Draft Regulations laid before Parliament under paragraph 8F(1) and (2), and paragraph 12(1), of Schedule 7 to the European Union (Withdrawal) Act 2018 (c. 16) and section 103(5) of the Railways and Transport Safety Act 2003 (c. 20) for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2026 No.

RAILWAYS

TRANSPORT

The Railways (Interoperability in Northern Ireland) (Convention on International Carriage by Rail) (Amendment) Regulations 2026

Made - - - - ***

Coming into force in accordance with regulation 1(1)

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The Secretary of State makes these Regulations in exercise of the powers conferred by section 8C(1) and (2) of, paragraph 1(1)(ab) and (3)(a) of Schedule 4 to, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018(**a**) ("the Withdrawal Act") and section 103 of, and paragraphs 2(a) and (b), 3(1) and (2)(a) to, Schedule 6 of the Railways and Transport Safety Act 2003(**b**).

In accordance with paragraph 3(1) of Schedule 4 to the Withdrawal Act, the Treasury's consent has been obtained prior to the making of these Regulations.

A draft of this instrument has been laid before Parliament and approved by a resolution of each House of Parliament in accordance with paragraphs 8F(1) and (2) and 12(1) of Schedule 7 to the Withdrawal Act 2018 and section 103(5) of the Railways and Transport Safety Act 2003.

PART 1

Introductory

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Railways (Interoperability in Northern Ireland) (Convention on International Carriage by Rail) (Amendment) Regulations 2026 and come into force on the 21st day after the day on which they are made.

(2) These Regulations extend to England and Wales, Scotland and Northern Ireland, save for regulation 52, which extends to Northern Ireland only.

Interpretation

2. In these Regulations—

"the 2008 Directive" means Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community (recast)(**c**);

"the 2011 Regulations" means the Railways (Interoperability) Regulations 2011(**d**);

(**a**) 2018 c. 16; section 8C was inserted by the European Union (Withdrawal Agreement) Act 2020 (c. 1), section 21. Paragraph 1(1)(ab) of Schedule 4 was inserted by the European Union (Withdrawal Agreement) Act 2020, section 28(a).
(**b**) 2003 c. 20; section 103(2) was amended by S.I. 2020/1447.
(**c**) OJ L 191, 18.7.2008, p. 1.
(**d**) S.I. 2011/3066; relevant amending instruments are S.I. 2013/20422013/3023, 2014/3217, 2015/1682, 2015/2022, 2016/275, 2016/645, 2019/345, 2020/318.

"the 2016 Directive" means Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union(**a**), as amended from time to time;

"Agency Regulation" means Regulation (EU) 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(**b**) as it has effect in EU law;

"approved body" has the meaning provided by regulation 2 of the 2011 Regulations;

"authorised representative" means any person established in the European Union or the United Kingdom who has received a written mandate from a manufacturer or a contracting entity to act on behalf of that manufacturer or contracting entity in relation to specified tasks;

"common safety methods" means the methods, developed pursuant to Article 6 of the Safety Directive, to describe how safety levels, achievement of safety targets, and compliance with other safety requirements are assessed, as revised and reissued from time to time;

"conformity assessment activity" means an activity related to the process of demonstrating whether specified requirements relating to a product, process, service, subsystem, person or body have been fulfilled;

"conformity assessment body" means an NI notified body or an NI designated body, or more than one of these as the case may be;

"contracting entity" means a person who contracts or intends to contract with another person for that other person to design, construct, renew or upgrade a subsystem;

"Conventional Directive" means Directive 2001/16/EC of the European Parliament and of the Council of 19 March 2001 on the interoperability of the trans-European conventional rail system(**c**);

"design operating state" means the normal operating mode of an interoperability constituent, subsystem or vehicle, and its foreseeable degraded conditions, including wear, within the range and conditions of use specified in its technical and maintenance files;

"DFI" means the Department for Infrastructure established by Article 3(1) of the Departments (Northern Ireland) Order 1999(**d**) and renamed by section 1(6) of the Departments Act (Northern Ireland) 2016(**e**);

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

"EC declaration of conformity or suitability for use" means a declaration constituting an attestation that an interoperability constituent has been subject to the procedures laid down in an applicable TSI for assessing conformity or suitability for use, drawn up in accordance with regulation 29 or in accordance with Articles 9 and 10 of the 2016 Directive;

"EC declaration of verification" means a declaration drawn up pursuant to regulation 20 or in accordance with Article 15 of the 2016 Directive;

(**a**) OJ L 138, 26.5.2016, p. 44.
(**b**) OJ L 138, 26.05.2016, p. 1.
(**c**) OJ L 110, 20.4.2001, p. 1.
(**d**) S.I. 1999/283 (N.I. 1), to which there are amendments not relevant to these Regulations.
(**e**) 2016 c. 5 (N.I.).

"EC verification assessment procedure" means the procedure set out in Annex IV to the 2016 Directive;

"ERTMS" means the European Rail Traffic Management System described in paragraph 2.2 of Annex I to Commission Implementing Regulation (EU) 2023/1695 of 10 August 2023 on the technical specification for interoperability relating to the control-command and signalling subsystems of the rail system in the European Union and repealing Regulation (EU) 2016/919(**a**);

"essential requirements" has the meaning provided by paragraph (9) of Article 2 of the 2016 Directive, modified such that any reference to "Union law" in Annex III to that Directive is read as a reference to "relevant law";

"EU notified body" means—

(a) a body in an EEA state which has been notified to the European Commission in accordance with Chapter VI of the 2016 Directive, unless that body's notification has been withdrawn, or

(b) a body in Switzerland deemed competent to undertake conformity assessment activities in accordance with the 2016 Directive by a Decision of the Community/Switzerland Inland Transport Committee(**b**)unless that body is no longer so deemed.

"European Commission" means the Commission of the European Union;

"European specification" has the meaning provided by Article 2(10) of the 2016 Directive;

"European Union Agency for Railways" means the Agency established by the Agency Regulation;

"European Vehicle Register" means the European Vehicle Register developed in accordance with Article 47(5) of the 2016 Directive;

"fixed installation" means any or all of the trackside control-command and signalling, energy and infrastructure subsystems specified in paragraph 1(a) and described in paragraphs 2.1 to 2.3 of Annex II to the 2016 Directive;

"functional subsystem" means a subsystem as specified in paragraph 1(b) of Annex II to the 2016 Directive;

"harmonised standard" has the meaning provided by paragraph 24 of Article 2 of the 2016 Directive;

"High-Speed Directive" means Council Directive 96/48/EC of 23 July 1996 on the interoperability of the trans-European high-speed rail system(**c**);

"infrastructure manager" has the meaning provided in paragraph (2) of Article 3 of Directive 2012/34/EU of the European Parliament and of the Council of 21 November 2012 establishing a single European railway area (recast)(**d**);

(**a**) OJ L 222, 8.9.2023, p. 380.

