.3, for “Article 9 and Annex III of Directive 2004/49/EC”, substitute “regulation 4 of the Railways (Safety Management) Regulations (Northern Ireland) 2006”;
  - (d) in point K.3, for “member state level” substitute “a national level”;
  - (e) in point M.2, for “Commission Regulation (EC) No 352/2009” substitute “Commission Implementing Regulation (EU) No 402/2013 as it has effect in Northern Ireland”;
  - (f) in point Q.2 for “national investigating body”, substitute “Rail Accident Investigation Branch”.
- (9) In Annex III (criteria for assessing conformity with the requirements for obtaining safety certificates to be issued in accordance with Article 10(2)(b) of Directive 2004/49/EC)—
- (a) for the heading, substitute “Criteria for assessing conformity with the requirements for obtaining Part B safety certificates”;
  - (b) in the paragraph headed “GENERAL”—
    - (i) after “Part B”, insert “safety”;
    - (ii) for “Article 10(2)(a) of Directive 2004/49/EC”, substitute “Regulation 5(4)(b)(ii) of the Railways (Safety Management) Regulations (Northern Ireland) 2006”.
- (10) In Annex IV (principles for supervision after the award of a Part A or Part B certificate)—
- (a) in the heading, for “Part A or Part B”, substitute “Part A safety certificate or Part B safety certificate”;
  - (b) in paragraph 1, omit “as referred to in Article 4(1) and 16(2)(e) of Directive 2004/49/EC”;

*Status: This version of this Instrument contains provisions that are prospective.*  
*Changes to legislation: There are currently no known outstanding effects for the Rail Safety (Amendment etc.) (EU Exit) Regulations 2019. (See end of Document for details)*

- (c) in paragraph 7, for “National safety authorities shall be accountable for their decisions in accordance with Article 17(3) of Directive 2004/49/EC”, substitute “ The decisions of national safety authorities shall be subject to judicial review. ”.

#### Textual Amendments

- F44** Words in reg. 17(7)(b) substituted (31.12.2020 immediately before IP completion day) by [The Railways \(Safety, Access, Management and Interoperability\) \(Miscellaneous Amendments and Transitional Provision\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/1310), regs. 1(2)(c), **7(5)**; 2020 c. 1, Sch. 5 para. 1(1)

#### Commencement Information

- I16** Reg. 17 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

#### Marginal Citations

- M12** S.R. [2006 No. 237](#); relevant amending instruments are S.R. [2011 No. 261](#), [S.I. 2011/343](#), S.R. [2013 No. 237](#) and S.R. [2016 No. 420](#).

### **Amendments to Commission Regulation (EU) No 1169/2010 on a common safety method for assessing conformity with the requirements for obtaining a railway safety authorisation** **N.I.**

**18.**—(1) Commission Regulation (EU) No 1169/2010 on a common safety method for assessing conformity with the requirements for obtaining a railway safety authorisation is amended as follows.

- (2) Omit Article 1 (subject matter).
- (3) In Article 2 (definition)—
  - (a) in the heading and in the first paragraph, for “definition” substitute “ definitions ”; and
  - (b) after the definition of “supervision”, insert—
 

“national safety authority” has the meaning provided for “safety authority” in the Railways (Safety Management) Regulations (Northern Ireland) 2006.”.
- (4) In Article 3 (procedures for assessing applications)—
  - (a) in paragraph 1, omit “for assessing their conformity with requirements in Directive [2004/49/EC](#)”;
  - (b) in paragraph 3—
    - (i) for “Union legislation” substitute “ legislation in Northern Ireland ”;
    - (ii) after the final sentence, insert “ Products or services provided by contractors or suppliers to railway undertakings shall be presumed to conform to safety requirements if the contractors, suppliers or products are certified in accordance with relevant certification schemes established under European Union legislation for the provision of such products and services, unless there are reasonable grounds for believing that they do not so conform. ”.
- (5) Omit the words following Article 5 (entry into force), up to but not including “Annex I”.
- (6) In Annex I (procedure for assessing conformity with requirements for obtaining safety authorisations), in the heading, for “Article 11(1)(a) and (b) of Directive [2004/49/EC](#)” substitute “ regulations 8, 9 and 10 of the Railways (Safety Management) Regulations (Northern Ireland) 2006 ”.
- (7) In Annex II (criteria for assessing conformity with the requirements for obtaining safety authorisations)—

