
STATUTORY INSTRUMENTS

2019 No. 345

**The Railways (Interoperability)
(Amendment) (EU Exit) Regulations 2019**

PART 2

Amendments to secondary legislation

Amendments to the Railways Interoperability Regulations 2011

2.—(1) The Railways (Interoperability) Regulations 2011⁽¹⁾ (“the Regulations”) are amended as follows.

(2) In regulation 2 (definitions)—

(a) after the definition of “the 1974 Act”, insert—

““approved body” has the meaning set out in regulation 30;

“authorised representative” means—

(a) a person who—

(i) immediately before exit day was established in an EEA state and appointed to act by a manufacturer or contracting entity to perform specified tasks for that manufacturer or contracting entity in relation to the Directive, and

(ii) on or after exit day continues to be so established and appointed by the manufacturer or contracting entity to perform those tasks; or

(b) a person who on or after exit day is appointed in accordance with regulation 3A;”;

(b) for the definition of “certificate of verification”, substitute—

““certificate of verification” means an EC certificate of verification or a UK certificate of verification;”;

(c) omit the definition of “the Commission”;

(d) in the definition of “Competent Authority”, for “DRDNI” substitute “DFI”;

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

““DFI” means the Department for Infrastructure as established by section 1(6) of the Departments Act (Northern Ireland) 2016⁽²⁾;”;

(f) after the definition of “DFI”, insert—

““EC certificate of verification” means a certificate drawn up by an EU notified body as part of the EC verification assessment procedure for a structural subsystem;”

⁽¹⁾ S.I. 2011/3066, amended by S.I. 2013/2042, 2013/3023, 2014/3217, 2015/1682, 2015/2022, 2016/275, and 2016/645.

⁽²⁾ 2016 c. 8 (N.I.).

- (g) in the definition of “EC declaration of conformity or suitability for use”, for “regulation 25”, substitute “Article 13 and Annex IV of the Directive”;
- (h) after the definition of “EC declaration of conformity or suitability for use”, insert—
 ““EC declaration of verification” means a declaration drawn up by a project entity in relation to a structural subsystem in accordance with Article 18 of and Annex V to the Directive;
 “EC verification assessment procedure” means the procedure set out in Annex VI to the Directive;”;
- (i) in the definition of “essential requirements”, for “Annex III to the Directive”, substitute “Schedule 2”;
- (j) after the definition of “essential requirements”, insert—
 ““European Commission” means the Commission of the European Union;”;
- (k) omit the definition of “European Railway Agency”;
- (l) omit the definition of “European specification”;
- (m) after the definition of “European vehicle number” insert—
 ““EU notified body” means a body which has been appointed by an EU Member State and notified by the EU Member State concerned to the European Commission and the other EU Member States pursuant to Article 20(1) of the Conventional Directive, Article 20(1) of the High-Speed Directive, or Article 28(1) of the Directive unless the appointment has been terminated;”;
- (n) in the definition of “functional subsystem” for “Annex II to the Directive”, substitute “Schedule 3”;
- (o) omit the definition of “functional TSI”;
- (p) for the definition of “interoperability”, substitute—
 ““interoperability” means the ability of the rail system to allow the safe and uninterrupted movement of trains which accomplish the required levels of performance for those lines;”;
- (q) after the definition of “interoperability constituent”, insert—
 ““ISV” means an intermediate statement of verification issued by—
 (a) an approved body in relation to the design stage or the production stage of a subsystem in accordance with section 2 of Schedule 4;
 (b) an EU notified body in relation to the design stage or the production stage of a subsystem in accordance with section 2 of Annex VI to the Directive;
 (c) a designated body at an intermediate stage of the UK verification assessment procedure referred to in section 3 of Schedule 4;
 (d) a designated body at an intermediate stage of the EC verification assessment procedure referred to in section 3 of Annex VI to the Directive;
 “NTRs” means National Technical Rules setting out standards, technical specifications and technical rules in relation to the rail system, as amended or varied from time to time, a list of which is published by the Secretary of State in accordance with regulation 3C;
 “NTSN” means a National Technical Specification Notice published by the Secretary of State pursuant to regulation 3B setting out the standards, technical specifications and technical rules in use in the United Kingdom as amended or varied from time to time;”;

