

Regulations made by the Secretary of State, laid before Parliament under paragraph 5(3) of Schedule 7 to the European Union (Withdrawal) Act 2018, for approval by resolution of each House of Parliament within 28 days beginning with the day on which the Regulations were made, subject to extension for periods of dissolution, prorogation or adjournment for more than four days.

STATUTORY INSTRUMENTS

2019 No. 837

EXITING THE EUROPEAN UNION

HEALTH AND SAFETY

TRANSPORT

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

Made - - - - *5th April 2019*

Laid before Parliament *9th April 2019*

Coming into force in accordance with regulation 1

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SCHEDULE — Schedules to be inserted into the Railways and Other Guided Transport Systems (Safety) Regulations 2006

The Secretary of State makes these Regulations in exercise of the powers conferred by section 8(1) of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018^(a).

The Secretary of State is of the opinion that, by reason of urgency, it is necessary to make these Regulations without a draft of the instrument being laid before, and approved by a resolution of, each House of Parliament.

PART 1

Introduction

Citation and commencement

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

Extent

- 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.

PART 2

Amendments to subordinate legislation

Amendments to the Railways and Other Guided Transport Systems (Safety) Regulations 2006

3.—(1) The Railways and Other Guided Transport Systems (Safety) Regulations 2006^(b) are amended as follows.

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

^(a) 2018 c. 16.

^(b) 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.

- 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;
- (c) 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;
- (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;”;
- (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 EU ECM Regulation;”;
- (f) omit the definition of “ECM Regulation”;
- (g) after the definition of “entity in charge of maintenance”, insert—
- ““EU ECM Regulation” means Commission Regulation (EU) No 445/2011^(a) on a system of certification of entities in charge of maintenance for freight wagons and amending Regulation (EC) No 653/2007 as it has effect or had effect in EU law, as the context dictates;”;
- (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^(b); or

(a) OJ No. L 122 11.05.2011, p. 22-46.

(b) 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).

- (b) as regards Northern Ireland, the Department for Infrastructure established by article 3(1) of the Departments (Northern Ireland) Order 1999^(a) and renamed by section 1(6) of the Departments Act (Northern Ireland) 2016^(b);
 - (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^(c)”;
 - (j) in the definition of “subsystem”, for “Directive”, substitute “Regulations”;
 - (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;
 - “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;”;
 - (l) in paragraph (3), for “within the meaning of section 1(7) of the Channel Tunnel Act 1987”, substitute “, save for regulations 18A(1) and (4), and 18B”.
- (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,
 the Office of Rail and Road must notify that authority or the European Railway Agency.
 - (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.”.
- (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.”;
 - (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.”.

(a) S.I. 1999/283 (N.I. 1).

(b) 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).

(c) 1987 c. 53.

(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)—

- (a) in paragraph (1)(a), for “an ECM certificate”, substitute “an EU ECM certificate or a UK-issued ECM certificate”;
- (b) in paragraph (1)(d), for “ECM Regulation”, substitute “EU ECM Regulation” and for “ECM certificate; or”, substitute “EU ECM certificate;”;
- (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; or”;

(d) for paragraph (1A), substitute—

“(1A) A person who is aggrieved by—

- (a) a decision of a certification body accredited or recognised in Great Britain for the purposes of the EU ECM Regulation either to refuse an application for an EU ECM certificate or taken by that body pursuant to Article 7(3), (4) or (7) of the EU ECM Regulation; or
- (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 paragraphs 7(3), (4) or (7) of Schedule 10,

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;
- (bb) a safety authority in a member State under provisions giving effect to article 10(2)(a) of the 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.

Amendments to the Railways (Access to Training Services) Regulations 2006

4.—(1) The Railways (Access to Training Services) Regulations 2006(a) are amended as follows.

(2) In regulation 2 (interpretation)—

- (a) omit the definition of “the Council Directive”;
- (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(b), 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.

PART 3

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

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.

Revocation of Commission Decision 2009/460/EC

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.

Revocation of Commission Regulation (EU) No 445/2011

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.

(a) S.I. 2006/598, to which there are amendments not relevant to these Regulations.

(b) OJ No. L 191 18.07.2008, p. 1-45.

Revocation of Commission Decision 2012/226/EU

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.

Revocation of Commission Implementing Decision 2013/753/EU

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.

Revocation of Commission Implementing Regulation (EU) 2018/763

10. Commission Implementing Regulation (EU) 2018/763 establishing practical arrangements for issuing single safety certificates to railway undertakings pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council, and repealing Commission Regulation (EC) No 653/2007 is revoked.

Amendment to Annex XIII to the Agreement on the European Economic Area

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.

PART 4

Amendments to retained direct EU legislation in respect of Great Britain

CHAPTER 1

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

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 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(a)”;
 - (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(b)”.
- (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.”.

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

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,

(a) S.I. 2013/407.

(b) The Rail Accident Investigation Branch was established by section 3 of the Railways and Transport Safety Act 2003 (c. 20).

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”;
- (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.”.

CHAPTER 2

Supervision and monitoring

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

14.—(1) 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 is amended as follows.

(2) In Article 1 (subject matter and scope)—

- (a) in paragraph 1, omit “as referred to in Annex IV to Regulation (EU) No 1158/2010 and Annex III to Regulation (EU) No 1169/2010 respectively”;
- (b) in paragraph 3, omit “under Article 16(2)(f) of Directive 2004/49/EC” and “the Member States”.

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

“Article 2

Definitions

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

‘supervision’ means the arrangements put in place by the national safety authority to oversee safety performance after it has granted a safety certificate or safety authorisation;

‘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 8 (coordination and cooperation), omit paragraph 1.

(5) Omit the words following Article 9 (entry into force), up to but not including “Annex”.

(6) In the Annex (supervision activities)—

- (a) in paragraph 4(b), for “its Member State”, substitute “Great Britain”;
- (b) in paragraph 4(c)—
 - (i) at the beginning, insert “where the national safety authority is the Office of Rail and Road,”;
 - (ii) for “the Member State”, substitute “Great Britain”;
- (c) in paragraph 5(c), for “its Member State”, substitute “the Secretary of State”.

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

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(a), 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—

(a) OJ No. L 237, 24.08.1991, p. 25-28.

- (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”.

CHAPTER 3

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

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(a) apply”;
 - (ii) omit paragraph (a);
 - (iii) in paragraph (b), omit “, by virtue of Article 15(1) of Directive 2008/57/EC”;
 - (c) in paragraph 4, for “Member State concerned which”, substitute “Secretary of State who”;
 - (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;

‘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;

(a) S.I. 2011/3066; relevant amending instruments are S.I. 2011/3066 and 2015/2022.

‘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;

‘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;

‘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;

‘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;

‘notified bodies’ means the bodies which are responsible for assessing the conformity or suitability for use of the interoperability constituents or for appraising the EC procedure for verification of the subsystems, as defined in Directives 96/48/EC(a) and 2001/16/EC(b);

‘notified national rule’ means national rules notified by Member States under Council Directive 96/48/EC, Directive 2001/16/EC of the European Parliament and of the Council, or Directive 2008/57/EC, and national safety rules as defined in the Railways and Other Guided Transport Systems (Safety) Regulations 2006;

‘proposer’ means one of the following—

- (a) a railway undertaking or an infrastructure manager;
- (b) an entity in charge of maintenance;
- (c) a contracting entity or a manufacturer which invites a 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;

(a) OJ No. L 191, 18.7.2008, p. 1–45.

(b) OJ No. L 110, 20.04.2001, p. 1–27.

‘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;

‘technical specification for interoperability’ (‘TSI’) means the specifications by which each subsystem or part of a subsystem is covered in order to meet the essential requirements and conventional rail systems as defined in Directive 96/48/EC and Directive 2001/16/EC;

‘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”;
 - (c) in paragraph 3(b), for “as defined by Article 2(j) of Directive 2008/57/EC or a body designated in accordance with Article 17 of that Directive”, substitute “a notified body or a designated body as defined in the Railways (Interoperability) Regulations 2011”;
 - (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”;
 - (j) in the final paragraph, omit “as referred to in Article 15(1) or Article 20 of Directive 2008/57/EC” and “in accordance with Article 18(2) of that Directive”.
- (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)—

- (a) in paragraph 1, for “Commission Regulation (EU) No 1158/2010 or Commission Regulation (EU) No 1169/2010”, 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”;
 - (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”;
 - (ii) after “Member State”, insert “of the European Union or 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).
- (13) In Article 15 (safety assessment reports), in paragraph 3, for “Without prejudice to Article 16 of Directive 2008/57/EC, the”, substitute “The”.
- (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 last two sentences.
- (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”;
 - (b) in point 1.1.5, for “Member States”, substitute “United Kingdom”;
 - (c) in point 2.3.3, omit “by 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”;
 - (e) in point 2.5.2, for “Union legislation” substitute “legislation in Great Britain”;
 - (f) in points 2.5.5 to 2.5.8, omit “harmonised” in each place it occurs;
 - (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”.

PART 5

Amendments to EU retained direct legislation in respect of Northern Ireland

CHAPTER 1

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

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(a);

“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”;

(a) 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.

- (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 (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”;
- (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.”.

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

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)—
 - (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.

CHAPTER 2

Supervision and monitoring

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

19.—(1) 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 is amended as follows.

(2) In Article 1 (subject matter and scope)—

- (a) in paragraph 1, omit “as referred to in Annex IV to Regulation (EU) No 1158/2010 and Annex III to Regulation (EU) No 1169/2010 respectively”;
- (b) in paragraph 3, omit “under Article 16(2)(f) of Directive 2004/49/EC” and “the Member States”.

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

“Article 2

Definitions

For the purposes of this Regulation—

‘supervision’ means the arrangements put in place by the national safety authority to oversee safety performance after it has granted a safety certificate or safety authorisation;

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

(4) In Article 8 (coordination and cooperation), omit paragraph 1.

(5) Omit the words following Article 9 (entry into force), up to but not including “Annex”.

(6) In the Annex (supervision activities)—

- (a) in paragraph 4(b), for “its Member State”, substitute “Northern Ireland”;
- (b) in paragraph 4(c)—
 - (i) at the beginning, insert “where the national safety authority is the Department for Infrastructure in Northern Ireland,”;
 - (ii) for “the Member State”, substitute “Northern Ireland”;
- (c) in paragraph 5(c) omit “to its Member State”.

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

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”.

CHAPTER 3

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

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”;
 - (c) in paragraph 4, for “Member State concerned which”, substitute “Secretary of State who”;
 - (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;

‘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;

‘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;

‘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;

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

‘notified bodies’ means the bodies which are responsible for assessing the conformity or suitability for use of the interoperability constituents or for appraising the EC procedure for verification of the subsystems, as defined in Directives 96/48/EC and 2001/16/EC;

‘notified national rule’ means national rules notified by Member States under Council Directive 96/48/EC, Directive 2001/16/EC of the European Parliament and of the Council, or Directive 2008/57/EC, and national safety rules as defined in the Railways (Safety Management) Regulations (Northern Ireland) 2006;

‘proposer’ means one of the following—

- (a) a railway undertaking or an infrastructure manager;
- (b) an entity in charge of maintenance;
- (c) a contracting entity or a manufacturer which invites a 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;

‘technical specification for interoperability’ (‘TSI’) means the specifications by which each subsystem or part of a subsystem is covered in order to meet the essential requirements and conventional rail systems as defined in Directive 96/48/EC and Directive 2001/16/EC;

‘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”;
 - (c) in paragraph 3(b), for “as defined by Article 2(j) of Directive 2008/57/EC or a body designated in accordance with Article 17 of that Directive”, substitute “a notified body or a designated body as defined in the Railways (Interoperability) Regulations 2011”;
 - (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”;
 - (j) in the final paragraph, omit “as referred to in Article 15(1) or Article 20 of Directive 2008/57/EC” and “in accordance with Article 18(2) of that Directive”.
- (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)—
- (a) in paragraph 1—
 - (i) for “Commission Regulation (EU) No 1158/2010 or Commission Regulation (EU) No 1169/2010” substitute “regulation 5 or 8 of the Railways (Safety Management) Regulations (Northern Ireland) 2006”;
 - (ii) after “Member State”, insert “of the European Union or 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).
- (13) In Article 15 (safety assessment reports), in paragraph 3, for “Without prejudice to Article 16 of Directive 2008/57/EC, the”, substitute “The”.
- (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 last two sentences.
- (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”;
 - (b) in point 1.1.5, for “Member States” substitute “United Kingdom”;
 - (c) in point 2.3.3, omit “by 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”;
 - (e) in point 2.5.2, for “Union legislation” substitute “legislation in Northern Ireland”;
 - (f) in points 2.5.5 to 2.5.8, omit “harmonised” in each place it occurs;
 - (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”.