*Status: This version of this Instrument contains provisions that are prospective.*  
*Changes to legislation: There are currently no known outstanding effects for the Rail Safety (Amendment etc.) (EU Exit) Regulations 2019. (See end of Document for details)*

- (a) in the heading, for “Article 11(1)(a) and (b) of Directive 2004/49/EC” substitute “regulations 8, 9 and 10 of the Railways (Safety Management) Regulations (Northern Ireland) 2006”;
  - (b) in point A.4, for “in accordance with Article 4(3) of Directive 2004/49/EC”, substitute “for the safe operation of the railway”;
  - (c) in point E.3, for “Article 9 and Annex III of Directive 2004/49/EC” substitute “regulation 4 of the Railways (Safety Management) Regulations (Northern Ireland) 2006”;
  - (d) in point K.3 for “member state level” substitute “a national level”;
  - (e) in point M.2, for “Commission Regulation (EC) No 352/2009” substitute “Commission Implementing Regulation (EU) No 402/2013 as it has effect in Northern Ireland”;
  - (f) in point Q.1, for “national bodies”, substitute “Rail Accident Investigation Branch”.
- (8) In Annex III (principles for supervision after the award of an authorisation)—
- (a) in paragraph 1, omit “as referred to in Article 4(1) and 16(2)(e) of Directive 2004/49/EC”;
  - (b) in paragraph 7, for “National safety authorities shall be accountable for their decisions in accordance with Article 17(3) of Directive 2004/49/EC”, substitute “The decisions of national safety authorities shall be subject to judicial review.”;
  - (c) omit paragraph 8.

**Commencement Information**

- I17** Reg. 18 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1
- I18** Reg. 18 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

CHAPTER 2 **N.I.**

Supervision and monitoring

PROSPECTIVE

**Amendments to Commission Regulation (EU) No 1077/2012 on a common safety method for supervision by national safety authorities after issuing a safety certificate or safety authorisation **N.I.****

<sup>F45</sup>19. ....

**Textual Amendments**

- F45** Reg. 19 omitted (31.12.2020 immediately before IP completion day) by virtue of The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), 7(6); 2020 c. 1, Sch. 5 para. 1(1)

## **Amendments to Commission Regulation (EU) No 1078/2012 on a common safety method for monitoring to be applied by railway undertakings, infrastructure managers after receiving a safety certificate or safety authorisation and by entities in charge of maintenance N.I.**

**20.**—(1) Commission Regulation (EU) No 1078/2012 on a common safety method for monitoring to be applied by railway undertakings, infrastructure managers after receiving a safety certificate or safety authorisation and by entities in charge of maintenance is amended as follows.

(2) In Article 1 (subject matter and scope), in paragraph 2(a), for “Article 10(2)(a) and 11(1)(a) and the provisions adopted to obtain the certification/authorisation specified in Article 10(2)(b) and 11(1)(b) of Directive [2004/49/EC](#)”, substitute “ regulations 5(4) and 8(3) of the Railways (Safety Management) Regulations (Northern Ireland) 2006 ”.

(3) For Article 2 (definitions), substitute—

### *“Article 2*

#### *Definitions*

For the purposes of this Regulation the following definitions shall apply.