- (r) omit the definition of “notified body”;
 - (s) in the definition of “notified national technical rules”, for “have been notified by the Secretary of State to the Commission”, substitute “were notified by the Secretary of State to the European Commission before exit day”;
 - (t) omit the definition of “Official Journal”;
 - (u) in the definition of “project entity”, omit “established in the EU”;
 - (v) for the definition of “rail system”, substitute—
 - ““rail system” means the structure composed of lines and fixed installations of the existing rail system in the United Kingdom plus the vehicles of all categories and origin travelling on that infrastructure;”;
 - (w) in the definition of “Safety Authority”, for “DRDNI”, substitute “DFI”;
 - (x) in the definition of “structural subsystem”, for “Annex II to the Directive”, substitute “Schedule 3”;
 - (y) in the definition of “subsystem”, for “Annex II to the Directive”, substitute “Schedule 3”;
 - (z) in the definition of “trans-European rail system”, omit “as those sections are amended from time to time”;
 - (aa) for the definition of “TSI”, substitute—
 - ““TSI” means technical specifications for interoperability adopted from time to time by the European Commission pursuant to the Directive, or the Conventional Directive, or the High Speed Directive, as those TSIs have effect in EU law, and as they are amended from time to time;”;
 - (bb) after the definition for “upgrading” insert—
 - ““UK certificate of verification” means a certificate drawn up by an approved body or designated body as part of the UK verification assessment procedure for a structural subsystem;
 - “UK declaration of conformity or suitability for use” means a declaration drawn up in accordance with regulation 25 and Schedule 7;
 - “UK declaration of verification” means a declaration of verification drawn up by a project entity in relation to a structural subsystem pursuant to regulation 16(3) and Schedule 5;
 - “UK specific case” means a special provision in relation to the technical specifications for a subsystem or an interoperability constituent to allow for its compatibility with the rail system, which is set out in an NTSN or an NTR and described in that NTSN or that NTR as a “UK specific case”;
 - “UK specific rules” means all UK specific cases and NTRs, including any dispensation granted against NTRs under regulation 46(1);
 - “UK verification assessment procedure” means the procedure referred to in regulation 17 and Schedule 4”;
 - (cc) omit the definition of “verification assessment procedure”;
 - (dd) omit the definition of “verification declaration”;
 - (ee) omit paragraph (2);
 - (ff) in paragraph (3), omit “Except for the references to the EU in the definitions of “the Commission” and “Official Journal””.
- (3) Schedules 1 and 2 have effect.
- (4) In regulation 3 (application)—

- (a) for sub-paragraph (1)(a), substitute—
 - “(a) the rail system;”;
- (b) in sub-paragraph (7), for “DRDNI”, substitute “DFI”.
- (5) After regulation 3, insert—

“Appointment and obligations of an authorised representative

3A.—(1) A manufacturer or contracting entity may, in writing, appoint a person established in the United Kingdom as its authorised representative to perform certain tasks pursuant to these Regulations.

(2) A manufacturer or contracting entity who has appointed an authorised representative to perform, on behalf of that manufacturer or contracting entity, a task under these Regulations remains responsible for the proper performance of that task.

(3) An authorised representative must comply with all the duties imposed on the manufacturer or contracting entity in relation to each obligation under these Regulations that the representative is appointed to perform, and will be subject to the same penalties as a manufacturer or contracting entity for failure to comply with those duties.”.

- (6) After new Regulation 3A, insert—

“PART 1A

National Technical Specification Notices and National Technical Rules

Publication of National Technical Specification Notices

3B.—(1) The Secretary of State may set standards to be complied with in relation to the design, construction, placing in service, upgrading, renewal, operation and maintenance of the parts of the rail system, as well as the professional qualifications and health and safety conditions of the staff who contribute to its operation and maintenance.

(2) Those standards may be set out in National Technical Specification Notices (NTSNs), which must be published by the Secretary of State.

(3) NTSNs may be varied from time to time by the Secretary of State.

(4) Any variation must be published by the Secretary of State.

(5) Regulations 39 and 40 apply to the enforcement of the standards set out in NTSNs as they apply to the enforcement of these Regulations.

(6) When the Secretary of State publishes an NTSN for the first time, and the NTSN is intended to take the place of a particular TSI as it had effect immediately before exit day, the NTSN must specify the TSI it replaces.

(7) When the Secretary of State publishes an NTSN or a variation of an NTSN and that NTSN substantially reproduces the provisions of a TSI, the NTSN must specify the title of the TSI it substantially reproduces at the time of publication.

Publication of a list of National Technical Rules

3C.—(1) The Secretary of State may set supplementary standards to be complied with in relation to the design, construction, placing in service, upgrading, renewal, operation and maintenance of the parts of the rail system, as well as the professional qualifications and health and safety conditions of the staff who contribute to its operation and maintenance.

- (2) Those standards may be set out in NTRs which supplement NTSNs.
- (3) On exit day, the Secretary of State must publish a list of all NTRs applying in the United Kingdom.
- (4) Where appropriate, the list must specify the notified national technical rule that an NTR replaces.
- (5) The list of NTRs may be varied from time to time by the Secretary of State.
- (6) Any variation to the list must be published by the Secretary of State.
- (7) Regulations 39 and 40 apply to the enforcement of the standards set out in NTRs as they apply to the enforcement of these Regulations.”.
- (7) In regulation 4 (requirement for authorisation)—
 - (a) in paragraph (1)—
 - (i) at the end of sub-paragraph (a), insert “or”,
 - (ii) at the end of sub-paragraph (b), omit “or”, and sub-paragraph (c);
 - (b) in paragraph (2), omit “in the United Kingdom”;
 - (c) in paragraph (3), before “verification assessment procedure”, insert “relevant EC or UK”;
 - (d) after paragraph 3, insert—

“(4) The requirements set out in paragraph (1) apply to a vehicle even if there is an extant authorisation granted in an EU Member State. A person wishing to put a vehicle into use in the UK which has such an authorisation must apply for an authorisation under regulation 6.”.
- (8) In regulation 5 (application for authorisation)—
 - (a) in paragraph (1)—
 - (i) at the end of sub-paragraph (a), insert “or”,
 - (ii) at the end of sub-paragraph (b), omit “or”, and sub-paragraph (c);
 - (b) for paragraph (2)(b), substitute—