Signed by Authority of the Secretary of State for Transport

5th April 2019

Sugg
Parliamentary Under Secretary of State
Department for Transport

SCHEDULE

Regulation 3(12)

Schedules to be inserted into the Railways and Other Guided Transport Systems (Safety) Regulations 2006

1. After Schedule 7 to the Railways and Other Guided Transport Systems (Safety) Regulations 2006, insert—

“SCHEDULE 8

Regulation 9A

Format for safety certificates and applications

(This Schedule substantially reproduces the provisions of 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, with amendments for the purpose of addressing deficiencies arising out of the UK's withdrawal from the EU.)

PART 1

1. Where Part A of a safety certificate is to be issued, renewed, updated, amended or revoked by the Office of Rail and Road, it must be in the form provided in Part 2.

2. Where Part B of a safety certificate is to be issued, renewed, updated, amended or revoked by the Office of Rail and Road, it must be in the form provided in Part 3

3. An application for a new, updated, amended or renewed—

- (a) Part A of a safety certificate;
- (b) Part B of a safety certificate; or
- (c) Part A of a safety certificate and Part B of a safety certificate where a combined application is made,

must be made in the form provided in Part 4.

PART 2

Part A of a safety certificate

4. The form referred to in paragraph 1 follows.

Safety Certificate – Part A

Safety certificate confirming acceptance of the safety management system under the Railways and Other Guided Transport Systems (Safety) Regulations 2006(a)

Identification number

1. Certified railway undertaking

Legal denomination:	
Railway undertaking name:	Acronym:
Company registration number (if applicable) :	VAT No:

2. Organisation issuing certificate

Organisation: Office of Rail and Road

3. Certificate information

This is a	- first/new certificate	<input type="checkbox"/>	Identification number of the previous certificate:
	- further/renewed certificate	<input type="checkbox"/>	
	- updated/amended certificate	<input type="checkbox"/>	
Validity from:		to:	
Type(s) of service(s):			
Transportation volume:			
Railway undertaking size:			

4. Applicable legislation

The Railways and Other Guided Transport Systems (Safety) Regulations 2006

5. Additional information

--

(a) S.I. 2006/599.

Date issued

Internal reference number

Signature

Authority's stamp

PART 3

Part B of a safety certificate

5. The form referred to in paragraph 2 follows.

Safety Certificate – Part B

Safety certificate confirming acceptance of the provisions adopted by the railway undertaking to meet specific requirements necessary for the safe operation on the UK network under the Railways and Other Guided Transport Systems (Safety) Regulations 2006(a)

Identification number

1. Certified railway undertaking

Legal denomination:	
Railway undertaking name:	Acronym:
Company registration number (if applicable):	VAT No:

2. Certificate issuing organisation

Organisation: Office of Rail and Road

3. Certificate information

- first/new certificate	<input type="checkbox"/>	Identification number of the previous certificate:
This is a - further/renewed certificate	<input type="checkbox"/>	
- updated/amended certificate	<input type="checkbox"/>	
Validity from:	to:	
Type(s) of service(s):		

4. Safety certificate - Part A (acceptance of the safety management system)

Identification number:

5. Lines operated

--

6. Specific conditions and obligations

--

(a) S.I. 2006/599.

7. Applicable legislation

The Railways and Other Guided Transport Systems (Safety) Regulations 2006

Date issued

Signature _____

Internal reference number

ORR stamp

PART 4

Application form for a safety certificate

6. The form referred to in paragraph 3 follows.

SAFETY CERTIFICATE APPLICATION

Application for a safety certificate confirming acceptance of a railway undertaking's safety management system (Part A safety certificate) and/or confirming acceptance of provisions adopted by the railway undertaking to meet specific requirements necessary for safe operation on the UK network (Part B safety certificate)

Safety authority reference number

SAFETY ORGANISATION/AUTHORITY CONTACT INFORMATION

1.1 Safety organisation/authority addressed for the request

1.2 Complete postal address (street, postal code, city, country)

2.1 This application is for a PART A SAFETY CERTIFICATE

2.2 First/New certificate

2.4 Updated/amended certificate

2.3 Further/Renewed certificate

2.5 Identification number of the previous Part A safety certificate

Type(s) of service(s) requested (select one or more) and estimated total volume of goods/passengers

Passenger transport	2.6 including high-speed services	<input type="checkbox"/>	2.8 Less than 200 million passenger-km per year	<input type="checkbox"/>
	2.7 excluding high-speed services	<input type="checkbox"/>	2.9 200 million or more passenger-km per year	<input type="checkbox"/>

			—			—
	2.10	including dangerous goods services	<input type="checkbox"/>	2.12	Less than 500 million tonne-km per year	<input type="checkbox"/>
Freight transport						
	2.11	excluding dangerous goods services	<input type="checkbox"/>	2.13	500 million or more tonne-km per year	<input type="checkbox"/>
2.14	Shunting only		<input type="checkbox"/>			
2.15	Service to begin in		<hr/>			

The applying railway undertaking belongs to the following categories for estimated number of employees

2.16	Micro enterprise	<input type="checkbox"/>	2.18	Medium sized enterprise	<input type="checkbox"/>
2.17	Small enterprise	<input type="checkbox"/>	2.19	Large enterprise	<input type="checkbox"/>

3.1 **This application is for a PART B SAFETY CERTIFICATE**

3.2	First/New certificate	<input type="checkbox"/>	3.4	Updated/amended certificate	<input type="checkbox"/>
3.3	Further/Renewed certificate	<input type="checkbox"/>	3.5	Identification number of the previous Part B safety certificate	<input type="checkbox"/>

Type(s) of service(s) requested and estimated volume of goods/passengers on the network where Part B will apply (one or more to be selected)

Passenger transport	3.6	including high-speed services	<input type="checkbox"/>	3.8	Less than 200 million passenger-km per year	<input type="checkbox"/>
	3.7	excluding high-speed services	<input type="checkbox"/>	3.9	200 million or more passenger-km per year	<input type="checkbox"/>
Freight transport	3.10	including dangerous goods services	<input type="checkbox"/>	3.12	Less than 500 million tonne-km per year	<input type="checkbox"/>
	3.11	excluding dangerous goods services	<input type="checkbox"/>	3.13	500 million or more tonne-km per year	<input type="checkbox"/>
3.14	Shunting only		<input type="checkbox"/>			
3.15	Service to begin in		_____			
3.16	Lines intended to be operated					

If the applicant already holds a valid Part A safety certificate (acceptance of the safety management system) it should provide the following information

3.17 Identification number of Part A safety certificate _____

3.18 Organisation that has issued Part A safety certificate _____

IF THE APPLICANT ALREADY HOLDS ONE (OR MORE) VALID PART B CERTIFICATE(S) IT SHOULD PROVIDE THE FOLLOWING INFORMATION

4.1 Identification number(s) of issued Part B safety certificate(s) _____

IF THE APPLICANT HAS AN OPERATOR LICENCE AND IS APPLYING FOR PART A AND/OR PART B CERTIFICATE(S) IT SHOULD PROVIDE THE FOLLOWING INFORMATION

4.2 Notification number of the licence _____

4.3 Organisation that has issued the licence _____

APPLICANT'S INFORMATION

5.1 Legal denomination _____

5.2 Railway undertaking name _____ 5.3 Acronym _____

5.4 Complete postal address (street, postal code, city, country) _____

5.5 Phone number _____ 5.6 Fax number _____

5.7 Email address _____ 5.8 Website _____

5.9 Company registration number _____ 5.10 VAT No _____

5.11 Other information _____

Contact person information

6.1 Family name and first name _____

6.2 Complete postal address (street, postal code, city, country) _____

6.3 Phone number _____ 6.4 Fax number _____

6.5 Email address _____

Applicant

(first name, family name)

Date _____

Signature _____

Internal reference number _____

Date application received _____

SPACE RESERVED FOR THE ADDRESSED OFFICE/AUTHORITY

**FRONT PAGE FOR ANNEXES
TO THE APPLICATION FORM**

DOCUMENTS SUBMITTED FOR

PART A

7.1 Summary of the manual of the safety management system

7.2 Copy of the operator licence (if applicable)

7.3 Not applicable

PART B

8.1 Copy of the Part A safety certificate

8.2 Copy of the operator licence (if applicable)

8.3 Not applicable

8.4 Copy of insurance or financial cover for liability, annexed to the operator licence

8.5 List of necessary rules and TSIs with reference to the processes in the safety management system and documents and how they are implemented

8.6 List of different categories of staff, either employed or contracted

8.7 Description of staff related processes of the safety management system required by national rules or TSIs and reference to the national relevant certificates where necessary

—

8.8 List of different types of rolling stock

8.9 Description of rolling stock related processes in the safety management system required by national rules or TSIs and reference to the national relevant certificates where necessary

8.10 Other (specify)

Internal reference number

Date application received

SPACE RESERVED FOR THE
ADDRESSED OFFICE/AUTHORITY

GUIDELINES FOR COMPILATION

Information to be entered into the Application Form for
Safety Certificates Part A and Part B

INTRODUCTION

This application form is to be used by railway undertakings applying for a Part A or Part B safety certificate. References in this document are made, unless otherwise mentioned, to the Railways and Other Guided Transport Systems (Safety) Regulations 2006 ("ROGS")(a).

A railway undertaking applying for either one of these certificates or both should use this application form to forward its request to the Office of Rail and Road as the safety authority. Its use will enable the authority to process the request without undue delay and within the terms fixed in ROGS regulation 7(3). Fields in the form should be completed in accordance with the information given below.

Key terms used in these Guidelines are explained in the Glossary at the end.

Safety Certificates Part A and Part B

This document allows a railway undertaking to apply either for a first/new Part A or Part B Certificate separately, or for both simultaneously. It can also be used to request either a further/renewed or updated/amended Part A and/or Part B certificate (as defined in ROGS regulations 8 and 9). It is possible to apply for a first/new Part A certificate alone, with a later, second application, for a first Part B Certificate. If applying only for a Part B certificate, it is necessary to hold a valid Part A Certificate.

Type and extent of railway operations

In accordance with regulation 8 of ROGS a safety certificate must be wholly or partly updated whenever the type or extent of the operation is substantially altered. Therefore it is important for the railway undertaking to make the "type" and "extent" of its total railway operations known to the safety authority.

"Type" of service is defined by the following categories:

- passenger transport, including high speed services, or
- passenger services excluding high-speed services;
- freight transport including dangerous goods services; or
- freight transport excluding dangerous goods service;
- shunting services only.