‘accident’ means an unwanted or unintended sudden event or a specific chain of such events which have harmful consequences; accidents are divided into the following categories: collisions, derailments, level-crossing accidents, accidents to persons caused by rolling stock in motion, fires and others;

‘entity in charge of maintenance’ means an entity in charge of maintenance of a vehicle, and registered as such in the National Vehicle Register;

‘incident’ means any occurrence, other than an accident, associated with the operation of trains and affecting the safety of operation;

‘infrastructure manager’ means any body or undertaking that is responsible in particular for establishing and maintaining railway infrastructure, or a part thereof, as defined in Article 3 of Directive [91/440/EEC](#), which may also include the management of infrastructure control and safety systems. The functions of the infrastructure manager on a network or part of a network may be allocated to different bodies or undertakings;

‘interfaces’ means all points of interaction during a system or subsystem life-cycle, including operation and maintenance where different actors of the rail sector will work together in order to manage the risks;

‘management system’ means either a safety management system as defined in the Railways (Safety Management) Regulations (Northern Ireland) 2006, or the system of maintenance of entities in charge of maintenance complying with requirements laid down in paragraph 3 of Regulation 16AA of the Railways (Safety Management) Regulations (Northern Ireland) 2006;

‘monitoring’ means the arrangements put in place by railway undertakings, infrastructure managers or entities in charge of maintenance to check their management system is correctly applied and effective;

‘national safety authority’ has the meaning provided for “safety authority” in the Railways (Safety Management) Regulations (Northern Ireland) 2006;

‘railway system’ means the totality of the subsystems in Northern Ireland for structural and operational areas, as defined in paragraph 2(1) to 2(7) of Annex II to Directive [2008/57/EC](#), as well as the management and operation of the system as a whole;

‘railway undertaking’ means a public or private undertaking, licensed according to applicable legislation, the activity of which is to provide transport of goods and/or passengers by rail on the basis that the undertaking must ensure traction; this also includes undertakings which provide traction only.”.

- (4) In Article 5 (reporting)—
- (a) in paragraph 1, omit “in accordance with Article 9(4) of Directive 2004/49/EC”;
  - (b) omit paragraphs 2 to 7.
- (5) Omit the words following Article 6 (entry into force), up to but not including “Annex”.

**Commencement Information**

**I19** Reg. 20 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

CHAPTER 3 **N.I.**

Risk evaluation and assessment

**Amendments to Commission Implementing Regulation (EU) No 402/2013 on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009 **N.I.****

**21.**—(1) Commission Implementing Regulation (EU) No 402/2013 on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009 is amended as follows.

- (2) Omit Article 1 (subject matter).
- (3) In Article 2 (scope)—
- (a) in paragraph 1, for “a Member State”, substitute “ Northern Ireland ”;
  - (b) in paragraph 3—
    - (i) in the first place that it occurs, for “Directive 2008/58/EC applies” substitute “ the Railways (Interoperability) Regulations 2011 apply ”;
    - (ii) omit paragraph (a);
    - (iii) in paragraph (b), omit “, by virtue of Article 15(1) of Directive 2008/57/EC”;
  - <sup>F46</sup>(c) in paragraph 4—
    - (i) for “TSIs” substitute “ NTSNs ”;
    - (ii) for the second sentence substitute “ If such contradictions occur, the proposer shall inform the Secretary of State, who may then decide to publish a variation of the NTSN in accordance with paragraphs (3) and (4) of regulation 3B of the Railways (Interoperability) Regulations 2011, and the Department for Infrastructure, who may then decide to issue an exemption in accordance with regulation 14 of those Regulations. ”]
  - (d) omit paragraphs 5 and 6.
- (4) For Article 3 (definitions) substitute—

*“Article 3*

*Definitions*

For the purposes of this Regulation the following definitions shall apply.

‘accident’ means an unwanted or unintended sudden event or a specific chain of such events which have harmful consequences; accidents are divided into the following categories:

collisions, derailments, level-crossing accidents, accidents to persons caused by rolling stock in motion, fires and others;

‘accreditation’ means an attestation by a national accreditation body that a conformity assessment body meets the requirements set by designated standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity;

‘actors’ means all parties which are, directly or through contractual arrangements, involved in the application of this Regulation;

[<sup>F47</sup>‘approved body’ has the meaning provided in regulation 2 of the Railways (Interoperability) Regulations 2011;]

‘assessment body’ means the independent and competent external or internal individual, organisation or entity which undertakes investigation to provide a judgement, based on evidence, of the suitability of a system to fulfil its safety requirements;

‘barrier’ means a technical, operational or organisational risk control measure outside the system under assessment that either reduces the frequency of occurrence of a hazard or mitigates the severity of the potential consequence of that hazard;