“(b) the UK declaration of verification;”;
 - (c) in paragraph (3), before “verification assessment procedure”, insert “UK”;
 - (d) in paragraph (7), for “DRDNI”, substitute “DFI”;
 - (e) omit paragraph (8).
- (9) In regulation 6 (authorisation for a vehicle already authorised for another Member State)—
 - (a) in the heading, for “another”, substitute “an EU”;
 - (b) for paragraph (1), substitute—

“(1) This regulation applies where an authorisation is required under regulation 4(4).”;
 - (c) in paragraph (3)—
 - (i) in sub-paragraph (a), for “4(1)(c)” substitute “4(4)”,
 - (ii) in sub-paragraph (b)(ii), after “applicable TSI”, insert “in force at the time when the vehicle was first authorised”,
 - (iii) at the end of sub-paragraph (b)(iv), omit “and”,
 - (iv) for sub-paragraph (b)(v), substitute—

“(v) any UK certificate of verification in relation to UK specific rules; and”,
 - (v) after sub-paragraph (b)(v), insert—

- “(vi) sufficient documentary evidence to satisfy the Safety Authority that the first authorisation has not been revoked.”;
- (vi) at the end of sub-paragraph (c)(iv), omit “and”;
- (vii) for sub-paragraph (c)(v), substitute—
 - “(v) any UK certificate of verification in relation to UK specific rules; and”;
- (viii) after sub-paragraph (c)(v), insert—
 - “(vi) sufficient documentary evidence to satisfy the Safety Authority that the first authorisation has not been revoked.”;
- (ix) in sub-paragraph (e), for “verification declaration”, substitute “UK declaration of verification”;
- (d) for paragraph (4), substitute—
 - “(4) If the first authorisation is a TSI conform authorisation, the Safety Authority may, after consultation with the applicant, by notice in writing require the applicant to carry out additional tests on the network concerned or risk analysis and to provide any additional information which the Safety Authority considers necessary in order to check compatibility between the vehicle and the network concerned, including compatibility with UK specific rules.”;
- (e) in paragraph (5), for “notified national technical rules”, substitute “UK specific rules”;
- (f) in paragraph (7)—
 - (i) for “notified national technical rules”, substitute “UK specific rules”;
 - (ii) omit the words from “or if the engagement”, to “notified body”;
- (g) omit paragraph (8);
- (h) for paragraph (9), substitute—
 - “(9) If a body is engaged in accordance with paragraph (7), in order for the application to proceed, the project entity must draw up a UK declaration of verification in relation to the project subsystem in accordance with Schedule 5, after the body appointed under paragraph (7) has, in accordance with Schedule 4, drawn up a UK certificate of verification and compiled a technical file.”;
- (i) omit paragraphs (10) and (11).
- (10) Schedule 3 has effect.
- (11) In regulation 7 (authorisation decision)—
 - (a) in paragraph (2)(a)—
 - (i) for “verification declaration”, substitute “UK declaration of verification”;
 - (ii) for “Annex V to the Directive”, substitute “Schedule 5”;
 - (b) at the end of paragraph (2)(b), omit “and”;
 - (c) at the end of paragraph (2)(c), insert—
 - “and,
 - (d) the project entity has satisfactorily completed any tests required by regulations 5(4), and 6(4) and 6(5).”;
 - (d) in paragraph (5)—
 - (i) for “5(1)(c) submitted in accordance with regulation 6”, substitute “6(1)”;
 - (ii) in sub-paragraphs (a) and (b), for “another Member State”, substitute “an EU Member State”.

- (12) Schedule 4 has effect.
- (13) In regulation 8 (determination of type)—
- (a) in paragraph (5), for “changes to TSIs or notified national technical rules”, substitute “material changes to the applicable standards”;
 - (b) for paragraph (6), substitute—

“(6) The Safety Authority must publish and keep up to date a list of determinations of type for vehicles issued in accordance with this regulation (including those determinations issued by the Safety Authority before exit day) and any modification, suspension or withdrawal of such a determination.

(6A) In maintaining that list, the Safety Authority may have regard to the requirements set out in Annex II to Commission Implementing [Decision 2011/665/EU](#) of 4 October 2011 on the European register of authorised types of railway vehicles⁽³⁾.”;
 - (c) after paragraph (8), insert—

“(9) In regulations 8, 9 and 10, “applicable standards” means the applicable standards in force at the time when type was determined, which are—

 - (a) before exit day, standards set out in TSIs and notified national technical rules;
 - (b) after exit day, standards set out in NTSNs and NTRs.