(**b**) The Community/Switzerland Inland Transport Committee is a body responsible for monitoring and application of the provisions of an Agreement of 21 June 1999 between the European Community and the Swiss Confederation on the Carriage of Goods and Passengers by Rail and Road. The Agreement can be found here: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2002:114:TOC.

(**c**) OJ L 235, 17.09.1996, p. 6.

(**d**) OJ L 343, 14.12.2012, p. 32.

"interoperability constituent", save in the expression "UK interoperability constituent", means any elementary component, group of components, sub-assembly or complete assembly of equipment incorporated or intended to be incorporated into a subsystem, upon which the interoperability of the rail system depends directly or indirectly, including both tangible objects and intangible objects;

"Irish border station" means a station in Ireland close to the border with Northern Ireland with network characteristics similar to stations in Northern Ireland;

"market surveillance authority" means the Health and Safety Executive for Northern Ireland(**a**);

"mobile subsystem" means the rolling stock subsystem and the on-board control-command and signalling subsystem;

"national safety authority in Ireland" means the body established in Ireland in accordance with paragraph (1) of Article 16 of the Safety Directive;

"network" means the lines, stations, terminals, and all kinds of fixed equipment needed to ensure safe and continuous operation of the rail system;

"NI designated body" means a person appointed in accordance with regulation 34(5), unless its appointment has been terminated;

"NI notified body" means a body that has been notified to the European Commission and the EEA states in accordance with regulation 34(1), unless its notification has been withdrawn;

"notified national rule" means a rule in use in Northern Ireland that has been implemented in the cases described in Article 13(2) or Article 14(4) of the 2016 Directive and notified by the DFI to the European Commission and the European Union Agency for Railways, as modified and further notified;

"one-stop shop" has the meaning provided by Article 12 of the Agency Regulation;

"operator", in relation to the use of an interoperability constituent or a project subsystem, means the infrastructure manager or railway undertaking with management responsibility for that interoperability constituent or project subsystem for the time being;

"owner" in relation to a structural subsystem, means any person who has an estate or interest in, or right over that structural subsystem, and whose agreement is needed before another may use it;

"placing in service" means all the operations by which a subsystem is put into its design operating state, and cognate expressions are to be construed accordingly;

"placing on the market" means the first making available of an interoperability constituent, subsystem or vehicle, ready to function in its design operating state, on the market in Northern Ireland, and cognate expressions are to be construed accordingly;

"Practical Arrangements Regulation" means Commission Implementing Regulation (EU) 2018/545 of 4 April 2018 establishing practical arrangements for the railway vehicle

(**a**) Formerly the Health and Safety Agency for Northern Ireland which was established under article 12 of the Health and Safety at Work (Northern Ireland) Order 1978 (S.I. 1978/1039 (N.I. 9)). It became the Health and Safety Executive for Northern Ireland by virtue of article 3(1) of the Health and Safety at Work (Amendment) (Northern Ireland) Order 1998 (S.I. 1998/2795 (N.I. 18)).

authorisation and railway vehicle type authorisation process pursuant to Directive (EU) 2016/797 of the European Parliament and of the Council(**a**) as it has effect in EU law;

"product" means a product obtained through a manufacturing process, including interoperability constituents and subsystems;

"project", save in the expressions "project entity" and "project subsystem", means a scheme for the construction, upgrading or renewal of the whole or part of any subsystem of the rail system, and where it is intended to carry out that construction, upgrading or renewal in parts, each of which are to be placed in service on a permanent basis independently of the other parts, it means any such part;

"project entity" means, in relation to a project, a contracting entity or manufacturer or the authorised representative of a contracting entity or manufacturer;

"project subsystem" means—

(a) the whole of a structural subsystem which is subject to the requirement for authorisation under these Regulations, other than when the structural subsystem is subject to the requirement because part of it is being upgraded or renewed, or

(b) in the case of a structural subsystem which is subject to the requirement for authorisation under these Regulations solely because part of it is being upgraded or renewed, that part of the structural subsystem;

"rail system", save in the expression "UK rail system", means the infrastructure composed of lines and fixed installations of the existing rail system in Northern Ireland plus the vehicles of all categories and origin travelling on that infrastructure;

"railway undertaking" has the meaning provided in point (1) of Article 3 of Directive 2012/34/EU of the European Parliament and of the Council of 21 November 2012 establishing a single European railway area (recast);

"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(**b**) as it has effect in EU law;

"relevant register" means a register of infrastructure published in accordance with regulation 43 or the European Vehicle Register;

"relevant State" means—

(a) Northern Ireland; or

(b) any EEA state;

"renewal" means any major substitution work on a subsystem or part of a subsystem which does not change the overall performance of the subsystem, and cognate words are to be construed accordingly;

"Safety Directive" means Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety (recast)(**c**);

"structural subsystem" means a subsystem specified in paragraph 1(a) of Annex II to the 2016 Directive;

(**a**) OJ L 90, 6.4.2018, p. 66.
(**b**) OJ L 218, 13.8.2008, p. 30.
(**c**) OJ L 138, 26.05.2016, p. 102.

"subsystem" save in the expressions "functional subsystem", "mobile subsystem", "project subsystem", and "structural subsystem", means the structural subsystems and functional subsystems referred to in paragraph 1 of Annex II to the 2016 Directive;

"technical specification", save in the expression "technical specification for interoperability", means a document that prescribes technical requirements to be fulfilled by a product, subsystem, process or service;

"Templates Regulation" means Commission Implementing Regulation (EU) 2019/250 of 12 February 2019 on the templates for 'EC' declarations and certificates for railway interoperability constituents and subsystems, on the model of declaration of conformity to an authorised railway vehicle type and on the 'EC' verification procedures for subsystems in accordance with Directive (EU) 2016/797 of the European Parliament and of the Council and repealing Commission Regulation (EU) No 201/2011(**a**) as it has effect in EU law;

"TSI" means a technical specification for interoperability adopted from time to time by the European Commission pursuant to the 2008 Directive, the Conventional Directive, the High-Speed Directive or the 2016 Directive, as that technical specification for interoperability has effect in EU law, and as it is amended from time to time;

"type", in relation to a vehicle, means its set of technical design characteristics, as specified in the EC-type examination certificate relating to it, such certificate being that described in the verification module set out at Module SB (EC-Type Examination) in Annex I of Commission Decision of 9 November 2010/713/EU on modules for the procedures for assessment of conformity, suitability for use and EC verification to be used in the technical specifications for interoperability adopted under Directive 2008/57/EC of the European Parliament and of the Council(**b**) as it has effect in EU law;

"UK interoperability constituent" means any elementary component, group of components, sub-assembly or complete assembly of equipment that is incorporated or intended to be incorporated into a subsystem upon which the interoperability of the UK rail system depends directly or indirectly; and the concept of a "constituent" covers both tangible objects and intangible objects such as software;

"UK national accreditation body" means the body appointed by the Secretary of State in accordance with Article 4 of 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(**c**);

"UK 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;

"UK(NI) indication" means the form of marking set out in Schedule 1 to the Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020(**d**);

"upgrading" means any major modification work on a subsystem or part of it which results in a change in the technical file accompanying the EC declaration of verification, if that technical file exists, and which improves the overall performance of the subsystem, and cognate words are to be construed accordingly;

(**a**) OJ L 42, 13.2.2019, p. 9.
(**b**) OJ L 319, 4.12.2010, p. 1.
(**c**) EUR 765/2008, as amended by S.I. 2019/696, 2019/1246, 2020/852, S.I. 2020/1359, 2020/1460, 2023/959 and 2025/82.
(**d**) S.I. 2020/1460, to which there are amendments not relevant to these Regulations.