"Extent" of service and of the railway undertaking is characterised by volume of passengers/goods and the estimated size of the railway undertaking in terms of employees working in the railway sector (micro, small, medium sized, large enterprise).

"Type" and "extent" of services for all Part B certificates, carried out by the same railway undertaking, must be covered by "type" and "extent" of services of the corresponding Part A certificate.

All the information contained in fields 2.6 to 2.19 and 3.6 to 3.16 is necessary to establish if services intended to be operated with the requested Safety Certificate are equivalent or not to other rail transport operations already carried out by the applicant under any existing valid certificate(s).

(a) S.I. 2006/599, which has been amended insofar as is relevant by S.I. 2007/950, 2013/950, 2011/1043, 2011/1860, 2011/3066, 2015/1682 and 2015/1917.

ADDITIONAL INFORMATION

Page 3 of the application form is intended as a reminder of the documents that must accompany each application. It is for use as a reference list both for the applicant and for the issuing organisation/authority and therefore is to be used as the front page of the annexes to the application form (each box must be checked according to the specific cases).

For easy reference and guidance, each field in the application form has been numbered and explained in the following pages.

A person authorised to approve the request submitted with the application form must sign the document, in the appropriate space, delivered to the safety organisation/authority. The name of the signing person must also be spelled out.

EXPLANATIONS AND INSTRUCTIONS FOR USE

- 1.1.- Name and address of the safety authority/organisation to which the application is being sent.
- 1.2. You should send this to the Office of Rail and Road at the relevant regional office.

- 2.1. If the application is for a Part A safety certificate, you should tick this box. You should then indicate the type and extent of the railway undertaking's services in boxes 2.6-2.19.
- 2.2. Select this box:
 - a) if applying for a Part A safety certificate for the first time;
 - b) if the previous safety certificate, for the same type and extent of service, was revoked; or
 - c) for any other case not covered by the following fields 2.3 and 2.4.
- 2.3. Select this box if applying to renew an existing safety certificate (to be renewed at intervals not exceeding five years (ROGS regulations 7(4)(c) and 9).
- 2.4. Select this box whenever the type or extent of the operation of a railway undertaking is to be substantially altered. You should submit your application and have it accepted before the substantial alterations(s) are introduced (ROGS regulation 8).
- 2.5. Where applicable, you should specify the identification number of your previous Part A certificate (in general, for renewals and amendments this will be the number of the one which is still current at the time of application).
- 2.6.- For passenger services, you should specify if the operations will include or exclude high-speed services. Whichever is selected, they are both inclusive of other type of passenger transport (i.e. regional, short, medium, long distance etc.) as well as of any other service necessary to carry out the passenger services (shunting operations, etc.). High-speed services shall comprise those on specially built high-speed lines equipped for speeds generally equal to or greater than 250 km/h: specially upgraded high-speed lines equipped for speeds of the order of 200 km/h, or specially upgraded high-speed lines which have special features as a result of topographical, relief or town planning constraints, on which the speed must be adapted to each case. This category also includes interconnecting lines between high-speed and conventional methods,
- 2.7.

lines through stations, accessed terminals, depots, etc. travelled at conventional speed by “high-speed” rolling stock.

- 2.8.- When applying for passenger services you should specify the estimated current or planned volume, in terms of passenger-km per year. Only one option should be selected.
- 2.9.
- 2.10.- For freight services, you should specify if the operations will include or exclude transport of dangerous goods. Whichever is selected, both are inclusive of any other type of freight transport not explicitly mentioned as well as any other service necessary to carry out the freight services (shunting operations, etc.). Railway undertakings carrying out rail transport services for internal railway needs only (e.g. track maintenance companies transferring working machines from one site to another or companies operating measurement trains) should be categorised as operating freight services (excluding dangerous goods).
- 2.11.
- 2.12.- When applying for freight services you should specify the estimated current or planned volume, in terms of tonne-km per year. Only one option should be selected.
- 2.13.
- 2.14. If you only intend to carry out shunting services without performing passenger or freight transport, then you should select box 3.
- 2.15. You should enter the date on which this service is intended to begin or, in the case of a renewed or amended certificate, the date on which the certificate is intended to become effective and replace the previous one.
- 2.16. If the number of employees working in all railway related activities, including contractors, is between 0 (thus providing only a job for the entrepreneur) and 9 persons, then you should select the option “Micro enterprise”. Only one option can be chosen among those available (2.16, 2.17, 2.18, 2.19).
- 2.17. If the number of employees working in all railway related activities, including contractors, is between 10 and 49 persons, then you should select the option “Small enterprise”.
- 2.18. If the number of employees working in all railway related activities, including contractors, is between 50 and 249 persons, then you should select the option “Medium sized enterprise”.
- 2.19. If the number of employees working in all railway related activities, including contractors, is 250 or more persons, then you should select the option “Large enterprise”.
- 3.1. If the application is for a Part B safety certificate you should tick this box. You should then indicate the type and extent of the railway undertaking's services for which the Part B application is made in boxes 3.6-3.14.
- 3.2. You should select this box:
- a) if applying for the first or any other new Part B safety certificate;
 - b) if the previous safety certificate, for the same type and extent of service, has been revoked;

- c) in any other case not covered by the following fields 3.3 and 3.4.
- 3.3. You should select this box if applying to renew your existing safety certificate (to be renewed at intervals not exceeding five years (ROGS regulations 7(4)(c) and 9)).
- 3.4. You should select this box whenever the type or extent of the operation of a railway undertaking is to be substantially altered. You should submit your application and have it accepted before the substantial alteration(s) is introduced (ROGS regulation 8).
- 3.5. Where applicable, you should specify the identification number of your previous Part B safety certificate (in general where making a renewal or amendment application, this will be the number of the one which is still current).
- 3.6.-3.7. Same as 2.6, 2.7 (see above).
- 3.8.-3.9. Same as 2.8, 2.9 (see above).
- 3.10.-3.11. Same as 2.10, 2.11 (see above).
- 3.12.-3.13. Same as 2.12, 2.13 (see above).
- 3.14. Same as 2.14 (see above).
- 3.15. Same as 2.15 (see above).
- 3.16. A Part B safety certificate may cover the whole railway network or only a defined part of it. You should therefore specify clearly all the lines where services (passenger, freight or shunting only) are intended to be operated. The names of the lines are those given in the Network Statement: railway undertakings must refer to the lines using these denominations/names. If the available space is not sufficient, the applicant must provide annexes to the application form and use this field to specify them.
- 3.17. You should only provide this information if you are applying for a new, renewed or updated/amended Part B safety certificate and already hold a valid Part A safety certificate. A copy of the Part A safety certificate should also be included with this application (see 8.1). If a Part A certificate is being applied for concurrently with the Part B you should write 'NOT APPLICABLE'.
- 3.18. You should enter the member State which issued the Part A safety certificate if applicable.
- 4.1. You should provide the identification number(s) of any existing valid Part B safety certificate(s) which you hold. It is not necessary for the applicant to submit a copy or copies of the Part B safety certificate(s) with the application.
- 4.2. This information is to be provided for either Part A and/or Part B safety certificates where the railway undertaking already has a valid operator licence. The information does not exempt you from submitting a copy of the licence together with the application.

Note: if you have a licence issued under the section 6 of the Railways Act 1993, you should enter the reference number here.

- 4.3. Where the operator licence was issued in a member State or an EEA state, you should enter the state which issued the licence.
- 5.1. If legal denomination and railway undertaking name differ, then both shall be included.
- 5.2.- 5.8. You should provide the necessary information to allow the issuing body to contact the railway undertaking. Telephone numbers should indicate the general contact number for the undertaking rather than the direct line of the person in charge of the certification process; telephone and fax numbers should include the country code; the e-mail address should refer to the general e-mail address of the railway undertaking; specification of the website (5.8) is not compulsory. The railway undertaking's contact information should indicate the company's main address or head office, avoiding references to specific person(s) (which should be given at 6.1 to 6.5).
- 5.9.- 5.10. The company registration number should relate to the railway undertaking for which the application is being made. If this differs between the Parts A and B applications then you should enter both and make it clear which is which. Similarly, this applies to VAT numbers.
- 5.11. Information, other than that clearly requested in the other fields, can be added if necessary.
- 6.1.- 6.5. During the certification process, the contact person is the interface between the railway undertaking submitting the request and the ORR. He/she provides support, assistance, information, clarifications, where necessary, and is the reference point for the ORR.
- 7.1. You should submit this documentation if applying for a Part A safety certificate (new, renewed or updated/amended certificate); 'Summary of the manual of the Safety Management System' means a document outlining the main elements of the railway undertaking's Safety Management System required under regulation 5 of and Schedule 1 to ROGS (in the case of a renewal or amendment application, this only needs to be for those parts of the SMS where there has been a change of information from the previously submitted documentation).
- 7.2. A railway undertaking must be licensed in accordance with the Operator Licensing Regulations. If a railway undertaking does not require a licence in accordance with those regulations you do not need to submit a copy of a valid licence and should select the 'Not applicable' option. If a licence has been applied for and not yet approved, refer to 4.2.
- 7.3. Refer to 7.2.
- 8.1. If the application is for a Part B safety certificate only (new, renewed or updated/amended certificate), then you should submit a copy of the valid Part A safety certificate.
- 8.2. Same as 7.2 (see above).
- 8.3. Same as 7.3 (see above).
- 8.4. A railway undertaking must be adequately insured or make equivalent arrangements (e.g. a financial guarantee) to cover its liabilities in the event of accidents in accordance with all applicable legal requirements. You are therefore required to submit details of the insurance or financial cover for liability with a safety certificate application.

- 8.5 You must list or submit documentation on the TSIs or parts of the TSIs and, where relevant, of the national safety rules and other rules applicable to staff, rolling stock and, in general, to the services intended to be operated with the requested certificate. Clear reference should be made to the processes and documents where the TSIs are applicable and implemented.
- 8.6 You must submit a complete list of the different categories of staff employed or contracted for services intended to be operated with the requested certificate.
- 8.7 You must submit a description or evidence of those processes within the Safety Management System that are related to staff, including evidence that they meet the requirements of the national rules and/or relevant TSIs and that the staff have been duly certified where relevant.
- 8.8 You must submit documentation on the different types of rolling stock intended to be operated with the requested certificate.
- 8.9 You must provide a description or evidence of those processes within the safety management system that are related to rolling stock, including evidence that they meet requirements of the national rules and/or relevant TSIs and that the rolling stock has been duly certified according to the requirements of the Railways (Interoperability) Regulations 2011(a).
- 8.10 Available space to specify other documents submitted with the application. Please identify number and type, together with a short description of the content of the document.

GLOSSARY OF TERMS

The following terms have the meanings given to them for the purposes of these Guidelines—

“dangerous goods” means those substances the carriage of which is prohibited by RID, or authorised only under the conditions prescribed therein;

“national rule” means notified national rules as defined in the Railways (Interoperability) Regulations 2011(b) and national safety rules as defined in the Railways and Other Guided Transport Systems (Safety) Regulations 2006;

“Network Statement” means the network statement required under regulation 13 of the Railways (Access, Management and Licensing of Railway Undertakings) Regulations 2016(e);

“operator licence” means any licence which authorises a person to provide a train service in Great Britain for the purposes of regulation 5 of the Operator Licensing Regulations;

“Operator Licensing Regulations” means the Railway (Licensing of Railway Undertakings) Regulations 2005(d);

“ORR” means the Office of Rail and Road(e);

“RID” means the Annex to the Regulation concerning the international carriage of dangerous goods by rail which forms Appendix C to the Convention Concerning International Carriage by Rail (COTIF)(f).