(10) In regulations 8, 9 and 10, any reference to “material” changes to standards does not include the replacement of the standards contained in TSIs or notified national technical rules by the standards published by the Secretary of State in accordance with regulations 3B and 3C on exit day and contained in NTSNs or NTRs.”.
- (14) In regulation 9 (type authorisation)—
- (a) in paragraphs (2)(b) and (3)(b), for “changes to the applicable TSI or notified national technical rules”, substitute “material changes to the applicable standards”;
 - (b) in paragraph (5), for the words “Commission Regulation” to the end of the sentence, substitute “Schedule 6”.
- (15) Schedule 5 has effect.
- (16) In regulation 10 (type authorisation: changes to TSIs etc)—
- (a) in the heading, for “TSIs etc”, substitute “applicable standards”;
 - (b) in paragraphs (1) and (5) for “TSI or notified national technical rules”, substitute “standards”.
- (17) In regulation 12(2)(c), for “TSI”, substitute “NTSN”.
- (18) In regulation 13 (authorisation requirements for the renewal or upgrading of subsystems)—
- (a) in paragraph (2)(c)—
 - (i) for “TSI, or part of a TSI”, substitute “NTSN, or part of an NTSN”;
 - (ii) for “derogations”, substitute “exemptions”;
 - (b) in paragraph (2)(d), for “TSI, or part of a TSI”, substitute “NTSN, or part of an NTSN”;
 - (c) in paragraph (5)(a)—
 - (i) for “strategy”, substitute “plan”;
 - (ii) for “TSI”, substitute “NTSN”;
 - (d) in paragraph (8)—

(3) OJ L 264, 8.10.2011, p.32.

- (i) for “derogations under regulation 14”, substitute “exemptions under regulations 14 and 14A”,
 - (ii) for “TSIs”, substitute “NTSNs”.
- (19) In regulation 14 (exemption from need to conform with TSIs (derogations))—
- (a) in the heading for “TSIs (derogations)”, substitute “NTSNs (exemptions)”;
 - (b) for “TSI” each time it occurs, substitute “NTSN”;
 - (c) in paragraph (1), for “a derogation”, substitute “an exemption”;
 - (d) in paragraph (2)—
 - (i) in sub-paragraph (a), for sub-paragraph (iii) substitute—
 - “(iii) concerns the design, construction, placing in service, upgrading, renewal, operation and maintenance of the parts of the rail system as well as the professional qualifications and health and safety conditions of the staff who contribute to its operation and maintenance.”,
 - (ii) omit sub-paragraph (c),
 - (iii) for sub-paragraph (f), substitute—
 - “(f) a project which employs innovative solutions which either do not comply with the relevant NTSNs or to which the assessment methods in those NTSNs cannot be applied.”;
 - (e) after paragraph (2), insert—
 - “(2A) In this regulation and in regulation 14A, a reference to a project at an advanced stage of development means a project whose planning or construction stage has reached a point where the impact of a change in technical specifications would present a significant legal, contractual, economic, financial, social or environmental impediment to the project concerned.”;
 - (f) omit paragraphs (3) to (6).
- (20) After regulation 14, insert—

“Application for exemptions

14A.—(1) Where a project entity applies for an exemption under regulation 14, they must apply to the Competent Authority in writing.

- (2) The following information must be included in the application for an exemption—
- (a) a description of the work, goods and services subject to the exemption, specifying the key dates, the location, and the operational and technical area;
 - (b) a precise reference to the NTSN (or its parts) from which an exemption is sought;
 - (c) a precise reference to, and details of, the alternative provisions which will be applied;
 - (d) for requests made under regulation 14(2)(a), evidence in support of the fact that the project is at an advanced stage of development;
 - (e) for requests made under regulation 14(2)(f), information which outlines how the solution deviates from or complements the applicable NTSNs;
 - (f) justification of the exemption, including the main reasons of a technical, economic, commercial, operational and/or administrative nature; and
 - (g) any other information justifying the application for an exemption.

(3) After receipt of the information specified in paragraph (2), the Competent Authority must determine the application for an exemption.

- (4) When the Competent Authority has made a determination it must inform the applicant of that determination.
- (5) When the Competent Authority makes a determination of a case under regulation 14(2) (f) (innovative solutions), and informs the applicant of the outcome of the application, the Competent Authority must also publish its determination.”.
- (21) In regulation 15 (essential requirements for project subsystems)—
- (a) in paragraph (1)(a), for “TSIs”, substitute “NTSNs”;
 - (b) in paragraph (1)(b), for “notified national technical rules”, substitute “NTRs”;
 - (c) after paragraph (1), insert—
 - “(1A) For the purposes of paragraph (1)(a), a project subsystem is deemed to conform with an applicable NTSN, save for any UK specific case set out in that NTSN, if—
 - (a) the person applying for an authorisation provides evidence that the project subsystem has been assessed under EU law as conforming with a TSI in force at the time when the application for authorisation is made; and
 - (b) the applicable NTSN specifies that it substantially reproduces the provisions of that TSI, in accordance with regulation 3B(6).”;
 - (d) in paragraph (2)—
 - (i) in sub-paragraph (a), for “TSIs”, substitute “NTSNs”,
 - (ii) in sub-paragraph (b), for “TSI”, substitute “NTSN”,
 - (iii) for sub-paragraph (c), substitute—
 - “(c) an exemption from conformity with the whole or part of a relevant NTSN has been granted in accordance with regulations 14 and 14A in relation to that subsystem; or”,
 - (iv) in sub-paragraph (d), for “a TSI”, substitute “an NTSN”.
- (22) In regulation 16 (role of project entity)—
- (a) for “notified national technical rules” each time it occurs, substitute “UK specific rules”;
 - (b) for paragraph (1)(a) substitute—
 - “(a) engage an EU notified body to carry out the EC verification assessment procedure, or engage an approved body to carry out the UK verification assessment procedure, other than in relation to UK specific rules;”;
 - (c) in paragraph (1)(b) for “a notified body”, substitute “an EU notified body or an approved body”;
 - (d) in paragraph (1)(c)—
 - (i) omit the words from “or if the engagement is made before the day” to “or a notified body.”,
 - (ii) after “to carry out the”, insert “UK”,
 - (iii) after “regulation 17”, insert “and Schedule 4”;
 - (e) in paragraph (2), for “a notified body”, substitute “an EU notified body or an approved body”;
 - (f) in paragraph (3)—
 - (i) for “verification declaration”, substitute “UK declaration of verification”,
 - (ii) for sub-paragraph (b), substitute—
 - “(b) either—