"vehicle" means a railway vehicle that runs on its own wheels on railway lines with or without traction and is composed of one or more structural and functional subsystems or parts of such subsystems.

Application

3.—(1) Subject to paragraphs (2) and (6) and save for regulations 53 and 54, these Regulations apply to the following—

(a) the rail system;

(b) subsystems located, operated or intended to be operated in Northern Ireland;

(c) interoperability constituents.

(2) These Regulations do not apply to any part of the rail system that the DFI determines falls within one or more of these categories—

(a) metros, trams and other light rail systems;

(b) networks that are functionally separate from the rest of the rail system and intended only for the operation of local, urban or suburban passenger services, as well as railway undertakings operating solely on these networks;

(c) infrastructure and vehicles reserved for a strictly local, historical or touristic use;

(d) light rail infrastructure occasionally used by heavy rail vehicles under the operational conditions of the light rail system where it is necessary for the purposes of connectivity of those vehicles only;

(e) vehicles primarily used on light rail infrastructure but equipped with some heavy rail components necessary to enable transit to be effected on a confined and limited section of heavy rail infrastructure for connectivity purposes only.

(3) For the purposes of paragraph (2), "light rail" has the meaning provided by paragraph (29) of Article 2 of the 2016 Directive.

(4) A person may make an application to the DFI for a determination under paragraph (2) and the DFI must consider any such application.

(5) The DFI must publish and keep up to date a list of the parts of the rail system that are excluded from the scope of these Regulations by virtue of determinations made under paragraph (2).

(6) These Regulations do not apply to—

(a) privately owned railway infrastructure and vehicles exclusively used on such infrastructure that exist solely for use by the owner for its freight operations, or

(b) railways the lines of which have a gauge of less than 350 millimetres and vehicles running on such lines.

PART 2

Subsystems

Requirement for authorisation for the placing in service of fixed installations

4.—(1) No person may place in service any fixed installation unless—

(a) the DFI has granted an authorisation under these Regulations for the placing in service of that fixed installation, or

(b) the DFI has determined under regulation 16 that for the upgrading or renewal of the fixed installation, a new authorisation is not required.

(2) The DFI must issue guidance on how to obtain an authorisation referred to in this regulation, and that guidance must—

(a) be disseminated in co-operation with the European Union Agency for Railways, and

(b) be made available free of charge.

(3) For the purposes of paragraph (1), the placing into service of a fixed installation does not include any testing or trials conducted in the relevant EC verification assessment procedure or for additional checks required by the DFI pursuant to regulation 6(3).

Requirement for authorisation for placing vehicles on the market

5. No person may place a vehicle on the market unless—

(a) the DFI or the European Union Agency for Railways has issued an authorisation for the placing of that vehicle on the market,

(b) in the case of a vehicle that has an area of use in Northern Ireland and in any part of Ireland beyond the Irish border stations, the European Union Agency for Railways has issued an authorisation for that vehicle, or

(c) an authorisation for placing the vehicle in question in service was granted under the 2008 Directive, providing that—

(i) that authorisation has not been revoked, and

(ii) that vehicle is intended for use only on any part of the network which was covered by that authorisation, or

(d) if required to do so under regulation 17, it has obtained an authorisation for placing on the market in its new design operating state following renewal or upgrade.

Application for authorisation for a fixed installation

6.—(1) An application for an authorisation for a fixed installation to be placed in service must be made to the DFI and be accompanied by—

(a) evidence of the safe integration of the subsystems, established on the basis of the relevant TSIs, notified national rules and the common safety methods,

(b) evidence of the technical compatibility of the subsystems with the subsystem into which they are being integrated, established on the basis of the relevant TSIs, notified national rules and relevant registers,

(c) the technical file compiled in accordance with regulation 21(5),

(d) an EC declaration of verification, and

(e) in the case of trackside control-command and signalling subsystems involving European Train Control System equipment or Global System for Mobile Communications – Railway equipment—

(i) evidence of the approval decision of the European Union Agency for Railways issued in accordance with regulation 7, and

(ii) where there has been a change to the draft tender specifications or to the description of the envisaged technical solutions that occurred after the approval decision,

evidence of compliance with the result of the procedure referred to in Article 30(2) of the Agency Regulation.

(2) Subject to paragraph (3), in considering an application the DFI must not require checks already carried out under the EC verification assessment procedure to be carried out again.

(3) The DFI may require such additional checks which it considers necessary in relation to the fixed installation if that fixed installation appears to the DFI not to meet the essential requirements.

(4) Where additional checks are required under paragraph (3) the DFI must—

(a) inform the applicant that the application cannot be determined before the additional checks are carried out, and

(b) notify the European Commission in writing as soon as reasonably practicable of any such additional checks it requires and the reasons for requiring those checks.

(5) Within the period of one month beginning with the day after the day on which the application is received, the DFI must respond in writing and confirm—

(a) that the application is complete, or

(b) what supplementary information is required for the completion of the file, together with a reasonable deadline for providing it.

ERTMS tender approval

7.—(1) A person who makes a call for tender in respect of an ERTMS tender (an "applicant") must obtain approval from the European Union Agency for Railways before the person issues that call for tender.

(2) Where an applicant seeks approval from the European Union Agency for Railways in respect of a call for an ERTMS tender, the applicant must submit to the European Union Agency for Railways a file that includes—

(a) the draft tender specification or the description of the envisaged technical solutions,

(b) documentary evidence of the conditions necessary for technical and operational compatibility of the subsystem with the vehicles intended to be operated on the relevant part of the network,

(c) documentary evidence of the compliance of technical solutions envisaged with the relevant TSIs, and

(d) any other relevant documents, including DFI opinions.

(3) The applicant must submit the application through the one-stop shop.

(4) The DFI may issue an opinion on the application either to the applicant before the submission of the application or to the European Union Agency for Railways after the submission of the application.