‘catastrophic accident’ means an accident typically affecting a large number of people and resulting in multiple fatalities;

‘code of practice’ means a written set of rules that, when correctly applied, can be used to control one or more specific hazards;

‘conformity assessment body’ means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

‘critical accident’ means an accident typically affecting a very small number of people and resulting in at least one fatality;

[<sup>F48</sup>‘designated body’ has the meaning provided in regulation 2 of the Railways (Interoperability) Regulations 2011;]

‘designated standard’ has the meaning provided in Article 3A;

‘entity in charge of maintenance’ means an entity in charge of maintenance of a vehicle, and registered as such in the National Vehicle Register;

[<sup>F49</sup>‘EU notified body’ has the meaning provided in regulation 2 of the Railways (Interoperability) Regulations 2011;]

‘hazard’ means a condition that could lead to an accident;

‘hazard identification’ means the process of finding, listing and characterising hazards;

‘hazard record’ means the document in which identified hazards, their related measures, their origin and the reference to the organisation which has to manage them are recorded and referenced;

‘highly improbable’ means an occurrence of failure at a frequency less than or equal to  $10^{-9}$  per operating hour;

‘improbable’ means an occurrence of failure at a frequency less than or equal to  $10^{-7}$  per operating hour;

‘incident’ means any occurrence, other than accident, associated with the operation of trains and affecting the safety of operation;

‘infrastructure manager’ means any body or undertaking that is responsible in particular for establishing and maintaining railway infrastructure, or a part thereof, as defined in Article 3 of Directive [91/440/EEC](#), which may also include the management of infrastructure control and



safety systems. The functions of the infrastructure manager on a network or part of a network may be allocated to different bodies or undertakings;

‘interfaces’ means all points of interaction during a system or subsystem life cycle, including operation and maintenance where different actors of the rail sector will work together in order to manage the risks;

‘investigation’ means a process conducted for the purpose of accident and incident prevention which includes the gathering and analysis of information, the drawing of conclusions, including the determination of causes and, when appropriate, the making of safety recommendations;

‘national accreditation body’ means the sole body in the United Kingdom that performs accreditation in accordance with Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9th July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93;

[<sup>F50</sup>‘national rule’ means NTRs as defined in regulation 2 of the Railways (Interoperability) Regulations 2011 and national safety rules as defined in regulation 2 of the Railways (Safety Management) Regulations (Northern Ireland) 2006;]

‘national safety authority’ has the meaning provided for “safety authority” in the Railways (Safety Management) Regulations (Northern Ireland) 2006;

F51  
...

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...

‘proposer’ means one of the following—

- (a) a railway undertaking or an infrastructure manager;
- (b) an entity in charge of maintenance;
- (c) [<sup>F53</sup>a contracting entity or manufacturer which invites—
  - (i) an approved body or a designated body to apply the UK verification assessment procedure in accordance with regulation 17 of and Schedule 4 to the Railways (Interoperability) Regulations 2011; or
  - (ii) an EU notified body to apply the EC verification procedure in accordance with Directive 2008/57/EC or a designated body according to Article 17(3) of that Directive;]

‘railway system’ means the totality of the subsystems in Northern Ireland for structural and operational areas, as defined in paragraph 2(1) to 2(7) of Annex II to Directive 2008/57/EC, as well as the management and operation of the system as a whole;

‘railway undertaking’ means a public or private undertaking, licensed according to applicable legislation, the activity of which is to provide transport of goods and/or passengers by rail on the basis that the undertaking must ensure traction; this also includes undertakings which provide traction only;

‘recognition’ means an attestation by a national body other than the national accreditation body that the assessment body meets the requirements set out in Annex II to this Regulation to carry out the independent assessment activity specified in Article 6(1) and (2);

‘reference system’ means a system proven in use to have an acceptable safety level and against which the acceptability of the risks from a system under assessment can be evaluated by comparison;

‘risk’ means the frequency of occurrence of accidents and incidents resulting in harm caused by a hazard and the degree of severity of that harm;