- (i) the EC verification assessment procedure has been carried out by an EU notified body, or
 - (ii) the UK verification assessment procedure has been carried out by an approved body,

and, if applicable in either case, the UK verification assessment procedure has been carried out by a designated body;”;
- (g) for sub-paragraph (c), substitute—
 - “(c) either—
 - (i) an EC certificate of verification has been drawn up by an EU notified body, or
 - (ii) a UK certificate of verification has been drawn up by an approved body,

and, if applicable in either case, a UK certificate of verification has been drawn up by a designated body; and”;
- (h) omit paragraph (4);
- (i) in paragraph (5), for “5(1)(c)”, substitute “6(1)”.
- (23) In regulation 17 (project subsystems: verification assessment procedure)—
 - (a) in the heading, after “Project subsystems:” insert “UK”;
 - (b) in paragraph (1)—
 - (i) in the opening words—
 - (aa) after “The”, insert “UK”,
 - (bb) for “a notified body”, substitute “an approved body”,
 - (cc) omit “other than in relation to notified national technical rules”,
 - (ii) in sub-paragraph (a), for “TSI” each time it occurs, substitute “NTSN”,
 - (iii) in sub-paragraph (b), for “Annex VI to the Directive”, substitute “Schedule 4”;
 - (c) in paragraph (2)—
 - (i) in the opening words—
 - (aa) for “notified body”, substitute “approved body”,
 - (bb) omit “other than in relation to notified national technical rules”,
 - (ii) in sub-paragraph (a)—
 - (aa) paragraph (i), for “Annex VI to the Directive”, substitute “Schedule 4”,
 - (bb) paragraph (v), for “TSI”, substitute “NTSN”,
 - (cc) for paragraph (vi) substitute—
 - “(vi) documentation or records of a determination of the Competent Authority in relation to an exemption from an applicable NTSN, pursuant to regulations 14 and 14A; and;”;
 - (d) in paragraph (3)—
 - (i) for “TSI”, substitute “NTSN”,
 - (ii) after “registers”, insert “or lists”,
 - (iii) for “Article 34” to the end of the sentence, substitute “regulations 8 (Determination of type), 35 (Register of infrastructure) and 36 (National vehicle register)”;
 - (e) in paragraph (4), at the start, after “The”, insert “UK”;

- (f) in paragraphs (4) and (5)—
 - (i) for “notified national technical rules”, substitute “UK specific rules”, and
 - (ii) for “Annex VI to the Directive”, substitute “Schedule 4”.
- (24) In regulation 18 (project subsystems: verification declaration)—
 - (a) in the heading, for “verification declaration”, substitute “UK declaration of verification”;
 - (b) in paragraph (1), for “verification declaration”, substitute “UK declaration of verification”;
 - (c) in paragraph (2), before “verification”, insert “UK”.
- (25) In regulation 19(1)—
 - (a) for “Member State”, substitute “country”;
 - (b) for “verification declaration”, substitute “UK declaration of verification”;
 - (c) in sub-paragraph (a)—
 - (i) in sub-paragraph (i), after “regulations 6(3)(b)”, insert “or (c)”,
 - (ii) for sub-paragraph (ii), substitute—
 - “(ii) the relevant UK declaration of verification, and;”
 - (d) in sub-paragraph (b), for “any other Member State that requests one”, substitute “the national body responsible for railway safety in the country in which the project subsystem is used, in response to a reasonable request from that body.”.
- (26) In regulation 20 (continuing duty on operator in relation to standards)—
 - (a) in paragraph (2)(a)—
 - (i) for “sub-paragraph (b)”, substitute “sub-paragraphs (b) and (ba)”,
 - (ii) for “the TSIs and notified national technical rules”, substitute “either the TSIs and notified national technical rules, or the NTSNs and NTRs”;
 - (b) in paragraph (2)(b)—
 - (i) for “a TSI or notified national technical rule”, substitute “an NTSN or NTR”,
 - (ii) for “TSI or rule” where it occurs, substitute “NTSN or NTR”;
 - (c) after paragraph (2)(b), insert—
 - “(ba) where a TSI or notified national technical rule referred to in sub-paragraph (a) has been replaced by an NTSN or by an NTR, either in conformity with the relevant NTSN or NTR currently in force or in conformity with the original TSI or rule.”;
 - (d) in paragraph (2)(c), for “TSI”, substitute “NTSN”;
 - (e) for paragraph (5), substitute—
 - “(5) In this regulation—
 - “functional NTSN” means an NTSN applying to a functional subsystem;
 - “project subsystem” includes a vehicle deemed to be authorised under these Regulations by the operation of regulation 44.”.
- (27) For regulation 23, substitute—

“Prohibition on placing interoperability constituents on the market

23.—(1) No person may place an interoperability constituent on the market for which there is an applicable NTSN with a view to its use on the rail system, unless—

- (a) the interoperability constituent meets the essential requirements that are relevant to an interoperability constituent of that type;
- (b) the appropriate procedure for assessing the conformity or suitability for use of the interoperability constituent has been carried out; and
- (c) subject to paragraph (2), a UK declaration of conformity or suitability for use in relation to that interoperability constituent has been drawn up.