(5) Following an application made under this regulation, the applicant must provide any supplementary information that is requested by the European Union Agency for Railways within the deadline set by it.

(6) If the applicant agrees with the European Union Agency for Railways' assessment of deficiencies identified in an application made under this regulation, the applicant must rectify the project design before submitting a new request for approval, except where the relevant project is in an advanced state of development as described in regulation 18(9) in which case it must rectify the project design but need not submit a new request for approval.

(7) If the applicant does not agree with the European Union Agency for Railways' assessment of deficiencies identified in an application made under this regulation, the applicant may request

a review of it within the period of one month beginning with the day after the day on which that assessment is received.

(8) If, following a review referred to in paragraph (7), the European Union Agency for Railways confirms its initial decision, the applicant is entitled to bring an appeal to the Board of Appeal in accordance with Article 19(5) of the 2016 Directive.

(9) In the event that the documents specified under paragraph (2)(a) are amended after an approval decision has been issued by the European Union Agency for Railways, the applicant must inform, as soon as possible, the DFI and the European Union Agency for Railways of the amendments through the one-stop shop.

Application for authorisation for a vehicle

8.—(1) Subject to paragraph (2), an application for an authorisation for a vehicle to be placed on the market must be made to the DFI, or the European Union Agency for Railways, through the one-stop shop and be accompanied by—

(a) evidence of the technical compatibility within the vehicle of the mobile subsystems of which the vehicle is composed, established on the basis of the relevant TSIs and where applicable, notified national rules;

(b) evidence of the safe integration within the vehicle of the mobile subsystems of which the vehicle is composed, established on the basis of the relevant TSIs, notified national rules and the common safety methods;

(c) the technical file compiled in accordance with regulation 21(5);

(d) the EC declaration of verification in evidence of the placing on the market of the mobile subsystems of which the vehicle is composed;

(e) a specification of the area of use of the vehicle and evidence that the technical compatibility of the vehicle with the network within that area of use has been checked and established on the basis of relevant notified national rules, the register of infrastructure referred to in regulation 43 and Commission Implementing Regulation (EU) 402/2013 of 30 April 2013 on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009(**a**) as it has effect in EU law.

(2) Where the area of use of the vehicle includes Ireland or any part of it in addition to Northern Ireland or any part of it, the application must be made to the European Union Agency for Railways, save where the area of use extends into Ireland only to the Irish border stations, in which case the application may be made to the DFI or the European Union Agency for Railways.

(3) Subject to paragraph (4), in considering an application, the DFI must not require checks already carried out under the EC verification assessment procedure to be carried out again.

(4) The DFI may require such additional checks which the DFI considers necessary in relation to the vehicle if that vehicle appears to the DFI not to meet the essential requirements.

(5) Where additional checks are required under paragraph (4) the DFI must—

(a) inform the applicant that the application cannot be determined before the additional checks are carried out, and

(b) notify the European Commission in writing as soon as reasonably practicable of any such additional checks it requires and the reasons for requiring those checks.

(6) Where an application for a vehicle to be placed on the market has been made to the European Union Agency for Railways and the application has been referred to the DFI for assessment in

(**a**) OJ L 121, 3.5.2013, p. 8.

accordance with Article 21(5)(b) of the 2016 Directive, the DFI must make the assessment referred to in that Article.

(7) Where the European Union Agency for Railways has, in accordance with Article 21(7) of the 2016 Directive, disagreed with a negative assessment made by the DFI of an application for authorisation, the DFI must cooperate with the European Union Agency for Railways with the intent of achieving a mutually acceptable assessment.

(8) Should a mutually acceptable assessment be unachievable, the assessment of the European Union Agency for Railways of the relevant authorisation must replace the negative assessment made by the DFI unless the DFI has referred the matter for arbitration to the Board of Appeal established under Article 55 of the Agency Regulation.

(9) Whenever tests are necessary in order to obtain documentary evidence of the technical compatibility referred to in paragraph (1)(a) and (e), the DFI may issue a temporary authorisation to the applicant in order for a vehicle to be used on the network for the purposes of practical verification.

(10) The infrastructure manager, in consultation with the applicant, must as far as possible ensure that any tests undertaken under a temporary authorisation granted under paragraph (9) take place within the period of three months beginning with the day after the day on which the applicant's application is received.

(11) Within the period of one month beginning with the day after the day on which the application is received, the DFI must respond in writing and confirm—

(a) that the file is complete, or

(b) what supplementary information is required for the completion of the file, together with a reasonable deadline for providing it.

Authorisation decision for fixed installations

9.—(1) The DFI must determine an application for an authorisation to place a fixed installation in service by—

(a) issuing an authorisation for the placing in service of the fixed installation, or

(b) refusing the application for authorisation.

(2) The DFI must issue an authorisation for placing in service of the fixed installation or a negative decision within a reasonable time period communicated to the applicant in advance, and in any event, within the period of four months beginning with the day after the day on which the DFI receives the application or, where the DFI has specified in accordance with regulation 6(5)(b) that supplementary information is required, within the period of four months beginning with the day after the day that information is received.

(3) Where the DFI refuses an application under paragraph (1)(b), the applicant may, within the period of one month beginning with the day after the day on which the applicant receives notification of that decision, request the DFI to review its decision.

(4) On receipt of a request for review of a decision in accordance with paragraph (3), the DFI must confirm or reverse that decision within two months beginning with the day after the day of receipt of the request for review.

(5) The DFI must only issue an authorisation for the placing in service of a fixed installation—

(a) where it is satisfied that an EC declaration of verification has been drawn up,

(b) where it has received the evidence referred to in regulation 6(1)(a) and (b),

(c) where it is satisfied that the project subsystem has been so designed, constructed and installed as to meet the essential requirements relating to that subsystem when placed in service,

(d) in the case of trackside control-command and signalling subsystems involving ERTMS equipment—

(i) where it is satisfied that an approval decision of the European Union Agency for Railways issued in accordance with regulation 7 has been complied with, and

(ii) where the change described in regulation 6(1)(e)(ii) has occurred, it is satisfied that there has been compliance with the result of the procedure referred to in Article 30(2) of the Agency Regulation, and

(e) where the applicant has satisfactorily completed any checks required by the DFI under regulation 6(3).

Authorisation decision for vehicles

10.—(1) The DFI must determine an application for an authorisation to place a vehicle on the market by—

(a) issuing an authorisation for the placing on the market of the vehicle, or

(b) refusing the application for authorisation.

(2) Where the DFI refuses an application under paragraph (1)(b), the applicant may, within the period of one month beginning with the day after the day on which the applicant receives notification of that decision, request through the one-stop shop that the DFI review its decision.

(3) On receipt of a request for review of a decision in accordance with paragraph (2), the DFI must confirm or reverse that decision within two months beginning with the day after the day of receipt of the request for review.