‘risk acceptance criteria’ means the terms of reference by which the acceptability of a specific risk is assessed; these criteria are used to determine that the level of a risk is sufficiently low that it is not necessary to take any immediate action to reduce it further;

‘risk acceptance principle’ means the rules used in order to arrive at the conclusion whether or not the risk related to one or more specific hazards is acceptable;

‘risk analysis’ means systematic use of all available information to identify hazards and to estimate the risk;

‘risk assessment’ means the overall process comprising a risk analysis and a risk evaluation;

‘risk estimation’ means the process used to produce a measure of the level of risks being analysed, consisting of the following steps: estimation of frequency, consequence analysis and their integration;

‘risk evaluation’ means a procedure based on the risk analysis to determine whether an acceptable level of risk has been achieved;

‘risk management’ means the systematic application of management policies, procedures and practices to the tasks of analysing, evaluating and controlling risks;

‘safety’ means freedom from unacceptable risk of harm;

‘safety acceptance’ means the status given to the change by the proposer based on the safety assessment report provided by the assessment body;

‘safety assessment report’ means the document containing the conclusions of the assessment performed by an assessment body on the system under assessment;

‘safety management system’ means the organisation and arrangements established by an infrastructure manager or a railway undertaking to ensure the safe management of its operations;

‘safety measures’ means a set of actions either reducing the frequency of occurrence of a hazard or mitigating its consequences in order to achieve and/or maintain an acceptable level of risk;

‘safety requirements’ means the safety characteristics (qualitative or quantitative, or when needed both qualitative and quantitative) necessary for the design, operation (including operational rules) and maintenance of a system in order to meet legal or company safety targets;

‘system’ means any part of the railway system which is subjected to a change whereby the change may be of a technical, operational or organisational nature;

‘systematic failure’ means a failure that occurs repeatedly under some particular combination of inputs or under some particular environmental or application conditions;

‘systematic fault’ means an inherent fault in the specification, design, manufacturing, installation, operation or maintenance of the system under assessment;

F54 ...

‘technical system’ means a product or an assembly of products including the design, implementation and support documentation; the development of a technical system starts with its requirements specification and ends with its acceptance; although the design of relevant interfaces with human behaviour is considered, human operators and their actions are not included in a technical system; the maintenance process is described in the maintenance manuals but is not itself part of the technical system;

‘vehicle’ means a railway vehicle suitable for circulation on its own wheels on railway lines, with or without traction; a vehicle is composed of one or more structural and functional subsystems or parts of such subsystems.”

(5) After Article 3 (definitions), insert—

*“Article 3A*

*Designated standards*

1. Subject to paragraphs 6 and 7, in this Regulation a “designated standard” means a technical specification which is—

- (a) adopted by a recognised standardisation body, for repeating or continuous application, with which compliance is not compulsory; and
- (b) designated by the Secretary of State by publishing the reference to the standard and maintaining that publication in a manner the Secretary of State considers appropriate.

2. For the purposes of paragraph 1, a “technical specification” means a document that prescribes technical requirements to be fulfilled by a product, process, service or system and which lays down one or more of the following—

- (a) the characteristics required of a product, including—
  - (i) levels of quality, performance, interoperability, environmental protection, health, safety or dimensions; and
  - (ii) the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures; and
- (b) production methods and processes relating to the product, where these have an effect on the characteristics of the product.

3. For the purposes of this article, a “recognised standardisation body” means any one of the following organisations—

- (a) the European Committee for Standardisation (CEN);
- (b) the European Committee for Electrotechnical Standardisation (Cenelec);
- (c) the European Telecommunications Standards Institute (ETSI);
- (d) the British Standards Institution (BSI).

4. When considering whether the manner of publication of a reference is appropriate in accordance with paragraph 1(b), the Secretary of State must have regard to whether the publication will draw the standard to the attention of any person who may have an interest in the standard.

5. Before publishing the reference to a technical specification adopted by the British Standards Institution, the Secretary of State must have regard to whether the technical specification is consistent with technical specifications adopted by the other recognised standardisation bodies.