(2) A person may place an interoperability constituent on the market in reliance on an EC declaration of conformity or suitability for use drawn up in relation to that interoperability constituent where one of the following conditions applies—

- (a) an EC declaration of conformity or suitability for use was drawn up before or after exit day, and there is no UK specific case applicable to the interoperability constituent; or
- (b) all of the following apply—
 - (i) an EC declaration of conformity or suitability for use was drawn up before exit day,
 - (ii) there is a UK specific case applicable to the interoperability constituent,
 - (iii) there is no material difference between the technical specifications of the applicable UK specific case and a pre-exit specific case against which the interoperability constituent was previously assessed, and
 - (iv) there are no other applicable UK specific cases.

(3) In this regulation, “a pre-exit specific case” means special provision in relation to the technical specifications for subsystems and interoperability constituents to allow for their compatibility with the rail system, which was applicable to the interoperability constituent and was set out and described in a TSI or notified national technical rule before exit day.

(4) In this regulation, a “material difference” in relation to technical specifications does not include the replacement of the standards contained in TSIs or notified national technical rules by the standards set by the Secretary of State in accordance with regulations 3B and 3C, and contained (after exit day) in NTSNs or NTRs.”.

(28) In regulation 24 (assessment procedure for interoperability constituents)—

- (a) for “applicable TSI” where it occurs, substitute “applicable NTSN”;
- (b) at the start of paragraph (1), insert “Subject to paragraph (4),”;
- (c) in paragraph (1) for “a notified body”, substitute “an approved body or, where assessment against an applicable UK specific case is required, a designated body”;
- (d) in paragraph (3) for “TSI”, substitute “NTSN”;
- (e) after paragraph (3), insert—

“(4) Except for cases which fall within regulation 23(2), where an EC declaration of conformity or suitability for use has already been drawn up, an assessment of the conformity or suitability for use against an applicable UK specific case must be carried out by a designated body in accordance with the procedure set out in the NTSN concerning the further assessment of interoperability constituents which hold an EC declaration of conformity or suitability for use.”.

(29) In regulation 25 (EC declaration of conformity or suitability for use)—

- (a) in the title to the regulation for “EC”, substitute “UK”;
- (b) in paragraph (1) for the opening words, substitute—

- “(1) Where neither a UK declaration of conformity or suitability for use, nor an EC declaration of conformity or suitability for use which satisfies one of the conditions in regulation 23(2) has been drawn up by the manufacturer or the manufacturer’s representative, a UK declaration of conformity or suitability for use must be drawn up by any person who—”;
- (c) in paragraph (2)—
- (i) at the start of the paragraph, for “An EC declaration”, substitute “A UK declaration”,
- (ii) for “Annex IV to the Directive”, substitute “Schedule 7”;
- (d) for paragraph (3), substitute—
- “(3) A person may only draw up a UK declaration of conformity or suitability for use if satisfied that the interoperability constituent satisfies the relevant conditions of the applicable NTSN, including any applicable UK specific case.”;
- (e) in paragraph (4)—
- (i) for “an EU Directive”, substitute “any enactment or rule of law”,
- (ii) for “an EC” substitute “a UK”;
- (f) after paragraph (4), insert—
- “(5) In this regulation, and in Schedule 7, the “manufacturer’s representative” means either an authorised representative or a person appointed by the manufacturer to perform specified tasks relating to the conformity or suitability for use of interoperability constituents, on or after exit day.”.
- (30) Schedule 6 has effect.
- (31) In regulation 26 (effect of conformity and suitability declarations)—
- (a) in the heading, for “conformity and suitability declarations”, substitute “declarations of conformity or suitability for use”;
- (b) in paragraph (1)—
- (i) in the opening words—
- (aa) for “an EC”, substitute “a UK”;
- (bb) after “suitability for use”, insert “or an EC declaration of conformity or suitability for use which satisfies the criteria set out in regulation 23(2)(a) or (b)”;
- (ii) in sub-paragraph (b), for “TSI”, substitute “NTSN”.
- (32) In regulation 27 (duties on operators)—
- (a) for “TSI”, substitute “NTSN”;
- (b) omit “located in the United Kingdom”.
- (33) Omit regulation 28.
- (34) In regulation 29 (notification to the Commission of incorrect declaration)—
- (a) in the heading, before “Commission”, insert “European”;
- (b) in paragraph (1)—
- (i) for “must immediately”, substitute “may”;
- (ii) for “Commission and the other Member States”, substitute “European Commission and EU Member States”;
- (c) in paragraph (2), for “must”, substitute “may”;
- (d) after paragraph (2), insert—

- “(3) This regulation does not apply in relation to the Channel Tunnel.”.
- (35) For the heading to Part 4, substitute “Approved and Designated Bodies”.
- (36) For regulation 30, substitute—