(4) The DFI must issue any authorisation for the placing on the market of a vehicle in accordance with the procedures set out in the Practical Arrangements Regulation and only where it is satisfied—

(a) that an EC declaration of verification has been drawn up,

(b) it has received the evidence referred to in regulation 8(1)(a) and (b),

(c) that the vehicle has been so designed, constructed and installed as to meet the essential requirements relating to that subsystem when placed on the market,

(d) that the vehicle's technical compatibility with the network in the area of use specified in the application for authorisation on the basis of the relevant TSIs, notified national rules and relevant registers, and the common safety methods has been established, and

(e) that the applicant has satisfactorily completed any checks required by the DFI under regulation 8(4).

(5) Authorisations for placing a vehicle on the market must state—

(a) the area of use,

(b) the values of the parameters set out in the TSIs and, where applicable, in the notified national rules, for checking the technical compatibility between the vehicle and the area of use,

(c) the vehicle's compliance with the relevant TSIs and sets of notified national rules, relating to the parameters referred to in sub-paragraph (b), and

(d) the conditions for use of the vehicle and other restrictions.

(6) Subject to paragraph (12), where the holder of an authorisation seeks to change the area of use for any vehicle in respect of which that authorisation has been issued by the DFI under these Regulations, it must apply to the DFI for the authorisation to be updated by supplementing the application that was provided under regulation 8(1) for that vehicle with the relevant documents for the additional area of use.

(7) The DFI must handle the application for the additional area of use in accordance with regulation 8(11) and issue an authorisation for placing on the market or a negative decision in accordance with paragraph (10).

(8) Where the DFI has issued an authorisation in accordance with this regulation, that authorisation is valid without requiring an extension of the area of use for vehicles travelling to Irish border stations, provided that—

(a) the DFI has consulted with the national safety authority in Ireland prior to issuing the authorisation, or

(b) the DFI and the national safety authority in Ireland have entered into a cross border agreement in relation to vehicles travelling to stations near the border in each other's territories.

(9) Where the applicant indicates in its application that the intended area of use of the vehicle includes Irish border stations, the DFI may only issue an authorisation—

(a) once the DFI has received confirmation from the national safety authority in Ireland that the relevant national rules notified under Article 14 of the 2016 Directive in Ireland and the obligations pertaining to any relevant cross-border agreements between DFI and the national safety authority in Ireland are met, and

(b) if the authorisation states that it is valid in relation to Irish border stations without an extension of its area of use beyond Northern Ireland.

(10) Subject to paragraph (11), the DFI must issue either an authorisation for placing a vehicle on the market or a negative decision within a reasonable time period communicated to the applicant in advance, and in any event, within the period of four months beginning with the day after the day on which the DFI receives the application or, where the DFI has specified that supplementary information is required in accordance with regulation 8(11)(b), within the period of four months beginning with the day after the day that information is received.

(11) If the DFI has determined in accordance with regulation 18(1) that the whole or part of a TSI is not to apply (a "derogation"), it must not issue an authorisation for placing a vehicle on the market until—

(a) in the circumstances described in regulation 18(2)(a) and (b), the European Commission has—

(i) made a decision in respect of the derogation, or

(ii) in accordance with regulation 18(8), been deemed to permit the derogation, or

(b) in the circumstance described in regulation 18(2)(c), it has communicated its determination to the European Commission.

(12) Where the applicant seeks to change the area of use for a vehicle for which—

(a) an authorisation has been issued by the European Union Agency for Railways, or

(b) an authorisation has been issued by the DFI and the proposed change will result in the area of use extending further into Ireland than the Irish border stations,

its application for an updated authorisation must be made to the European Union Agency for Railways.

(13) Where a vehicle has been authorised by the DFI under the 2011 Regulations or the Railways (Interoperability) Regulations 2006(**a**) (a "pre-2026 vehicle"), an applicant seeking a change in its area of use must apply under regulation 8 for an authorisation to place the vehicle on the market, such application to be made only in respect of the extension to the area of use.

(**a**) S.I. 2006/397, amended by S.I. 2011/3066.

(14) Where an application for authorisation to place a vehicle on the market is made in order to extend the area of use of a pre-2026 vehicle, the applicant need not provide the items set out in regulation 8(1)(c) and (d).

Checks before first use of authorised vehicles

11.—(1) Before a railway undertaking first uses a vehicle in the area of use specified in its authorisation for placing on the market, it must check that the vehicle—

(a) has a valid authorisation for placing on the market in accordance with regulation 10 and has been registered on the European Vehicle Register,

(b) is compatible with the route where it is to be used, on the basis of relevant TSIs and the register of infrastructure, or, where such a register does not exist or is incomplete, any other relevant information to be provided by the infrastructure manager free of charge and within a reasonable period of time, and

(c) is properly integrated in the composition of the train where it is intended to operate, taking into account the safety management system set out in regulation 4 of the Railways (Safety Management) Regulations (Northern Ireland) 2006(**a**) and the TSI on operation and traffic management.

(2) For the purposes of paragraph (1), the railway undertaking may carry out tests and may in so doing request the cooperation of the infrastructure manager.

(3) The infrastructure manager must make every effort to ensure that any tests take place within three months beginning with the day after the day the railway undertaking's request under paragraph (2) is received.

(4) In this regulation, "register of infrastructure" means the register of infrastructure published in accordance with regulation 43(1).

Type authorisation

12.—(1) If the DFI issues an authorisation in accordance with regulation 10 the DFI must also issue an authorisation of vehicle type in relation to the relevant vehicle in respect of the same area of use as that vehicle.

(2) An application may be made to the DFI for authorisation of a vehicle type through the one-stop shop, in accordance with the Practical Arrangements Regulation.

(3) Where the applicant indicates in its application under paragraph (2) that the intended area of use of vehicles of the relevant type includes Irish border stations, the DFI may only issue an authorisation of vehicle type if—

(a) the DFI has received confirmation from the national safety authority in Ireland that the relevant national rules notified under Article 14 of the 2016 Directive in Ireland and the obligations pertaining to any relevant cross-border agreements are met, and

(b) the authorisation states that the authorisation is valid in relation to the Irish border stations without an extension of the area of use.

(4) The DFI must ensure that an authorisation of vehicle type issued under paragraph (1), or under Article 46 of the Practical Arrangements Regulation following an application under paragraph (2)—

(a) describes the basic design characteristics of the vehicle, and

(b) is registered with the European register of authorised types of vehicles established by the European Union Agency for Railways in accordance with Commission Implementing

(**a**) S.R. 2006 No. 237, amended by S.I. 2020/277.

Decision 2011/665/EU of 4 October 2011 on the European register of authorised types of railway vehicles(**a**) as it has effect in EU law.