6. The Secretary of State may remove from publication the reference to a standard which has been published in accordance with paragraph 1(b).

7. Where the Secretary of State removes the reference to a standard from publication, that standard is no longer a designated standard.”.
- (6) In Article 4 (significant changes), for the first sentence of paragraph 1, substitute “ The proposer shall consider the potential impact of a change on the safety of the railway system. ”.
- (7) In Article 6 (independent assessment)—
- (a) in paragraph 1, omit “Union or”;
  - (b) in paragraph 3(a), for “Directive [2004/49/EC](#)”, substitute “ regulation 16AA of the Railways (Safety Management) Regulations (Northern Ireland) 2006 ”;
  - [<sup>F55</sup>(c) in paragraph 3(b), “for a notified body as defined by Article 2(j) of Directive [2008/57/EC](#) or a body designated in accordance with Article 17 of that Directive”, substitute “ an EU notified body or an approved body ”;]
  - (d) in paragraph 4, for “Without prejudice to Union legislation, the” substitute “ The ”;
  - (e) in paragraph 4(a) and (b), omit the words following “service”;
  - (f) in paragraph 4(c), omit the words following “operation”;
  - (g) in paragraph 4(d), omit the words following “framework”;
  - (h) in paragraph 4(e), omit the words following “maintenance”;
  - (i) in paragraph 4(f), omit the words following “framework”;
  - [<sup>F56</sup>(j) in the final paragraph—
    - (i) omit “as referred to in Article 15(1) or Article 20 of Directive [2008/57/EC](#)”;
    - (ii) for “a notified body in accordance with Article 18(2) of that Directive”, substitute “ an approved body ”.]
- (8) In Article 7 (accreditation/recognition of the assessment body)—
- (a) omit “referred to in Article 13(1)” in both places where it occurs;
  - (b) for “under the requirement of Article 9(2)” substitute “ where it fulfils the requirements set out in Annex II and the accreditation functions of the national safety authority are demonstrably independent of its other functions ”.
- (9) In Article 8 (acceptance of accreditation/recognition)—
- [<sup>F57</sup>(a) in paragraph 1—
    - (i) for “Commission Regulation (EU) No 1158/2010 or Commission Regulation (EU) No 1169” substitute “ regulation 5 or 8 of the Railways (Safety Management) Regulations (Northern Ireland) 2006 ”;
    - (ii) for “by a Member State in accordance with Article 7” substitute “ in Great Britain ”;]
    - (b) omit paragraph 2.
- (10) In Article 9 (types of recognition of the assessment body)—
- (a) in paragraph 1(a), after “Member State” insert “ of the European Union ”;
  - (b) omit paragraph 1(c);
  - (c) in paragraph 1(d), for “by the Member State” substitute “ in the United Kingdom ”;
  - (d) omit paragraph 2.
- (11) In Article 10 (validity of recognition)—
- (a) in paragraph 1 for “Article 9(2)”, substitute “ where the national safety authority is recognised as an assessment body ”;