“Approved bodies

- 30.**—(1) An approved body is a body which—
- (a) has been approved by the Secretary of State pursuant to the procedure set out in regulation 31; or
 - (b) immediately before exit day was a notified body which has not received notice from the Secretary of State terminating its appointment as a notified body.
- (2) In this Regulation, “a notified body” means a body which has been—
- (a) appointed by the Strategic Rail Authority⁽⁴⁾ as a notified body and notified to the European Commission and EU Member States pursuant to regulation 5 of the Railways (Interoperability) (High-Speed) Regulations 2002⁽⁵⁾;
 - (b) appointed by the Secretary of State as a notified body and notified to the European Commission and EU Member States pursuant to regulation 25 of the Railways (Interoperability) Regulations 2006⁽⁶⁾ or regulation 31 of these Regulations as they had effect immediately before exit day.”.
- (37) In regulation 31 (appointment of notified bodies and designated bodies)—
- (a) in the heading, for “notified bodies”, substitute “approved bodies”;
 - (b) for “a notified body” each time it occurs, substitute “an approved body”;
 - (c) for “notified” in paragraphs (6)(b), (8)(a) and (b), and (9)(a) and (b), each time it occurs, substitute “approved”;
 - (d) in paragraphs (2)(b), (3), and (7)(b) for “Annex VIII to the Directive”, substitute “Schedule 8”.
- (38) Schedule 7 has effect.
- (39) In regulation 32 (notified bodies and designated bodies: certificates etc)—
- (a) in the heading, for “notified bodies”, substitute “approved bodies”;
 - (b) for “a notified body” each time it occurs, substitute “an approved body”;
 - (c) in paragraphs (1) and (2), before “certificate of verification”, insert “UK”;
 - (d) in paragraphs (1) and (3), for “an EC declaration”, substitute “a UK declaration”;
 - (e) in paragraph (2), for “Annex VI to the Directive”, substitute “Schedule 4”;
 - (f) in paragraph (3), for “European specifications or TSIs”, substitute “NTSNs”;
 - (g) after paragraph (3), insert—

“(3A) A designated body must not confirm that a UK declaration of conformity or suitability for use can be drawn up in respect of an interoperability constituent unless satisfied that the constituent conforms to such of the UK specific cases as are required by regulation 25.”;
 - (h) in paragraph (5), for “notified body”, substitute “approved body”.
- (40) In regulation 33 (fees of notified bodies and designated bodies)—

⁽⁴⁾ Established under section 201 of the Transport Act 2000 (c. 38) and abolished by S.I. 2006/2925.

⁽⁵⁾ S.I. 2002/1166, revoked with savings by S.I. 2006/397.

⁽⁶⁾ S.I. 2006/397, revoked with savings by S.I. 2011/3066.

- (a) in the heading, for “notified bodies”, substitute “approved bodies”;
 - (b) in paragraph (1) for “a notified body”, substitute “an approved body”;
 - (c) in paragraphs (2)(a) and (2)(b)(i), for “notified body”, substitute “approved body”.
- (41) After regulation 34, insert—

“Register of approved bodies

34A.—(1) The Secretary of State must—

- (a) assign an approved body identification number to each approved body; and
 - (b) compile and maintain a register of—
 - (i) approved bodies;
 - (ii) their approved body identification number;
 - (iii) the activities for which they have been approved; and
 - (iv) any restrictions on those activities.
- (2) The register referred to in paragraph (1) must be made publicly available.

UK national accreditation body

34B.—(1) The Secretary of State may authorise the UK national accreditation body to carry out the following activities on behalf of the Secretary of State—

- (a) assessing whether a body meets the approved body or designated body requirements;
- (b) exercising functions in accordance with regulation 31;
- (c) compiling and maintaining the register of approved bodies in accordance with regulation 34A.

(2) In this regulation—

“RAMS” means Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93;

“UK national accreditation body” means the body appointed by the Secretary of State in accordance with Article 4 of RAMS.”

(42) In regulation 36 (national vehicle register)—

- (a) omit paragraph (4);
- (b) for paragraph (9), substitute—

“(9) Where a vehicle is also registered in an EU Member State the registration entity may notify the entity responsible for the national vehicle register in that EU Member State of any relevant changes to the National Vehicle Register.”;

(c) in paragraph (10)—

- (i) for sub-paragraph (a), substitute—

“(a) by the Safety Authority or the Rail Accident Investigation Branch(7);”;