(a) S.I. 2011/3066.

(b) S.I. 2011/3066.

(c) S.I. 2016/645.

(d) S.I. 2005/3050.

(e) The Office of Rail and Road was established by section 15 of the Railways and Transport Safety Act 2003 as the Office of Rail Regulation and subsequently renamed by the Office of Rail Regulation (Change of Name) Regulations 2015/1682.

(f) January 2019 edition, <https://cit-rail.org/en/rail-transport-law/cotif/>. COTIF is given effect under the Railways (Convention on International Carriage by Rail) Regulations 2005 (S.I. 2005/2092).

SCHEDULE 9

Regulation 18A(4)

Applications for UK-issued ECM certificates by entities in charge of maintenance

(This Schedule substantially reproduces Annexes IV and V of 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, with amendments for the purpose of addressing deficiencies arising out of the UK's withdrawal from the EU.)**(a)**

PART 1

- 1.** Applications to certification bodies must be made—
 - (a) where the applicant is an entity in charge of maintenance for freight wagons applying for a UK-issued ECM certificate, in the form provided in Part 2;
 - (b) where the applicant is a contractor applying for a maintenance functions certificate, in the form provided in Part 3.
- 2.**—(1) A UK-issued ECM certificate must be issued in the form provided in Part 4.
(2) A maintenance functions certificate must be issued in the form provided in Part 5.
- 3.** For the purposes of this Schedule, a “maintenance functions certificate” is a certificate issued pursuant to paragraph 8 of Schedule 10.

(a) The operative provisions of Commission Regulation (EU) No 445/2011 are substantially reproduced in Schedule 10.

PART 2

Application for a UK-issued ECM certificate

4. The application form referred to in paragraph 1(a) follows.

Application for a UK-issued ECM Certificate

Application for a certification confirming acceptance of the maintenance system of an entity in charge of maintenance (ECM) in conformity with the Railways and Other Guided Transport Systems (Safety) Regulations 2006

Certification body contact information

- 1.1 Organisation addressed for the application _____
- 1.2 Certification body reference number _____
- 1.3 Complete postal address (street, postal code, city, country) _____

Applicant information

- 2.1 Legal title _____
- 2.2 Complete postal address (street, postal code, city, country) _____

- 2.3 Phone number _____ 2.4 Fax number _____
- 2.5 Email address _____ 2.6 Website _____
- 2.7 Registration business No. _____ 2.8 VAT No. _____

2.9 Other information _____

Contact person information

3.1 Family name and first name _____

3.2 Complete postal address (street, postal code, city, country) _____

3.3 Phone number _____ 3.4 Fax number _____

3.5 Email address _____

Application details

4.1 Application reference (given by the applicant)

This application is for a

4.2 New certificate 4.3 Updated/amended certificate

4.4 Renewal certificate

Operational details

Type of company

5.1 RU/IM 5.2 Keeper

5.3 Others Specify: _____

Scope of activities

5.4 Covers tank wagons for dangerous goods YES/NO
Covers other wagons specialised in transport of dangerous goods YES/NO

5.5 Maintenance development 5.5.1 5.5.2 5.5.3
5.6 Fleet maintenance management 5.6.1 5.6.2 5.6.3
5.7 Maintenance delivery 5.7.1 5.7.2 5.7.4

Submitted documents

6.1 Maintenance system documentation

6.2 Others Specify: _____

Signatures

Applicant _____
(first name, family name)

Date _____ Signature: _____

Certification Body _____

Internal reference Number _____

Date application received _____

Date _____ Signature: _____

SPACE RESERVED FOR THE ADDRESSED OFFICE /AUTHORITY

PART 3

Application for a maintenance functions certificate

5. The form referred to in paragraph 1(b) follows.

Application for a Maintenance Functions Certificate

Application for a certification confirming acceptance of the maintenance system in conformity with the Railways and Other Guided Transport Systems (Safety) Regulations 2006.

Certification body contact information

1.1 Organisation addressed for the application _____

1.2 Certification body reference number _____

1.3 Complete postal address (street, postal code, city, country) _____

Applicant information

2.1 Legal title _____

2.2 Complete postal address (street, postal code, city, country) _____

2.3 Phone number _____ 2.4 Fax number _____

2.5 Email address _____ 2.6 Website _____

2.7 Registration business No. _____ 2.8 VAT No. _____

2.9 Other information _____

Contact person information

3.1 Family name and first name _____

3.2 Complete postal address (street, postal code, city, country) _____

3.3 Phone number _____ 3.4 Fax number _____

3.5 Email address _____

Application details

4.1 Application reference (given by the applicant)
This application is for a

4.1.1 New certificate 4.1.2 Updated/amended certificate

4.1.3 Renewal certificate

Operational details

Type of company

5.1 RU/IM 5.2 Keeper

5.3 Others Specify: _____

Scope of activities

- 5.4 Covers tank wagons for dangerous goods YES/NO
Covers other wagons specialised in transport of dangerous goods YES/NO
- 5.5 Maintenance development Yes No Partial
5.6 Fleet maintenance management Yes No Partial
5.7 Maintenance delivery Yes No Partial

For partial maintenance functions, the sub-functions for which the application is submitted

Submitted documents

- 6.1 Maintenance system documentation
- 6.2 Others Specify: _____

Signatures

Applicant _____
(first name, family name)

Date _____ Signature: _____

Certification Body _____

Internal reference number _____

Date application received _____

6.2 Others Specify: _____

Date _____ Signature: _____

SPACE RESERVED FOR THE ADDRESSED OFFICE /AUTHORITY

PART 4

UK-issued ECM certificate

6. The form referred to in paragraph 2(1) follows.

UK-issued ECM certificate

Confirming acceptance of the maintenance system of an entity in charge of maintenance (ECM) in conformity with the Railways and Other Guided Transport Systems (Safety) Regulations 2006.

1. Certified entity in charge of maintenance

Legal title:	
Commercial designation or acronym (voluntary):	
Complete postal address (street, postal code, city, country):	
Registration Business No:	VAT No:

2. Certification body

Legal title:
Complete postal address (street, postal code, city, country):
Certification body reference number:

3. Certification information

This is a	- new certificate	<input type="checkbox"/>	EU ECM or UK-issued ECM identification number of the previous certificate:
	- renewed certificate	<input type="checkbox"/>	
	- updated/amended certificate	<input type="checkbox"/>	
Validity from:		to:	
Type of company: (railway undertaking keeper, maintenance supplier, etc.)			

4. Scope of ECM activities

Covers tank wagons for dangerous goods	Yes/No
Covers other wagons specialised in transport of dangerous goods	Yes/No

5. Additional information

--

Date issued and validity	
Signature	
Internal reference number	
Certification body's stamp	

PART 5

Maintenance functions certificate

7. The form referred to in paragraph 2(2) follows.

Maintenance Functions Certificate

Confirming acceptance of the maintenance system in conformity with the Railways and Other Guided Transport Systems (Safety) Regulations 2006.

1. Certified organisation

Legal title:	
Commercial designation or acronym (voluntary):	
Complete postal address (street, postal code, city, country):	
Registration Business No:	VAT No:

2. Certification body

Legal title:
Complete postal address (street, postal code, city, country):
Certification body reference number:

3. Certification information

This is a	- new certificate	<input type="checkbox"/>	EU ECM or UK-issued ECM Identification Number of the previous certificate:
	- renewed certificate	<input type="checkbox"/>	
	- updated/amended certificate	<input type="checkbox"/>	
Validity from:		to:	
Type of company: Railway Undertaking (railway undertaking keeper, maintenance supplier, etc.)			

4. Scope of maintenance activities

Covers tank wagons for dangerous goods	Yes/No
Covers other wagons specialised in transport of dangerous goods	Yes/No

5. Maintenance functions

Maintenance development	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Fleet maintenance management	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Maintenance delivery	Yes <input type="checkbox"/>	No <input type="checkbox"/>

For partial maintenance functions, the sub-functions for which this certificate is valid

6. Additional information

Date issued and validity	
Signature	
Internal reference number	
Certification body's stamp	

System of certification of entities in charge of maintenance in respect of Great Britain

(This Schedule substantially reproduces the provisions of 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 other than Annexes IV and V, with amendments for the purpose of addressing deficiencies arising out of the UK's withdrawal from the EU.)(a)

PART 1

Principles

Purpose

1. This Schedule sets out a system of certification of entities in charge of maintenance for freight wagons for the purpose of providing evidence that such an entity has established its maintenance system and can meet the requirements for ensuring the safe state of running of any freight wagon for which it is in charge of maintenance.

Scope

2.—(1) The system of certification applies to any entity in charge of maintenance for freight wagons to be used on the railway network within Great Britain.

(2) Maintenance workshops or any organisation taking on a subset of the functions specified in paragraph 4 may apply the system of certification on a voluntary basis, based on the principles specified in paragraph 8 and Part 2.

(3) References to an infrastructure manager in paragraphs 5 and 7 are to be understood as relating to its operations with freight wagons for transporting materials for construction or for infrastructure maintenance activities. When it operates freight wagons for this purpose, an infrastructure manager is to be deemed to do so in the capacity of a railway undertaking.

Interpretation

3. In this Schedule—

“accreditation” has the meaning in 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;

“causes” means actions, omissions, events or conditions, or a combination thereof, which led to the accident or incident;

“common safety methods” (“CSMs”) means the methods developed to describe how safety levels and achievement of safety targets and compliance with other safety requirements are assessed;

“designated standard” has the meaning provided in Article 3A of Commission Implementing Regulation (EU) No 402/2013 on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009, as it has effect in Great Britain;

(a) Annexes IV and V of Commission Regulation (EU) No 445/2011 are substantially reproduced in Schedule 9.

“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;

“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;

“maintenance workshop” means a mobile or fixed entity composed of staff, including those with management responsibility, tools and facilities organised to deliver maintenance of vehicles, parts, components or sub-assemblies of vehicles;

“national safety authority” means one or both of the safety authority in Great Britain and the safety authority for the tunnel system;

“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;

“release to service” means the assurance given to the fleet maintenance manager by the entity delivering the maintenance that maintenance has been delivered according to the maintenance orders;

“return to operation” means the assurance, based on a release to service, given to the user, such as a railway undertaking or a keeper, by the entity in charge of maintenance that all appropriate maintenance works have been completed and the wagon, previously removed from operation, is in a condition to be used safely, possibly subject to temporary restrictions of use.

Maintenance system

4.—(1) The maintenance system is to be composed of the following functions—

- (a) the management function, which supervises and coordinates the maintenance functions referred to in paragraphs (b) to (d) and ensures the safe state of the freight wagon in the railway system;
- (b) the maintenance development function, which is responsible for the management of the maintenance documentation, including the configuration management, based on design and operational data as well as on performance and return on experience;
- (c) the fleet maintenance management function, which manages the freight wagon’s removal for maintenance and its return to operation after maintenance;
- (d) the maintenance delivery function, which delivers the required technical maintenance of a freight wagon or parts of it, including the release to service documentation.

(2) The entity in charge of maintenance must ensure that the functions referred to in sub paragraph (1) comply with the requirements and assessment criteria set out in Part 4.

(3) The entity in charge of maintenance must carry out the management function itself, but may outsource the maintenance functions referred to in paragraphs (b) to (d) of sub paragraph (1), or parts of them, to other contracting parties subject to the provisions of paragraph 8. Where it resorts to outsourcing, the entity in charge of maintenance must ensure that the principles set out in Part 2 are applied.