(5) Where an applicant is applying for authorisation to place a vehicle or series of vehicles on the market in reliance on a declaration of conformity to an authorised type (such declaration of conformity to be established in accordance with paragraph (8)), its application must be submitted in accordance with regulation 8, save that where an application is made under this paragraph, paragraphs (1), (4) and (5) of regulation 8 do not apply.

(6) The DFI must determine any application made under paragraph (5) in accordance with regulation 10, save that for applications under paragraph (5) regulation 10(4) does not apply.

(7) The DFI must not grant an authorisation on the basis of an application made under paragraph (5) unless it is satisfied that the vehicle or series of vehicles in respect of which the application is made conforms to the description set out in the authorisation of vehicle type.

(8) The declaration of conformity to an authorised type referred to in paragraph (5) must be—

(a) consistent with the Templates Regulation,

(b) established in accordance with—

(i) the verification procedures of the relevant TSIs, or

(ii) where TSIs do not apply, the conformity assessment procedures as defined in modules B, D, F and H1 in Annex 2 to Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products and repealing Council Decision 93/465/EEC(**b**) as it has effect in EU law.

(9) Where the DFI has granted an authorisation to place a vehicle or series of vehicles on the market following an application under paragraph (5), it need not issue a further authorisation of vehicle type under paragraph (1).

(10) Where an authorisation of a vehicle type needs to be renewed as referred to in regulation 13(3), the checks performed by the DFI may only concern the applicable changes to the TSI or notified national rule.

(11) In this regulation, "conforms" means conforms in all the respects which materially affect compliance with the applicable essential requirements.

Type authorisation: changes to TSIs and notified national rules

13.—(1) Where the DFI makes a modification to a notified national rule that is material to a pre-issued authorisation of vehicle type, the modification to the notified national rule has no effect on the validity of any pre-issued authorisation to place a vehicle on the market, but the notified national rule as modified must state whether any pre-issued authorisation of vehicle type remains valid or needs to be renewed.

(2) A change to an applicable TSI has no effect on the validity of a pre-issued authorisation to place a vehicle on the market.

(3) Where there has been a change to an applicable TSI or, pursuant to paragraph (1), a modification to an applicable notified national rule so that an authorisation of vehicle type needs to be renewed, an applicant who wishes to continue with an in-progress application under regulation 12(5) must provide the DFI with the documentation referred to in regulation 8(1)(a) and (b).

(4) Where the DFI has received the further material referred to in paragraph (3), it—

(a) may require additional tests in accordance with regulation 8(4) and (5);

(**a**) OJ L 264, 8.10.2011, p. 32.
(**b**) OJ L 218, 13.8.2008, p. 82.

(b) must determine the application in accordance with regulation 10 and paragraph (5).

(5) For the purposes of paragraphs (3) and (4), the documentation to be provided and the additional checks to be carried out must relate only to the changes to the applicable TSI or notified national rule.

(6) In this regulation, a "pre-issued" authorisation to place a vehicle on the market or authorisation of vehicle type is an authorisation to place a vehicle on the market or authorisation of vehicle type issued before the relevant modification to a notified national rule or the relevant change to a TSI.

Non-compliance of vehicles or vehicle types with essential requirements

14.—(1) Where a railway undertaking finds, during operation, that a vehicle it is using does not meet one of the applicable essential requirements, it must take the necessary corrective measures in order to bring the vehicle into conformity.

(2) Where a railway undertaking takes corrective measures under paragraph (1), it may inform the DFI, the European Union Agency for Railways and any national safety authorities in other relevant States concerned of the measures taken.

(3) Where the railway undertaking has evidence that the non-compliance existed at the time the authorisation for placing the vehicle on the market of a relevant State was issued, it must inform the DFI, the European Union Agency for Railways and any other national safety authorities in other relevant States concerned.

(4) Where the DFI becomes aware that a vehicle or a vehicle type for which an authorisation for placing on the market of a relevant State has been issued does not meet one of the applicable essential requirements, it must inform the railway undertaking using the vehicle and require it to take the necessary corrective measures in order to bring the vehicle or vehicle type into conformity.

(5) Where the DFI has become aware of the non-conformity of a vehicle or vehicle type in accordance with paragraph (4), it must inform the European Union Agency for Railways and any national safety authorities in other relevant States concerned including those where an application for authorisation for placing on the market of a relevant State for a vehicle of the same type is ongoing.

(6) Where the DFI becomes aware that—

(a) corrective measures taken by a railway undertaking or imposed by the DFI in accordance with paragraph (1) or (4) do not ensure conformity with the applicable essential requirements, and

(b) the non-conformity leads to a serious safety risk,

the DFI may apply temporary safety measures.

(7) The DFI, following a review of the effectiveness of any measures imposed by it in accordance with paragraph (6) to address a serious safety risk, may decide to—

(a) revoke the authorisation it issued for the placing on the market of the vehicle in respect of which temporary safety measures have been taken, or

(b) amend the authorisation it issued for the placing on the market of the vehicle in respect of which temporary safety measures have been taken,

where there is evidence that the vehicle did not meet one of the applicable essential requirements at the time when the authorisation for placing the vehicle on the market was issued.

(8) The DFI must, where it revokes or amends any authorisation it has issued, update any relevant registers and notify the railway undertakings using vehicles of the same type as the vehicle or type subject to the revocation or amendment that the revocation or amendment has taken place.

(9) A railway undertaking receiving a notification in respect of its vehicles under paragraph (8) must assess the compliance of those vehicles with the essential requirements and where non-compliance is established must take corrective measures in accordance with paragraph (1).

(10) Where the non-compliance with essential requirements described in paragraph (1) or (4) is limited to an identifiable part of a vehicle's area of use, the authorisation may be amended to omit such a part.

(11) A vehicle in respect of which an authorisation described in paragraph (7) has been revoked must not be used unless a new authorisation to place that vehicle on the market has been granted further to regulation 10 or Article 21 of the 2016 Directive.

(12) In this regulation—

"placing on the market of a relevant State" means the first making available of a vehicle, ready to function in its design operating state, on the market in a relevant State, and cognate expressions are to be construed accordingly;

"temporary safety measures" includes the suspension of type authorisation of a vehicle.

Revocation of vehicle and vehicle type authorisations

15.—(1) Where the DFI has decided, pursuant to regulation 14(7), to revoke or amend an authorisation it issued, it must immediately notify the relevant railway undertaking of its decision and give reasons.

(2) Where a railway undertaking has received—

(a) a notification of a decision from the DFI under paragraph (1), or

(b) a notification of a decision from the European Union Agency for Railways to revoke or amend an authorisation,

it may, within the period of one month beginning with the day after the day it receives notification of that decision, request a review of that decision from the body that issued it.