- (ii) in sub-paragraph (b)—

(aa) for sub-paragraph (i), substitute—

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

- “(i) the Office of Rail and Road, DFI, the Intergovernmental Commission, or any EU regulatory body designated in accordance with relevant EU law,”
- (bb) for sub-paragraph (ii), substitute—
- “(ii) the European Union Agency for Railways”,
- (cc) at the end of sub-paragraph (iv), omit “or”,
- (dd) at the end of sub-paragraph (v), omit the full stop, and insert—
- “; or
- (vi) the national body or bodies responsible for railway safety in the country where the project subsystem is used.”;
- (d) in paragraph (11), for “DRDNI”, substitute “DFI”;
- (e) after paragraph (11), insert—
- “(12) In this regulation, “the European Union Agency for Railways” means the agency for railway safety and interoperability established by Regulation (EU) No 2016/796 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Railways and repealing Regulation (EC) No 881/2004(8).”.
- (43) In regulation 37(10), for “DRDNI”, substitute “DFI”.
- (44) In regulation 38, for “DRDNI” each time it occurs, substitute “DFI”.
- (45) In regulation 40(5), for “DRDNI”, substitute “DFI”.
- (46) In regulation 41(1) after “EC” insert “or UK”.
- (47) In regulation 42 (notice of improper drawing up of the EC declaration of conformity or suitability for use for an interoperability constituent)—
- (a) in the heading after “EC” insert “or UK”;
- (b) in paragraphs (1) and (2)(a), for “the requirements of regulation 25”, substitute “relevant EU law, or the UK declaration of conformity or suitability for use has not been drawn up in accordance with the requirements of regulation 25 and Schedule 7”.
- (48) In regulation 45 (accessibility for people with reduced mobility)—
- (a) for paragraph (a), substitute—
- “(a) the TSI relating to persons with reduced mobility set out in the Annex to [Decision 2008/164/EC](#) of the European Commission of 21 December 2007, or any amended version of it, or Commission Regulation 1300/2014 of the European Commission of 18 November 2014 which replaced it, or the NTSN that replaced Commission Regulation 1300/2014, or any variation of that NTSN, or any NTSN which replaces it.”;
- (b) in paragraph (d)—
- (i) after “TSI replacing it,”, insert “or the NTSN”,
- (ii) in sub-paragraph (ii), for “has been granted under regulation 14”, substitute “was granted under regulation 14 before exit day, or an exemption from part of it has been granted under regulations 14 and 14A”.
- (49) In regulation 46 (dispensations)—
- (a) in paragraph (1), for “notified national technical rules”, substitute “NTRs”;
- (b) in paragraph (2), omit “for the purposes of Article 17(3) of the Directive”.

(50) After regulation 47, insert—

“Further savings and transitional arrangements

47A.—(1) Where a structural subsystem was authorised to be placed in service on the rail system in accordance with regulation 7 or regulation 9 as they had effect before exit day and that authorisation has not been revoked, it is treated as authorised under these Regulations as they have effect on or after exit day.

(2) Where an application for authorisation was made pursuant to regulation 5 as it had effect before exit day and that authorisation was not issued before exit day, it is, on or after exit day, treated as a valid application under these Regulations and any EC declaration of verification and technical file submitted with that application are treated as a UK declaration of verification and technical file submitted in accordance with these Regulations as they have effect on or after exit day.

(3) Where an application for type authorisation was made pursuant to regulation 9 as it had effect before exit day and that authorisation was not issued before exit day, it is, on or after exit day, treated as a valid application under these Regulations and any reference to an applicable TSI or notified national technical rule in the documentation accompanying that application is treated as a reference to the applicable NTSN or NTR which replaces them.

(4) Where a Competent Authority has made a decision about the requirement for authorisation and the extent to which TSIs must apply to a project subsystem pursuant to regulation 13(8) before exit day, a reference to a TSI in that decision is treated as a reference to the NTSN that replaces it.

(5) Where an application for a decision by the Competent Authority as to whether an authorisation is required was made pursuant to regulation 13 as it had effect before exit day and the Competent Authority has not made the decision before exit day, it is treated as an application under regulation 13 as it has effect on or after exit day, and any reference in that application to TSIs or parts of TSIs is treated as a reference to the NTSNs or parts of NTSNs that replace them.

(6) A derogation granted against a TSI by the Competent Authority in accordance with Article 9 of the Directive and these Regulations as they had effect before exit day is treated on or after exit day as an exemption granted by the Competent Authority against the NTSN which replaces that TSI in accordance with regulations 14 and 14A.

(7) Except for a project subsystem authorised under regulation 9, if a project subsystem was authorised before exit day, the project entity must (in addition to the requirements of regulation 19(2)) keep the documents it was required to retain in accordance with regulation 19(1)(a) as it had effect before exit day.

(8) Where an interoperability constituent was placed on the market anywhere in the European Union before exit day, it is treated on or after exit day as an interoperability constituent placed on the UK market in accordance with Part 3.

(9) Where a notified body (as defined in regulation 30(2)) was engaged before exit day to carry out an EC verification assessment procedure in relation to TSIs or notified national technical rules pursuant to Annex VI of the Directive and regulation 16 as it had effect before exit day, the work carried out by that body before exit day is treated as work undertaken pursuant to regulation 16 and Schedule 4 as they have effect from exit day to carry out the UK verification assessment procedure in relation to NTSNs.

(10) Where a designated body was engaged before exit day to carry out an EC verification assessment procedure in relation to TSIs or notified national technical rules pursuant to Annex VI of the Directive and regulation 16 as it had effect before exit day, the work carried out by that body before exit day is treated as work undertaken pursuant to regulation 16 and Schedule 4

as they have effect from exit day to carry out the UK verification assessment procedure in relation to UK specific rules.

(11) A dispensation from a notified national technical rule granted by the Competent Authority pursuant to regulation 46 as it had effect before exit day, is treated on or after exit day as a dispensation from the NTR specified as replacing it.”.

(51) In the heading of the Schedule to the Regulations, after “Schedule” insert “1”.