(4) Regardless of the outsourcing arrangements in place, the entity in charge of maintenance is responsible for the outcome of the maintenance activities it manages and must establish a system to monitor performance of those activities.

Relationships between parties in the maintenance process

5.—(1) Each railway undertaking or infrastructure manager must ensure that the freight wagons it operates, before their departure, have a certified entity in charge of maintenance and that the use of the wagon corresponds to the scope of the certificate.

(2) All parties involved in the maintenance process must exchange relevant information about maintenance in accordance with the criteria listed in paragraphs 27 and 28.

(3) Following contractual arrangements, a railway undertaking may request information for operational purposes on the maintenance of a freight wagon. The entity in charge of the maintenance of the freight wagon must respond to such requests either directly or through other contracting parties.

(4) Following contractual arrangements, an entity in charge of maintenance may request information on the operation of a freight wagon. The railway undertaking or the infrastructure manager must respond to such requests either directly or through other contracting parties.

(5) All contracting parties must exchange information on safety-related malfunctions, accidents, incidents, near-misses and other dangerous occurrences as well as on any possible restriction on the use of freight wagons.

(6) The certificates of entities in charge of maintenance are to be accepted as proof of the ability of a railway undertaking or infrastructure manager to meet the requirements governing maintenance and the control of contractors and suppliers specified in Part 3, points in B.1, B.2, B.3 and C.1 of Commission Regulation (EU) No 1158/2010 of 9th December 2010 on a common safety method for assessing conformity with the requirements for obtaining railway safety certificates as it has effect in Great Britain, and in Commission Regulation (EU) No 1169/2010 of 10th December 2010 on a common safety method for assessing conformity with the requirements for obtaining a railway safety authorisation as it has effect in Great Britain, unless the national safety authority can demonstrate the existence of a substantial safety risk.

(7) If a contracting party, in particular a railway undertaking, has a justifiable reason to believe that a particular entity in charge of maintenance does not comply with the requirements of regulation 18A, or with paragraph 55B of the Schedule to the Channel Tunnel (Safety) (Amendment) Order 2013, or with the certification requirements of this Schedule, it must promptly inform the certification body thereof. The certification body must take appropriate action to check if the claim of non-compliance is justified and must inform the parties involved, including the competent national safety authority if relevant, of the results of its investigation.

(8) When there is a change of entity in charge of maintenance, the registration holder must inform in due time the registration entity, as defined in the Interoperability Regulations, so that the latter may update the National Vehicle Register.

(9) The former entity in charge of maintenance must deliver the maintenance documentation to either the registration holder or the new entity in charge of maintenance.

(10) The former entity in charge of maintenance is relieved of its responsibilities when it is removed from the National Vehicle Register. If on the date of de-registration of the former entity in charge of maintenance any new entity has not acknowledged its acceptance of entity in charge of maintenance status, the registration of the vehicle is suspended.

Certification bodies

6.—(1) UK-issued ECM certificates may be awarded by any competent certification body, chosen by the applicant entity in charge of maintenance.

(2) Certification bodies must comply with the general criteria and principles set out in Part 3 and with any subsequent sectoral accreditation schemes.

(3) Decisions taken by the certification bodies are subject to judicial review.

(4) In order to harmonise approaches to the assessment of applications, certification bodies within the United Kingdom must cooperate with each other.

System of certification for entities in charge of maintenance

7.—(1) Certification must be based on an assessment of the ability of the entity in charge of maintenance to meet the relevant requirements in Part 4 and to apply them consistently. It must include a system of surveillance to ensure continuing compliance with the applicable requirements after award of the UK-issued ECM certificate.

(2) The entities in charge of maintenance must apply for certification using the form in Part 2 of Schedule 9 and providing documentary evidence of the procedures specified in Part 4. They must promptly submit all supplementary information requested by the certification body. In assessing applications, certification bodies must apply the requirements and assessment criteria set out in Part 4.

(3) The certification body must take a decision no later than 4 months after all the information required and any supplementary information requested has been submitted to it by the entity in charge of maintenance applying for the certificate. The certification body must undertake the necessary assessment at the site or sites of the entity in charge of maintenance prior to the award of the certificate. The decision on the award of the certificate must be communicated to the entity in charge of maintenance using the relevant form in Part 4 of Schedule 9.

(4) A UK-issued ECM certificate is valid for a period up to 5 years. The holder of the certificate must without delay inform the certification body of all significant changes in the circumstances applying at the time the original certificate was awarded to allow the certification body to decide whether to amend, renew or revoke it.

(5) The certification body must set out in detail the reasons on which each of its decisions is based. The certification body must notify its decision and the reasons to the entity in charge of maintenance, together with an indication of the process, time limit for appeal and the contact details of the appeal body.

(6) The certification body must conduct surveillance at least once a year at selected sites, geographically and functionally representative of all the activities of those entities in charge of maintenance it has certified, to verify that the entities still satisfy the criteria set out in Part 4.

(7) If the certification body finds that an entity in charge of maintenance no longer satisfies the requirements on the basis of which it issued the UK-issued ECM certificate, it must agree an improvement plan with the entity in charge of maintenance, or limit the scope of application of the certificate, or suspend the certificate, depending on the degree of non-compliance. In the event of continuous non-compliance with the certification requirements or any improvement plan, the certification body must limit the scope of or revoke the UK-issued ECM certificate, giving reasons for its decision, together with an indication of the process and time limit for appeal and the contact details of the appeal body.

(8) When a railway undertaking or an infrastructure manager applies for a safety certificate or safety authorisation, the following provisions apply concerning the freight wagons it uses—

- (a) where the freight wagons are maintained by the applicant, either the applicant must include as part of its application a valid UK-issued ECM certificate, if available, or its capacity as entity in charge of maintenance must be assessed as part of its application for a safety certificate or safety authorisation;
- (b) where the freight wagons are maintained by parties other than the applicant, the applicant must ensure, through its safety management system, the control of all

risks related to its activity, including the use of such wagons, whereby, in particular, the provisions of paragraph 5 apply.

(9) Certification bodies and national safety authorities must conduct an active exchange of views in all circumstances in order to avoid any duplication of assessment.

System of certification for outsourced maintenance functions

8.—(1) Where the entity in charge of maintenance decides to outsource one or more of the functions referred to in paragraph 4(1)(b), (c) and (d), or parts of them, voluntary certification of the contractor under the certification system of this Schedule creates a presumption of conformity of the entity in charge of maintenance with the relevant requirements set out in Part 4, as far as these requirements are covered by the voluntary certification of the contractor. In the absence of such certification, the entity in charge of maintenance must demonstrate to the certification body how it complies with all the requirements set out in Part 4 with regard to the functions it decides to outsource.

(2) The contractors referred to in sub-paragraph (1) must apply for certification using the relevant form in Part 3 of Schedule 9. Certification in respect of outsourced maintenance functions, or parts of them, must be issued by the certification bodies, following the same procedures in paragraphs 6 and 7, adapted to the specific case of the applicant. In assessing applications for certificates in respect of outsourced maintenance functions, or parts of them, certification bodies must follow the principles set out in Part 2.

Role of the supervision regime

9. If a national safety authority has a justified reason to believe that a particular entity in charge of maintenance does not comply with the requirements of regulation 18A or with paragraph 55B of the Schedule to the Channel Tunnel (Safety) (Amendment) Order 2013 or with the certification requirements of this Schedule, it must immediately take the necessary decision and inform the Secretary of State, the certification body and other interested parties of its decision.

PART 2

Principles to be used for organisations applying for a certificate in respect of maintenance functions outsourced by an entity in charge of maintenance

10. For certification of an entity or organisation taking on one or more of the functions referred to in paragraph 4(1)(b), (c) and (d), or parts of them, the following requirements and assessment criteria contained in Part 4 apply—

- (a) requirements and assessment criteria set out in section 1 of Part 4, adapted to the organisation's type and extent of service;
- (b) requirements and assessment criteria describing the specific maintenance function or functions.

11. For certification of a maintenance workshop taking on the maintenance delivery function, the following requirements and assessment criteria contained in Part 4 apply—

- (a) the requirements and assessment criteria set out in section 1 of Part 4, which must be adapted to the specific activity of a maintenance workshop providing the maintenance delivery function;
- (b) the processes describing the maintenance delivery function.

PART 3

Criteria for accreditation or recognition of certification bodies involved in the assessment and award of UK-issued ECM certificates

Organisation

12. The certification body must document its organisational structure, showing the duties, responsibilities and authorities of management and other certification staff and any committees. Where the certification body is a defined part of a legal entity, the structure must include the line of authority and the relationship to other parts within the same legal entity.

Independence

13. The certification body must be organisationally and functionally independent in its decision-making from railway undertakings, infrastructure managers, keepers, manufacturers and entities in charge of maintenance and must not provide similar services. The independence of the staff responsible for the certification checks must be guaranteed. No official must be remunerated on the basis of either the number of checks performed or the results of those checks.

Competence

14.—(1) The certification body and the staff deployed must have the required professional competence, in particular regarding the organisation of the maintenance of freight wagons and the appropriate maintenance system.

(2) The certification body must demonstrate—

- (a) sound experience in assessing management systems;
- (b) knowledge of the applicable requirements of the legislation.

(3) The team established for surveillance of the entities in charge of maintenance must be experienced in the relevant fields, and in particular must demonstrate—

- (a) appropriate knowledge and understanding of the applicable legislation;
- (b) relevant technical competence;
- (c) a minimum of 3 years of relevant experience in maintenance in general;
- (d) sufficient experience in freight wagon maintenance or at least in maintenance in equivalent industrial sectors.

Impartiality

15. The certification body's decisions must be based on objective evidence of conformity or non-conformity obtained by the certification body, and must not be influenced by other interests or by other parties.

Responsibility

16. The certification body is not responsible for ensuring ongoing conformity with the requirements for certification. The certification body has the responsibility to assess sufficient objective evidence upon which to base a certification decision.

Openness

17. A certification body needs to provide public access to, or disclosure of, appropriate and timely information about its audit process and certification process. It also needs to provide information about the certification status, including the granting, extension,

maintenance, renewal, suspension, reduction in scope, or withdrawal of certification, of any organisation, in order to develop confidence in the integrity and credibility of certification. Openness is a principle of access to, or disclosure of, appropriate information.

Confidentiality

18. To gain the privileged access to information needed to assess conformity with the requirements for certification adequately, a certification body must keep confidential any commercial information about a client.

Responsiveness to complaints

19. The certification body must establish a procedure to handle complaints about decisions and other certification-related activities.

Liability and financing

20. The certification body must be able to demonstrate that it has evaluated the risks arising from its certification activities and that it has adequate arrangements, including insurance or reserves, to cover liabilities arising from its operations in each field of its activities and the geographic areas in which it operates.

PART 4

Requirements and assessment criteria for organisations applying for a UK-issued ECM certificate or for a certificate in respect of maintenance functions outsourced by an entity in charge of maintenance

Section 1

Management function requirements and assessment criteria

Leadership: commitment to the development and implementation of the maintenance system of the organisation and to the continuous improvement of its effectiveness

21. The organisation must have procedures for—

- (a) establishing a maintenance policy appropriate to the organisation's type and extent of service and approved by the organisation's chief executive or his or her representative;
- (b) ensuring that safety targets are established, in line with the legal framework and consistent with an organisation's type, extent and relevant risks;
- (c) assessing its overall safety performance in relation to its corporate safety targets;
- (d) developing plans and procedures for reaching its safety targets;
- (e) ensuring the availability of the resources needed to perform all processes to comply with the requirements of this Part;
- (f) identifying and managing the impact of other management activities on the maintenance system;
- (g) ensuring that senior management is aware of the results of performance monitoring and audits and takes overall responsibility for the implementation of changes to the maintenance system;
- (h) ensuring that staff and staff representatives are adequately represented and consulted in defining, developing, monitoring and reviewing the safety aspects of all related processes that may involve staff.