(3) Upon receipt of the request for a review from a railway undertaking, the DFI—

(a) must suspend the decision under review, and

(b) must decide, within the period of one month beginning with the day after the day on which the request was received, whether to confirm or reverse that decision.

(4) Where there is disagreement between the European Union Agency for Railways and the DFI concerning the need to amend or revoke an authorisation, the arbitration procedure provided for in Article 21(7) of the 2016 Directive must be followed.

(5) Where the result of the arbitration procedure provided for in Article 21(7) of the 2016 Directive is that the authorisation is neither to be amended nor revoked, the temporary safety measures referred to in regulation 14(6) must be suspended.

(6) If the decision of—

(a) the DFI is confirmed, the holder of the authorisation may bring an appeal in accordance with regulation 45;

(b) the European Union Agency for Railways is confirmed, the holder of the authorisation may bring an appeal in accordance with Article 26(5) of the 2016 Directive.

(7) Where the DFI decides to revoke an authorisation for placing on the market which it has issued, it must—

(a) inform the European Union Agency for Railways,

(b) give reasons for its decision, and

(c) update the European Vehicle Register.

(8) Where the DFI in accordance with this regulation, or the European Union Agency for Railways in accordance with Article 26 of the 2016 Directive, has decided to revoke either an authorisation to place a vehicle on the market or an authorisation of vehicle type—

(a) no person may—

(i) use a vehicle in reliance on that authorisation or make any application to extend its area of use,

(ii) place a vehicle of that vehicle type on the market, and

(b) any person who has placed a vehicle of the relevant vehicle type on the market must withdraw it from the market.

Authorisation requirements for the renewal or upgrading of fixed installations

16.—(1) In respect of a project for the renewal or upgrading of a fixed installation, the project entity must apply to the DFI for a decision as to whether an authorisation is required.

(2) An application made under paragraph (1) is invalid unless it is accompanied by the following information—

(a) a file setting out details of the project,

(b) the project entity's assessment of whether there are any new or changed safety risks resulting from the works envisaged and how any such risks will be managed, and

(c) an indication of any TSI, or part of a TSI, with which there may be non-compliance following the renewal or upgrade.

(3) Within the period of one month beginning with the day after the day on which the application is received, the DFI must respond in writing and confirm—

(a) that the application is complete, or

(b) what supplementary information is required for the completion of the application, together with a reasonable deadline within which to provide it.

(4) The project entity must provide the DFI with such supplementary information requested under paragraph (3) as the project entity is reasonably able to supply and the project entity must give an explanation in writing where the information requested is not supplied.

(5) In making a decision as to the requirement for authorisation, the DFI must consider factors including—

(a) the extent to which the overall safety level of the fixed installation concerned may be adversely affected by the works envisaged;

(b) whether the new authorisation is required by the TSIs;

(c) any relevant requirements of the national implementation plan(**a**);

(d) any changes made to the values of the parameters referred to in regulation 10(5)(b) on the basis of which the existing authorisation was granted.

(6) The DFI must make its decision as to the requirement for authorisation within the period of four months beginning with the day after the day on which the DFI receives a complete application.

(**a**) In defining the standards which must be met in order to meet the essential requirements, TSIs may require member States and Northern Ireland to produce a national implementation plan for how they plan to comply with a particular TSI.

Authorisation requirements for the renewal or upgrading of vehicles

17. A vehicle with an authorisation for placing on the market which subsequently undergoes renewal or upgrade is required to obtain an authorisation for placing on the market in its new design operating state if—

(a) changes are made to the values of the parameters referred to regulation 10(5)(b) which are outside the range of acceptable parameters as defined in the TSIs,

(b) the overall safety level of the vehicle concerned may be adversely affected by the works envisaged, or

(c) it is required to obtain an authorisation for placing on the market in its new design operating state by the relevant TSIs.

Derogation from need to conform with TSIs

18.—(1) The DFI may determine that, in the circumstances or cases specified in paragraph (2), the whole or part of a relevant TSI is not to apply in relation to a subsystem ("a derogation").

(2) The circumstances or cases comprise—

(a) any project which—

(i) is for a proposed new subsystem,

(ii) is for the renewal or upgrading of an existing subsystem, or

(iii) concerns any condition referred to in Article 1(1) of the 2016 Directive,

and the project is at an advanced stage of development or is the subject of a contract in the course of performance when the applicable TSI is published,

(b) any project concerning a proposed renewal, extension or upgrading of an existing subsystem or part of it, when the application of the TSI would compromise the economic viability of the project or the compatibility of the project with the rail system, or

(c) where, following an accident or a natural disaster, the conditions for the rapid restoration of the network do not economically or technically allow for partial or total application of the relevant TSIs, in which case the non-application of the TSIs will be limited to the period before the restoration of the network.

(3) The DFI must communicate to the European Commission within one year of entry into force of each TSI, a list of projects that are taking place in Northern Ireland and which in its view satisfy the criteria set out in paragraph (2)(a).

(4) Where any of paragraph (2)(a), (b) or (c) applies, the DFI must communicate to the European Commission its decision not to apply one or more TSIs or parts of them.

(5) Where paragraph (2)(a) or (b) applies the DFI must submit to the European Commission—

(a) a request for non-application of the applicable TSIs or parts of them,

(b) a file setting out the justification for the request described in sub-paragraph (a), and

(c) details of alternative provisions that the DFI intends to apply instead of the relevant TSIs.

(6) In respect of the file referred to in paragraph (5)(b)—

(a) the information to be included in it,

(b) its format, and

(c) its means of communication to the European Commission,

are as mandated in Commission Implementing Regulation (EU) 2020/424 of 19 March 2020 on submitting information to the Commission as regards non-application of technical specifications for interoperability in accordance with Directive (EU) 2016/797 as it has effect in EU law.

(7) The DFI may apply the alternative provisions referred to in paragraph (5)(c) pending the decision of the European Commission.

(8) The European Commission is deemed to have permitted the derogation if it has made no decision within a period of four months beginning with the day after the day it received the file referred to in paragraph (5)(b).

(9) For the purposes of this regulation, a project is at an advanced stage of development if it is at a planning or construction stage which has reached a point where a change in the technical specifications may compromise the viability of the project as planned.

Essential requirements for project subsystems

19.—(1) For the purposes of these Regulations, the essential requirements for a project subsystem are met if the project subsystem conforms with all applicable TSIs and, where paragraph (2) applies, the requirements of applicable notified national rules.

(2) This paragraph applies to a project subsystem where—

(a) the TSIs do not cover, or do not fully cover, certain aspects corresponding to the essential requirements applicable to that project subsystem,

(b) a derogation communicated to or permitted by the European Commission under regulation 18 applies,

(c) a specific case requires the application of technical rules not included in the relevant TSI,

(d) that project subsystem interfaces with existing systems that must be specified using national rules, such use of national rules to be limited to the assessment of technical compatibility of a vehicle with the network,

(e) it forms part of a network or vehicle not covered by TSIs, or

(f) it is subject to an urgent temporary preventative measure, in particular following an accident.