- (b) in paragraph 2(a), for “harmonised format of safety certificates provided in Annex I to Commission Regulation (EC) No 653/2007”, substitute “ safety certificates in the form provided in Part 2 of Schedule 6 to the Railways (Safety Management) Regulations (Northern Ireland) 2006 ”;
  - (c) omit paragraph 3.
- (12) Omit Article 12 (relaxed criteria where a significant change is not to be mutually recognised), Article 13 provision of information to the Agency) and Article 14 (support from the Agency to accreditation or recognition of the assessment body).
- [<sup>F58</sup>(13) In Article 15 (safety assessment reports)—
- (a) in paragraph 3 for “Without prejudice to Article 16 of Directive 2008/57/EC, the”, substitute “ The ”;
  - (b) in paragraph 4—
    - (i) for “In the case referred to in point (a) of Article 2(3)” substitute “ Where the application of this Regulation or part of this Regulation is required by a relevant NTSN ”;
    - (ii) for “notified body” substitute “ approved body ”;]
- (14) In Article 17 (risk control management and audits)—
- (a) in paragraph 1, for “Article 9 of Directive 2004/49/EC”, substitute “ regulation 4 of the Railways (Safety Management) Regulations (Northern Ireland) 2006 ”;
  - (b) in paragraph 2, for “Article 14a(3) of Directive 2004/49/EC”, substitute “ regulation 16AA of the Railways (Safety Management) Regulations (Northern Ireland) 2006 ”;
  - (c) in paragraph 3—
    - (i) for “As part of the tasks defined in Article 16(2)(e) of Directive 2004/49/EC, the” substitute “ The ”;
    - (ii) omit “do not fall within the scope of Regulation (EU) No 445/2011 but are”;
  - (d) omit paragraph 4.
- (15) In Article 18 (feedback and technical progress)—
- (a) in paragraph 1, for “referred to in Article 9(4) of Directive 2004/49/EC”, substitute “ pursuant to regulation 18(1) of the Railways (Safety Management) Regulations (Northern Ireland) 2006 ”;
  - (b) omit paragraphs 2 to 6.
- (16) Omit Article 19 (repeal).
- (17) In Article 20 (entry into force and application), omit the [<sup>F59</sup>last sentence].
- (18) In Annex I (general principles applicable to the risk management process)—
- (a) in point 1.1.4(a), for “Article 10(2)(a) or Article 11(1)(a) of Directive 2004/49/EC”, substitute “ regulation 5(4)(b)(i) or regulation 8(1)(b)(ii) of the Railways (Safety Management) Regulations (Northern Ireland) 2006 ”;
- [<sup>F60</sup>(aa) in point 1.1.4(b)—
- (i) for “a TSI” substitute “ an NTSN ”;
  - (ii) for “notified national rules” substitute “ national rules ”;]
  - (b) in point 1.1.5, for “Member States” substitute “ United Kingdom ”;
- [<sup>F61</sup>(bb) in point 1.2.1, for “TSIs” substitute “ NTSNs ”;
- (bc) in point 1.2.6, for “notified national rule” substitute “ national rule ”;]

- [<sup>F62</sup>(c) in point 2.3.3—
- (i) for “TSIs”, in both places it occurs substitute “ NTSNs ”;
  - (ii) omit “by Directive 2008/57/EC”;
  - (iii) for “TSP” substitute “ NTSN ”;]
- [<sup>F63</sup>(cc) in point 2.3.4, omit “notified in accordance with Article 8 of Directive 2004/49/EC and Article 17(3) of Directive 2008/57/EC”];
- (d) in point 2.4.2(a), for “and would therefore still qualify for approval in the Member State where the change is to be introduced”, substitute “ in the United Kingdom ”;
- [<sup>F64</sup>(e) in point 2.5.2—
- (i) for “Union legislation” substitute “ legislation applying in Northern Ireland ”;
  - (ii) for “notified national rules” substitute “ national rules ”;]
- (f) in points 2.5.5 to 2.5.8, omit “harmonised” in each place it occurs;
- [<sup>F65</sup>(ff) in point 2.5.5, for “definition (23) and definition (35)” substitute “ catastrophic accident or critical accident ”.]
- (g) in point 2.5.6—
- (i) omit “They shall be the most demanding design targets that can be required for mutual recognition.”;
  - (ii) omit “of a Member State”;
- (h) omit point 2.5.10;
- (i) in point 2.5.11—
- (i) for “Member State where the system is being used” substitute “ United Kingdom ”;
  - (ii) for “harmonised design target”, substitute “ design target ”;
  - (iii) omit “of the harmonised one”.
- (19) In Annex II (criteria for accreditation or recognition of the assessment body), in paragraph 2, for “By analogy to Article 28 of Directive 2008/57/EC concerning the notification of notified bodies, the”, substitute “ The ”.