Risk assessment: a structured approach to assess risks associated with the maintenance of freight wagons, including those directly arising from operational processes and the activities of other organisations or persons, and to identify the appropriate risk control measures

22.—(1) The organisation must have procedures for—

- (a) analysing risks relevant to the extent of operations carried out by the organisation, including the risks arising from defects and construction non-conformities or malfunctions throughout the lifecycle;
- (b) evaluating the risks referred to in paragraph (a);
- (c) developing and putting in place risk control measures.

(2) The organisation must have procedures and arrangements in place to recognise the need and commitment to collaborate with keepers, railway undertakings, infrastructure managers, or other interested parties.

(3) The organisation must have risk assessment procedures to manage changes in equipment, procedures, organisation, staffing or interfaces, and to apply Commission Implementing Regulation (EU) No 402/2013, as it has effect in Great Britain.

(4) When assessing risk, an organisation must have procedures to take into account the need to determine, provide and sustain an appropriate working environment.

Monitoring: a structured approach to ensure that risk control measures are in place, working correctly and achieving the organisation's objectives

23.—(1) The organisation must have a procedure to regularly collect, monitor and analyse relevant safety data, including—

- (a) the performance of relevant processes;
- (b) the results of processes, including all contracted services and products;
- (c) the effectiveness of risk control arrangements;
- (d) information on experience, malfunctions, defects and repairs arising from day-to-day operation and maintenance.

(2) The organisation must have procedures to ensure that accidents, incidents, near-misses and other dangerous occurrences are reported, logged, investigated and analysed.

(3) For a periodic review of all processes, the organisation must have an internal auditing system which is independent, impartial and acts in a transparent way. This system must have procedures in place to—

- (a) develop an internal audit plan, which can be revised depending on the results of previous audits and monitoring of performance;
- (b) analyse and evaluate the results of the audits;
- (c) propose and implement specific corrective measures/actions;
- (d) verify the effectiveness of previous measures/actions.

Continuous improvement: a structured approach to analyse the information gathered through regular monitoring, auditing, or other relevant sources and to use the results to learn and to adopt preventive or corrective measures in order to maintain or improve the level of safety

24. The organisation must have procedures to ensure that—

- (a) identified shortcomings are rectified;
- (b) new safety developments are implemented;
- (c) internal audit findings are used to bring about improvement in the system;

- (d) preventive or corrective actions are implemented, when needed, to ensure compliance of the railway system with standards and other requirements throughout the lifecycle of equipment and operations;
- (e) relevant information relating to the investigation and causes of accidents, incidents, near-misses and other dangerous occurrences is used to learn and, where necessary, to adopt measures in order to improve the level of safety;
- (f) relevant recommendations from the national safety authority, from the national investigation body and from industry or internal investigations are evaluated and implemented if appropriate;
- (g) relevant reports/information from railway undertakings/infrastructure managers and keepers or other relevant sources are considered and taken into account.

Structure and responsibility: a structured approach to define the responsibilities of individuals and teams for secure delivery of the organisation’s safety objectives

25.—(1) The organisation must have procedures to allocate responsibilities for all relevant processes throughout the organisation.

(2) The organisation must have procedures to clearly define safety-related areas of responsibility and the distribution of responsibilities to specific functions associated with them as well as their interfaces. These include the procedures indicated above between the organisation and the keepers and, where appropriate, railway undertakings and infrastructure managers.

(3) The organisation must have procedures to ensure that staff with delegated responsibilities within the organisation have the authority, competence and appropriate resources to perform their functions. Responsibility and competence should be coherent and compatible with the given role, and delegation must be in writing.

(4) The organisation must have procedures to ensure the coordination of activities related to relevant processes across the organisation.

(5) The organisation must have procedures to hold those with a role in the management of safety accountable for their performance.

Competence management: a structured approach to ensure that employees have the competences required in order to achieve the organisation’s objectives safely, effectively and efficiently in all circumstances

26.—(1) The organisation must set up a competence management system providing for—

- (a) the identification of posts with responsibility for performing within the system all the processes necessary for compliance with the requirements of this Part;
- (b) the identification of posts involving safety tasks;
- (c) the allocation of staff with the appropriate competence to relevant tasks.

(2) Within the organisation’s competence management system, there must be procedures to manage the competence of staff, including at least—

- (a) identification of the knowledge, skills and experience required for safety-related tasks as appropriate for the responsibilities;
- (b) selection principles, including basic educational level, mental aptitude and physical fitness;
- (c) initial training and qualification or certification of acquired competence and skills;
- (d) assurance that all staff are aware of the relevance and importance of their activities and how they contribute to the achievement of safety objectives;
- (e) ongoing training and periodical updating of existing knowledge and skills;
- (f) periodic checks of competence, mental aptitude and physical fitness where appropriate;

- (g) special measures in the case of accidents/incidents or long absences from work, as required.

Information: a structured approach to ensure that important information is available to those making judgments and decisions at all levels of the organisation

27.—(1) The organisation must have procedures to define reporting channels to ensure that, within the entity itself and in its dealings with other actors, including infrastructure managers, railway undertakings and keepers, information on all relevant processes is duly exchanged and submitted to the person having the right role both within its own organisation and in other organisations, in a prompt and clear way.

(2) To ensure an adequate exchange of information, the organisation must have procedures—

- (a) for the receipt and processing of specific information;
- (b) for the identification, generation and dissemination of specific information;
- (c) for making available reliable and up-to-date information.

(3) The organisation must have procedures to ensure that key operational information is—

- (a) relevant and valid;
- (b) accurate;
- (c) complete;
- (d) appropriately updated;
- (e) controlled;
- (f) consistent and easy to understand, including the language used;
- (g) made known to staff before it is applied;
- (h) easily accessible to staff, with copies provided to them where required.

(4) The requirements set out in paragraph 7(1), (2) and (3) apply in particular to the following operational information—

- (a) checks of the accuracy and completeness of the National Vehicle Register regarding the identification, including means, and registration of the freight wagons maintained by the organisation;
- (b) maintenance documentation;
- (c) information on support provided to keepers and, where appropriate, to other parties, including railway undertakings/infrastructure managers;
- (d) information on the qualification of staff and subsequent supervision during maintenance development;
- (e) information on operations, including mileage, type and extent of activities, incidents and accidents, and requests of railway undertakings, keepers and infrastructure managers;
- (f) records of maintenance performed, including information on deficiencies detected during inspections and corrective actions taken by railway undertakings or by infrastructure managers such as inspections and monitoring undertaken before the departure of the train or en route;
- (g) release to service and return to operation;
- (h) maintenance orders;
- (i) technical information to be provided to railway undertakings/infrastructure managers and keepers for maintenance instructions;
- (j) emergency information concerning situations where the safe state of running is impaired, which may consist of—

- (i) the imposition of restrictions of use or specific operating conditions for the freight wagons maintained by the organisation or other vehicles of the same series even if maintained by other entities in charge of maintenance, whereby this information should also be shared with all involved parties;
- (ii) urgent information on safety-related issues identified during maintenance, such as deficiencies detected in a component common to several types or series of vehicles;
- (k) all relevant information/data needed to submit the annual maintenance report to the certification body and to the relevant customers, including keepers, whereby this report must also be made available upon request to a safety authority or the safety authority for the tunnel system.

Documentation — a structured approach to ensure the traceability of all relevant information

28.—(1) The organisation must have adequate procedures in place to ensure that all relevant processes are duly documented.

- (2) The organisation must have adequate procedures in place to—
 - (a) regularly monitor and update all relevant documentation;
 - (b) format, generate, distribute and control changes to all relevant documentation;
 - (c) receive, collect and archive all relevant documentation.

Contracting activities — a structured approach to ensure that subcontracted activities are managed appropriately in order for the organisation’s objectives to be achieved

29.—(1) The organisation must have procedures in place to ensure that safety related products and services are identified.

(2) When making use of contractors and/or suppliers for safety related products and services, the organisation must have procedures in place to verify at the time of selection that—

- (a) contractors, subcontractors and suppliers are competent;
- (b) contractors, subcontractors and suppliers have a maintenance and management system that is adequate and documented.

(3) The organisation must have a procedure to define the requirements that such contractors and suppliers have to meet.

(4) The organisation must have procedures to monitor the awareness of suppliers and/or contractors of risks they entail to the organisation’s operations.

(5) When the maintenance/management system of a contractor or supplier is certified, the monitoring process described in paragraph 23 may be limited to the results of the contracted operational processes referred to in paragraph 23(1)(b).

(6) At least the basic principles for the following processes must be clearly defined, known and allocated in the contract between the contracting parties—

- (a) responsibilities and tasks relating to railway safety issues;
- (b) obligations relating to the transfer of relevant information between both parties;
- (c) the traceability of safety-related documents.

SECTION 2

Requirements and assessment criteria for the maintenance development function

30. The organisation must have a procedure to identify and manage all maintenance activities affecting safety and safety-critical components.

31. The organisation must have procedures to guarantee conformity with the essential requirements for interoperability, including updates throughout the lifecycle, by—

- (a) ensuring compliance with the specifications related to the basic parameters for interoperability as set out in the relevant TSIs;
- (b) verifying in all circumstances the consistency of the maintenance file with the authorisation of placing-in-service, including the requirements of a safety authority or the safety authority for the tunnel system, the declarations of conformity to TSIs, the declarations of verification, and the technical file;
- (c) managing any substitution in the course of maintenance in compliance with the requirements of the relevant TSIs;
- (d) identifying the need for risk assessment regarding the potential impact of the substitution in question on the safety of the railway system;
- (e) managing the configuration of all technical changes affecting the system integrity of the vehicle.

32. The organisation must have a procedure to design and to support the implementation of maintenance facilities, equipment and tools specifically developed and required for maintenance delivery. The organisation must have a procedure to check that these facilities, equipment and tools are used, stored and maintained according to their maintenance schedule and in conformity with their maintenance requirements.

33. When freight wagons start operations, the organisation must have procedures to—

- (a) obtain the initial documentation and to collect sufficient information on planned operations;
- (b) analyse the initial documentation and to provide the first maintenance file, also taking into account the obligations contained in any associated guarantees;
- (c) ensure that the implementation of the first maintenance file is done correctly.

34. To keep the maintenance file updated throughout the lifecycle of a freight wagon, the organisation must have procedures to—

- (a) collect at least the relevant information in relation to—
 - (i) the type and extent of operations effectively performed, including, but not limited to, operational incidents with a potential to affect the safety integrity of the freight wagon;
 - (ii) the type and extent of operations planned;
 - (iii) the maintenance effectively performed;
- (b) define the need for updates, taking into account the limit values for interoperability;
- (c) make proposals for and approve changes and their implementation, with a view to a decision based on clear criteria, taking into account the findings from risk assessment;
- (d) ensure that the implementation of changes is done correctly.

35. When the competence management process is applied to the maintenance development function, at least the following activities affecting safety must be taken into account—

- (a) assessment of the significance of changes for the maintenance file and proposed substitutions in the course of maintenance;
- (b) engineering disciplines required for managing the establishment and the changes of maintenance file and the development, assessment, validation and approval of substitutions in the course of maintenance;
- (c) joining techniques, including welding and bonding, brake systems, wheel sets and draw gear, non-destructive testing techniques and maintenance activities on

specific components of freight wagons for the transport of dangerous goods such as tanks and valves.

36. When the documentation process is applied to the maintenance development function, the traceability of at least the following elements needs to be guaranteed—

- (a) the documentation relating to the development, assessment, validation and approval of a substitution in the course of maintenance;
- (b) the configuration of vehicles, including, but not limited to, components related to safety;
- (c) records of the maintenance performed;
- (d) results of studies concerning return on experience;
- (e) all the successive versions of the maintenance file, including risk assessment;
- (f) reports on the competence and supervision of maintenance delivery and fleet maintenance management;
- (g) technical information to be provided to support keepers, railway undertakings and infrastructure managers.

SECTION 3

Requirements and assessment criteria for the fleet maintenance management function

37. The organisation must have a procedure to check the competence, availability and capability of the entity responsible for maintenance delivery before placing maintenance orders. This requires that the maintenance workshops are duly qualified to decide upon the requirements for technical competences in the maintenance delivery function.

38. The organisation must have a procedure for the composition of the work package and for the issue and release of the maintenance order.

39. The organisation must have a procedure to send freight wagons for maintenance in due time.

40. The organisation must have a procedure to manage the removal of freight wagons from operation for maintenance or when defects have been identified.

41. The organisation must have a procedure to define the necessary control measures applied to the maintenance delivered and the release to service of the freight wagons.

42. The organisation must have a procedure to issue a notice to return to operation, taking into account the release to service documentation.

43. When the competence management process is applied to the fleet maintenance management function, at least the return to operation must be taken into account.

44. When the information process is applied to the fleet maintenance management function, at least the following elements need to be provided to the maintenance delivery function—

- (a) applicable rules and technical specifications;
- (b) the maintenance plan for each freight wagon;
- (c) a list of spare parts, including a sufficiently detailed technical description of each part to allow like-for-like replacement with the same guarantees;
- (d) a list of materials, including a sufficiently detailed description of their use and the necessary health and safety information;
- (e) a dossier that defines the specifications for activities affecting safety and contains intervention and in-use restrictions for components;

- (f) a list of components or systems subject to legal requirements and a list of these requirements, including brake reservoirs and tanks for the transport of dangerous goods;
- (g) all additional relevant information related to safety according to the risk assessment performed by the organisation.

45. When the information process is applied to the fleet maintenance management function, at least the return to operation, including restrictions on use relevant to users (railway undertakings and infrastructure managers), needs to be communicated to interested parties.

46. When the documentation process is applied to the fleet maintenance management function, at least the following elements need to be recorded—

- (a) maintenance orders;
- (b) return to operation, including restrictions on use relevant to railway undertakings and infrastructure managers.

SECTION 4

Requirements and assessment criteria for the maintenance delivery function

47. The organisation must have procedures to—

- (a) check the completeness and appropriateness of the information delivered by the fleet maintenance management function in relation to the activities ordered;
- (b) control the use of the required, relevant maintenance documents and other standards applicable to the delivery of maintenance services in accordance with maintenance orders;
- (c) ensure that all relevant maintenance specifications in the maintenance orders are available to all involved staff (e.g. they are contained in internal working instructions);
- (d) ensure that all relevant maintenance specifications, as defined in applicable regulations and specified standards contained in the maintenance orders, are available to all involved staff (e.g. they are contained in internal working instructions).

48. The organisation must have procedures to ensure that—

- (a) components (including spare parts) and materials are used as specified in the maintenance orders and supplier documentation;
- (b) components and materials are stored, handled and transported in a manner that prevents wear and damage and as specified in the maintenance orders and supplier documentation;
- (c) all components and materials, including those provided by the customer, comply with relevant national and international rules as well as with the requirements of relevant maintenance orders.

49. The organisation must have procedures to determine, identify, provide, record and keep available suitable and adequate facilities, equipment and tools to enable it to deliver the maintenance services in accordance with maintenance orders and other applicable specifications, ensuring—

- (a) the safe delivery of maintenance, including the health and safety of maintenance staff;
- (b) ergonomics and health protection, also including the interfaces between users and information technology systems or diagnostic equipment.

50. Where necessary to ensure valid results, the organisation must have procedures to ensure that its measuring equipment is—

- (a) calibrated or verified at specified intervals, or prior to use, against international, national or industrial measurement standards; where no such standards exist, the basis used for calibration or verification must be recorded;
- (b) adjusted or re-adjusted as necessary;
- (c) identified to enable the calibration status to be determined;
- (d) safeguarded from adjustments that would invalidate the measurement result;
- (e) protected from damage and deterioration during handling, maintenance and storage.

51. The organisation must have procedures to ensure that all facilities, equipment and tools are correctly used, calibrated, preserved and maintained in accordance with documented procedures.

52. The organisation must have procedures to check that the performed maintenance tasks are in accordance with the maintenance orders and to issue the notice to release to service that includes eventual restrictions of use.

53. When the risk assessment process, in particular paragraph 22.4, is applied to the maintenance delivery function, the working environment includes not only the workshops where maintenance is done but also the tracks outside the workshop buildings and all places where maintenance activities are performed.

54. When the competence management process is applied to the maintenance delivery function, at least the following activities affecting safety must be taken into account—

- (a) joining techniques, including welding and bonding;
- (b) non-destructive testing;
- (c) final vehicle testing and release to service;
- (d) maintenance activities on brake systems, wheel sets and draw gear and maintenance activities on specific components of freight wagons for the transport of dangerous goods, such as tanks, valves, etc.;
- (e) other identified specialist areas affecting safety.

55. When the information process is applied to the maintenance delivery function, at least the following elements must be provided to the fleet maintenance management and maintenance development functions—

- (a) works performed in accordance with the maintenance orders;
- (b) any possible fault or defect regarding safety which is identified by the organisation;
- (c) the release to service.

56. When the documentation process is applied to the maintenance delivery function, at least the following elements must be recorded—

- (a) clear identification of all facilities, equipment and tools related to activities affecting safety;
- (b) all maintenance works performed, including personnel, tools, equipment, spare parts and materials used and taking into account—
 - (i) relevant national rules where the organisation is established;
 - (ii) requirements laid down in the maintenance orders, including requirements regarding records;
 - (iii) final testing and decision regarding release to service;
- (c) the control measures required by maintenance orders and the release to service;
- (d) the results of calibration and verification, whereby, for computer software used in the monitoring and measurement of specified requirements, the ability of the

software to perform the desired task must be confirmed prior to initial use and reconfirmed as necessary;

- (e) the validity of the previous measuring results when a measuring instrument is found not to conform to requirements.

SCHEDULE 11

Regulation 18B

Common Safety Targets

Application

1. This Schedule applies to the mainline railway(a).

Interpretation

2. In this Schedule—

“fatalities and weighted serious injuries” (“FWSIs”) means a measurement of the consequences of significant accidents combining fatalities and serious injuries, where 1 serious injury is considered statistically equivalent to 0.1 fatalities;

“level crossing users” means all persons using a level crossing to cross a railway line by any means of transportation or by foot;

“national reference value” (“NRV”) means a reference measure indicating the maximum tolerable level for a railway risk category;

“others” means all persons who are not passengers, staff or employees including the staff of contractors, level crossing users or unauthorised persons on railway premises;

“passenger-km” means the unit of measure representing the transport of one passenger by rail over a distance of one kilometre;

“passenger train-km” means the unit of measure representing the movement of a passenger train over one kilometre;

“risk category” means one of the railway risk categories specified by Article 7(4)(a) and (b) of the Directive;

“risk to society as a whole” means the collective risk to all categories of persons listed in Article 7(4)(a) of the Directive;

“safety enhancement plan” means a plan to implement the organisational structure, responsibilities, procedures, activities, capabilities and resources required to reduce the risk for one or more risk categories;

“staff or employees including the staff of contractors” means any persons whose employment is in connection with a railway and is at work at the moment of the accident; it includes the crew of the train and persons handling rolling stock and infrastructure installations;

“track-km” means the length measured in kilometres of the railway network where each track of a multiple track railway line is to be counted;

“train-km” means the unit of measure representing the movement of a train over one kilometre; the distance used is the distance actually run, if available, otherwise the standard network distance between the origin and destination must be used;

(a) This Schedule substantially reproduces the provisions of Commission Decision 2009/460/EC on the adoption of a common safety method for assessment of achievement of safety targets, Commission Decision 2012/226/EU on the second set of common safety targets as regards the rail system, and Commission Implementing Decision 2013/753/EU amending Decision 2012/226/EU on the second set of common safety targets for the rail system, insofar as they continue to have effect in Great Britain following the withdrawal of the United Kingdom from the European Union and with amendments to address deficiencies arising out of this.

“unauthorised persons on railway premises” means any persons present on railway premises where such presence is forbidden, with the exception of level crossing users;

Measurement units for NRVs and CSTs

3. The measurement units for NRVs must be expressed in compliance with the mathematical definition of risk. The consequences of accidents which must be considered for each of the risk categories are the FWSIs.

4. For the purpose of assessment of achievement of the NRVs for the passenger and level crossing user risk categories, compliance with one or both of these NRVs must be considered sufficient.

Principles for the assessment of achievement of NRVs and CSTs

5. The following principles apply for assessing achievement of NRVs and CSTs—

- (a) for each risk category for which the NRV is equal to or lower than the corresponding CST, the achievement of the NRV also automatically implies the achievement of the CST;
- (b) the assessment of achievement of the NRV must be carried out according to the procedure described in paragraph 8 and the NRV represents the maximum tolerable level of the risk to which it refers, without prejudice to provisions of the range of tolerance laid down in paragraph 10;
- (c) for each risk category for which the NRV is higher than the corresponding CST, the CST represents the maximum tolerable level of the risk to which it refers;
- (d) the assessment of achievement is to be carried out in compliance with the requirements deriving from the impact assessment.

6. The assessment of achievement of the NRVs and CSTs must be carried out annually by the Office of Rail and Road, taking into consideration the most recent four preceding reporting years, including those years in which the assessment of achievement of the NRVs and CSTs in the United Kingdom was conducted by the European Railway Agency.

7. The outcome of the assessment of achievement referred to in paragraph 5 is to be classified as follows—

- (a) acceptable safety performance;
- (b) possible deterioration of safety performance; or
- (c) probable deterioration of safety performance

and published by the Office of Rail and Road.

Procedure for assessment of achievement of NRVs and CSTs

8. The procedure for the assessment of achievement of NRVs is composed of four different steps as described in the following paragraphs. The overall decisional flowchart of the procedure is shown in paragraph 15, where positive and negative decisional arrows correspond respectively to a ‘passed’ and a ‘failed’ result of the different assessment steps.

9.—(1) The first assessment step must verify whether the observed safety performance is complying with the NRV or not.

(2) The observed safety performance must be measured by using the measurement units listed in paragraph 14 and data gathered by the Office of Rail and Road in respect of railway accidents and related consequences, with time series which must include the most recent years of observations as specified in paragraph 6.

(3) The observed safety performance must be expressed in terms of—

- (a) safety performance in the single most recent reported year; and

(b) moving weighted average (MWA), as specified in paragraph 13.

(4) The values returned must then be compared with the NRV, and if one of these values does not exceed the NRV, the safety performance is to be considered acceptable. If this is not the case, the procedure must continue with the second assessment step.

10.—(1) The second assessment step must consider the safety performance to be acceptable if the MWA does not exceed the NRV plus a 20% range of tolerance.

(2) If this condition is not satisfied, the Office of Rail and Road must obtain the specifics of the single highest-consequence accident, in terms of FWSIs, in the most recent years of observation as referred to in paragraph 6, excluding the years used to set the NRV.