#### Textual Amendments

- F46** Reg. 21(3)(c) substituted (31.12.2020 immediately before IP completion day) by [The Railways \(Safety, Access, Management and Interoperability\) \(Miscellaneous Amendments and Transitional Provision\) \(EU Exit\) Regulations 2019 \(S.I. 2019/1310\)](#), regs. 1(2)(c), [7\(7\)\(a\)](#); 2020 c. 1, Sch. 5 para. 1(1)
- F47** Words in reg. 21(4) inserted (31.12.2020 immediately before IP completion day) by [The Railways \(Safety, Access, Management and Interoperability\) \(Miscellaneous Amendments and Transitional Provision\) \(EU Exit\) Regulations 2019 \(S.I. 2019/1310\)](#), regs. 1(2)(c), [7\(7\)\(b\)\(i\)](#); 2020 c. 1, Sch. 5 para. 1(1)
- F48** Words in reg. 21(4) inserted (31.12.2020 immediately before IP completion day) by [The Railways \(Safety, Access, Management and Interoperability\) \(Miscellaneous Amendments and Transitional Provision\) \(EU Exit\) Regulations 2019 \(S.I. 2019/1310\)](#), regs. 1(2)(c), [7\(7\)\(b\)\(ii\)](#); 2020 c. 1, Sch. 5 para. 1(1)
- F49** Words in reg. 21(4) inserted (31.12.2020 immediately before IP completion day) by [The Railways \(Safety, Access, Management and Interoperability\) \(Miscellaneous Amendments and Transitional Provision\) \(EU Exit\) Regulations 2019 \(S.I. 2019/1310\)](#), regs. 1(2)(c), [7\(7\)\(b\)\(iii\)](#); 2020 c. 1, Sch. 5 para. 1(1)

- F50** Words in reg. 21(4) inserted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(7)(b)(iv)**; 2020 c. 1, Sch. 5 para. 1(1)
- F51** Words in reg. 21(4) omitted (31.12.2020 immediately before IP completion day) by virtue of The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(7)(b)(v)**; 2020 c. 1, Sch. 5 para. 1(1)
- F52** Words in reg. 21(4) omitted (31.12.2020 immediately before IP completion day) by virtue of The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(7)(b)(vi)**; 2020 c. 1, Sch. 5 para. 1(1)
- F53** Words in reg. 21(4) substituted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(7)(b)(vii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F54** Words in reg. 21(4) omitted (31.12.2020 immediately before IP completion day) by virtue of The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(7)(b)(viii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F55** Reg. 21(7)(c) substituted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(7)(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F56** Reg. 21(7)(j) substituted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(7)(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F57** Reg. 21(9)(a) substituted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(7)(d)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F58** Reg. 21(13) substituted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(7)(e)**; 2020 c. 1, Sch. 5 para. 1(1)
- F59** Words in reg. 21(17) substituted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(7)(f)**; 2020 c. 1, Sch. 5 para. 1(1)
- F60** Reg. 21(18)(aa) inserted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(7)(g)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F61** Reg. 21(18)(bb)(bc) inserted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(7)(g)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F62** Reg. 21(18)(c) substituted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(7)(g)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F63** Reg. 21(18)(cc) inserted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(7)(g)(iv)**; 2020 c. 1, Sch. 5 para. 1(1)

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**Status:** This version of this Instrument contains provisions that are prospective.  
**Changes to legislation:** There are currently no known outstanding effects for the Rail Safety (Amendment etc.) (EU Exit) Regulations 2019. (See end of Document for details)

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- F64** Reg. 21(18)(e) substituted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(7)(g)(v)**; 2020 c. 1, Sch. 5 para. 1(1)
- F65** Reg. 21(18)(ff) inserted (31.12.2020 immediately before IP completion day) by The Railways (Safety, Access, Management and Interoperability) (Miscellaneous Amendments and Transitional Provision) (EU Exit) Regulations 2019 (S.I. 2019/1310), regs. 1(2)(c), **7(7)(g)(vi)**; 2020 c. 1, Sch. 5 para. 1(1)

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**Commencement Information**

- I20** Reg. 21 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Signed by authority of the Secretary of State for Transport

Department for Transport

*Sugg*  
Parliamentary Under Secretary of State



**Status:**

This version of this Instrument contains provisions that are prospective.

**Changes to legislation:**

There are currently no known outstanding effects for the The Rail Safety (Amendment etc.) (EU Exit) Regulations 2019.