(3) If this single accident is more severe, in terms of consequences, than the most severe single accident included in the data used for setting the NRV, it must be excluded from the statistics.

(4) The MWA must then be recalculated to check whether it lies within the abovementioned range of tolerance.

(5) If this is the case, the safety performance must be considered acceptable. If this is not the case, the procedure must continue with the third assessment step.

11. The third assessment step must verify whether it is the first time in the last three years that the second assessment step did not return evidence of acceptable safety performance. If this is the case, the outcome of the third assessment step must be classified as 'passed'. The procedure shall continue with the fourth step, whatever the outcome of the third step may be.

12.—(1) The fourth assessment step must verify whether the number of significant accidents per train-km, with respect to the previous years, remained stable or decreased. The criteria for this appraisal are whether there has been a statistically significant increase in the number of relevant significant accidents per train-km. This must be evaluated by using an upper Poisson tolerance bound which will determine the acceptable variability based on the number of accidents that occurred in the member States of the European Union.

(2) If the number of significant accidents per train-km does not exceed the abovementioned tolerance bound, it is assumed that there has not been a statistically significant increase, and the outcome of this assessment step must be classified as passed.

(3) Depending on the risk category to which the different NRVs under assessment of achievement refer, the significant accidents to be considered for carrying out this assessment step are as follows—

- (a) risks to passengers: all relevant significant accidents;
- (b) risks to staff or employees, including the staff of contractors: all relevant significant accidents;
- (c) risks to level crossing users: all relevant significant accidents included in the risk category of level crossing accidents;
- (d) risks to unauthorised persons on railway premises: all relevant significant accidents included in the risk category of accidents to persons caused by rolling stock in motion;
- (e) risks to others: all relevant significant accidents;
- (f) risk to society as a whole: all significant accidents.

Moving weighted averaging process for the annual assessment of achievement of NRVs

13. For each of the risk categories to which the MWA is applied for carrying out, in each year Y (starting from $Y = 2010$), the assessment steps described in paragraphs 9 to 12, the following phases must be applied for calculating the MWA_Y —

- (a) calculation of the annual observations OBS_i returned by the corresponding indicators in paragraph 14 after providing as input the relevant data for the relevant years (the index i takes the values as defined in the formula in sub paragraph (e));
- (b) calculation of the 5-year average (AV) of annual observation OBS_i ;
- (c) calculation of the absolute value of the difference $ABSDIFF_i$ between each annual observation OBS_i and the AV . If $ABSDIFF_i < 0.01 * AV$, the $ABSDIFF_i$ is attributed a constant value equal to $0.01 * AV(a)$;
- (d) calculation of the weight W_i by taking the inverse of $ABSDIFF_i$;
- (e) calculation of the MWA_Y as follows—

$$MWA_Y = \frac{\sum_{i=x}^N W_i \times OBS_i}{\sum_{i=x}^N W_i};$$

where i is a natural number and $x = Y - 6$; $N = Y - 2$.

Measurement units for NRVs and CSTs

14. The following table sets out the measurement units for NRVs and CSTs.

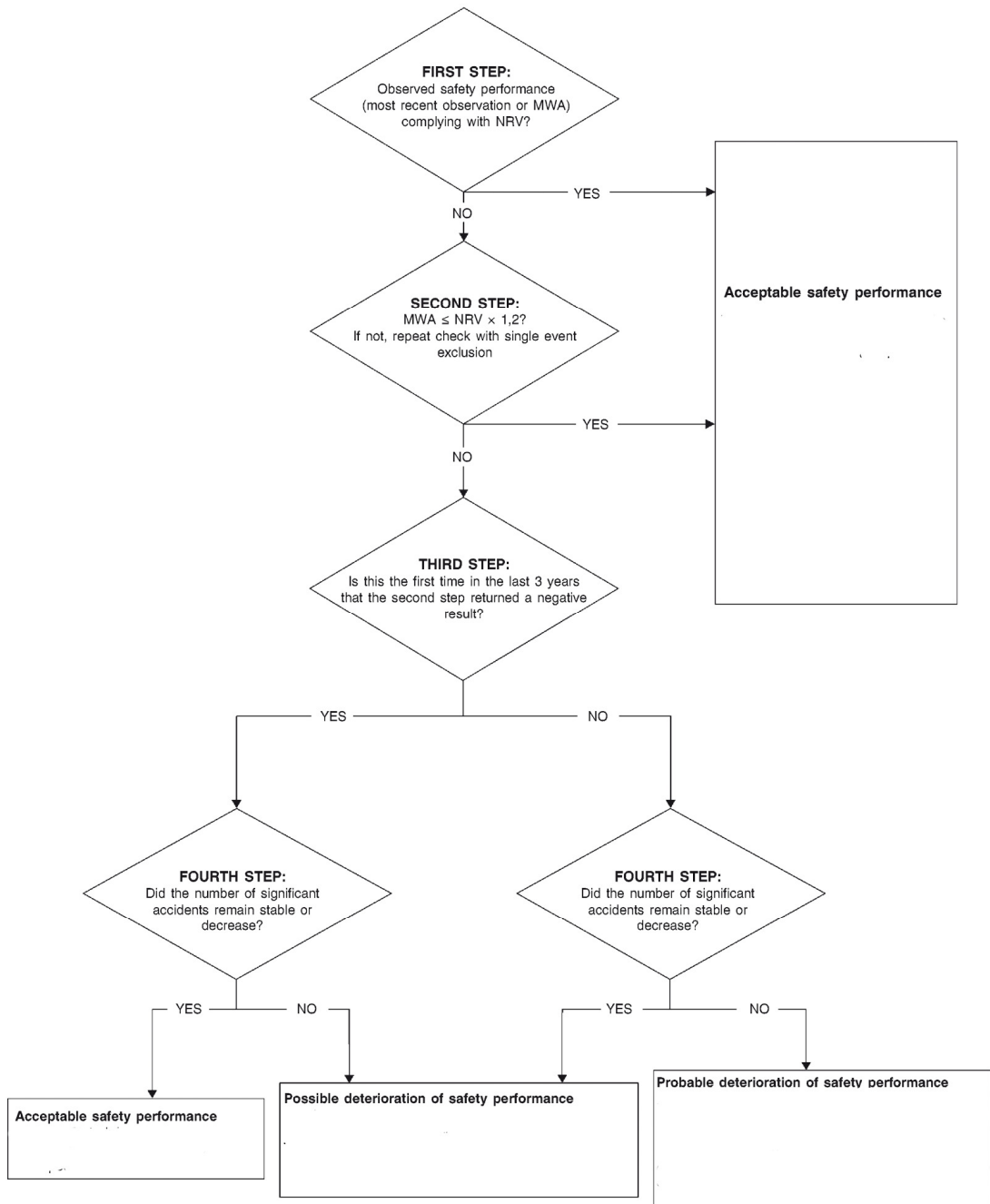
<i>Risk category</i>	<i>Measurement units</i>	<i>Scaling bases</i>
1. Passengers	1.1 Number of passenger FWSIs per year arising from significant accidents/Number of passenger train-km per year	Passenger train-km per year
	1.2 Number of passenger FWSIs per year arising from significant accidents/Number of train-km per year	Passenger-km per year
2. Employees	2. Number of employee FWSIs per year arising from significant accidents/Number of passenger-km per year	Train-km per year
3. Level crossing users	3.1 Number of level-crossing user FWSIs per year arising from significant accidents/Number of train-km per year	Train-km per year
	3.2 Number of level-crossing user FWSIs per year arising from significant accidents/[(Number of Train-km per year x Number of level crossings)/Track-km]	(Train-km per year x Number of level crossings)/Track-km
4. Others	4. Yearly number of FWSIs to	Train-km per year

(a) Asterisks in this paragraph have been used to indicate multiplication signs.

	persons belonging to the category 'others' arising from significant accidents/Number of train-km per year	
5. Unauthorised persons on railway premises	5. Number of FWSIs to unauthorised persons on railway premises per year arising from significant accidents/Number of train-km per year	Train-km per year
6. Whole society	6. Total number of FWSIs per year arising from significant accidents/Number of train-km per year	Train-km per year

Decision flowchart

15. The flowchart referred to in paragraph 8 follows.



Values for NRVs

16. The following table sets out the values of the NRVs for the purposes of this Schedule.

<i>NRV</i>	<i>Risk category</i>	<i>Value</i>
1.1 (x 10 ⁻⁹)	Risk to passengers	2.73
1.2 (x 10 ⁻⁹)		0.028
2 (x 10 ⁻⁹)	Risk to employees	5.17

3.1 (x 10 ⁻⁹)	Risk to level crossing users	23.5
3.2		n/a
4 (x 10 ⁻⁹)	Risk to persons classified as others	7.00
5 (x 10 ⁻⁹)	Risk to unauthorised persons on railway premises	84.5
6 (x 10 ⁻⁹)	Societal risk	120.0

Values for CSTs

17. The following table sets out the values for the CSTs.

<i>Risk category</i>	<i>CST value (x 10⁻⁶)</i>		<i>Measurement units</i>
Risk to passengers	CST. 1.1	0.17	Number of passenger FWSIs per year arising from significant accidents/Number of passenger train-km per year
	CST 1.2	0.00165	Number of passenger FWSIs per year arising from significant accidents/Number of passenger-km per year
Risk to employees	CST 2	0.0779	Number of employee FWSIs per year arising from significant accidents/Number of train-km per year
Risk to level crossing users	CST 3.1	0.710	Number of level-crossing user FWSIs per year arising from significant accidents/Number of train-km per year
	CST 3.2	n/a	Number of level-crossing user FWSIs per year arising from significant accidents/[(Number of Train-km per year x Number of level crossings)/Track-km]
Risk to others	CST 4	0.0145	Yearly number of FWSIs to persons belonging to the category 'others' arising from significant accidents/Number of train-km per year
Risk to unauthorised persons on railway premises	CST 5	2.05	Number of FWSIs to unauthorised persons on railway premises per year arising from significant accidents/Number of train-km per year
Risk to society as a whole	CST 6	2.59	Total number of FWSIs per year arising from significant accidents/Number of train-km per year"

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers conferred by section 8(1) of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018 (c.16) in order to address failures of retained EU law to operate effectively and other deficiencies (in particular

under section 8(2)(a), (d) and (g)) arising from the withdrawal of the UK from the European Union.

These Regulations make amendments to legislation in the field of railway safety, including safety certification and authorisation, supervision and monitoring by safety authorities, risk assessment and evaluation, access to training services, certification in respect of entities in charge of maintenance and the use of common safety targets.

Part 2 makes correcting amendments to the Railways and Other Guided Transport Systems (Safety) Regulations 2006 (S.I. 2006/599) and the Railways (Access to Training Services) Regulations 2006 (S.I. 2006/598).

Part 3 revokes directly effective Decisions, Regulations and Implementing Regulations made pursuant to Directive 2004/49/EC (OJ No. L164, 30.04.04 p. 44) (“retained direct EU legislation”) where they are no longer relevant or have been restated elsewhere and amends Annex XIII of the Agreement on the European Economic Area so far as that annex forms part of domestic law by virtue of section 3(2)(b) of the European Union (Withdrawal) Act 2018.

Part 4 makes correcting amendments to retained direct EU legislation in respect of Great Britain and Part 5 makes correcting amendments to retained direct EU legislation in respect of Northern Ireland.

An impact assessment has not been produced for this instrument as no, or no significant, impact on the private or voluntary sector is foreseen. An Explanatory Memorandum has been produced for this instrument and is published alongside this instrument at www.legislation.gov.uk.

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