(3) In this regulation, "specific case" has the meaning provided in Article 2(13) of the 2016 Directive.

Role of project entity

20.—(1) In order for an application for an authorisation to place a vehicle on the market or to place a fixed installation into service to be valid, a project entity must—

(a) engage an EU notified body or an NI notified body to carry out the EC verification assessment procedure, other than in relation to notified national rules, in accordance with regulation 21;

(b) ensure that an EU notified body or an NI notified body, whether that originally engaged or another, continues to be engaged until authorisation under these Regulations is given or refused;

(c) where there are applicable notified national rules, engage an NI designated body to carry out an EC verification assessment procedure in accordance with regulation 21.

(2) The engagement of an EU notified body or an NI notified body under paragraph (1)(a) must begin at the design stage and cover the entire manufacturing period through to the acceptance stage before the project subsystem is placed on the market or in service.

(3) A project entity must not draw up an EC declaration of verification in relation to a project subsystem unless—

(a) the project entity is satisfied that the essential requirements are met, including interfaces with the rail system;

(b) the EC verification assessment procedure has been carried out by an EU notified body or an NI notified body in accordance with regulation 21;

(c) an EC certificate of verification has been drawn up by an EU notified body or an NI notified body;

(d) the EC verification assessment procedure has been carried out by an NI designated body where there are applicable notified national rules permitting this;

(e) an EC certificate of verification has been drawn up by an NI designated body where there are applicable notified national rules permitting this;

(f) a technical file has been prepared containing the information and documents specified in regulation 21(5) and, if applicable, regulation 21(7).

(4) Where a project entity is making an application for authorisation of a vehicle type in accordance with regulation 12(2) or there has been a change to an applicable TSI or notified national rule in accordance with regulation 13, this regulation and regulation 21 only apply to the extent necessary to satisfy the DFI that an authorisation must be granted under these Regulations.

Project subsystems: EC verification assessment procedure

21.—(1) The EC verification assessment procedure for an EU notified body or an NI notified body carrying out an assessment in relation to TSIs must—

(a) in relation to a project subsystem, comply with the procedure specified in the TSI or part of the TSI with which that project subsystem is required to conform;

(b) assess the interface between the project subsystem and the rail system to the extent that such an assessment is possible based on the available information referred to in paragraph (3).

(2) Where the EC verification assessment procedure is carried out by an NI notified body, a UK(NI) indication must be placed on the EC certificate of verification in relation to the project subsystem alongside any conformity marking, logo or similar required under EU law.

(3) The assessment under paragraph (1)(b) must be based on information available in the relevant TSI and in any relevant registers.

(4) The EC verification assessment procedure for an NI designated body carrying out an assessment in relation to notified national rules is the applicable procedure set out in Annex IV to the 2016 Directive.

(5) The applicant for an authorisation to place in service or place on the market must compile a technical file containing—

(a) the items required by paragraph 2.4 of Annex IV to the 2016 Directive;

(b) documents relating to the conditions and limits of use of the project subsystem;

(c) documents relating to the characteristics of the project subsystem;

(d) manuals and instructions relating to the servicing, constant or routine monitoring, adjustment and maintenance of the project subsystem.

(6) In the event that a renewal or upgrade of a subsystem resulting in an amendment to the technical file affects the validity of the EC verification assessment procedure already carried out, the applicant must assess the need for a new EC declaration of verification under this regulation.

(7) The NI designated body carrying out an assessment in relation to notified national rules must compile a technical file in accordance with Annex IV to the 2016 Directive and the Practical Arrangements Regulation.

Requirement for EC declaration of verification for placing on the market of mobile subsystems

22. No person may place on the market a mobile subsystem except where an EC declaration of verification has been drawn up in respect of that subsystem pursuant to regulation 20.

Project subsystems: EC declaration of verification

23.—(1) A project subsystem in relation to which an EC declaration of verification has been drawn up pursuant to regulation 20 is presumed for the purposes of these Regulations to meet the essential requirements unless there are reasonable grounds for believing that it does not so conform.

(2) The presumption set out in paragraph (1) does not apply where a person fails or refuses to make available to the DFI a copy of the documentation which the person is required to retain by virtue of the EC verification assessment procedure applying to the project subsystem or pursuant to regulation 24.

Retention of technical file

24. The project entity must retain the technical file compiled in accordance with regulation 21(5) and, on request, provide a copy of that technical file to the DFI, the European Union Agency for Railways, the national safety authority in Ireland, or any body established in a member State in accordance with Article 16(1) of the Safety Directive.

Continuing duty on operator in relation to standards

25.—(1) This regulation applies where a project subsystem with an authorisation under these Regulations is in use on, or is part of, the rail system.

(2) The operator of the project subsystem must ensure that the project subsystem is operated and maintained—

(a) subject to paragraph (3), in conformity with the TSIs and notified national rules against which the subsystem was assessed for that authorisation,

(b) in conformity with any functional TSI applying to that subsystem, and

(c) in accordance with any condition in the authorisation to the extent that the condition still applies.

(3) In circumstances where a TSI or notified national rule referred to in paragraph (2)(a) has been varied or replaced, the operator of the project subsystem must ensure that the project subsystem is operated and maintained either in conformity with the varied or replaced TSI or notified national rule or in conformity with the original TSI or notified national rule.

(4) In this regulation—

"functional TSI" means a TSI applying in relation to a functional subsystem;

"project subsystem" includes a vehicle deemed to be authorised under these Regulations pursuant to regulation 51.

Fees payable to the DFI

26.—(1) The DFI may charge a person applying for an authorisation under regulation 6 or 8, or a person applying for a new authorisation following an upgrade or renewal, a fee, if that fee—

(a) does not exceed the sum of the costs reasonably incurred by the DFI in carrying out the work relating to the application, and

(b) is set out in an invoice that includes a statement of the work done and the costs reasonably incurred and specifies the period to which the statement relates.

(2) A fee charged under this regulation must be paid on or before the 30th day after the date of the invoice that the DFI has sent or given to the person who is required to pay the fee, or on such later day as the DFI has specified.

(3) A fee that has not been paid in accordance with paragraph (2) is recoverable as a civil debt.

(4) Failure to pay a fee does not constitute an offence.

(5) The DFI may charge such reasonable fee in connection with, or incidental to, carrying out its functions under regulation 18 as it may determine.

PART 3

Interoperability constituents

Prohibition on placing interoperability constituents on the market

27. No person may place an interoperability constituent on the market for which there is an applicable TSI 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, as set out in the relevant TSI, for assessing the conformity or suitability for use of the interoperability constituent has been carried out, and

(c) an EC declaration of conformity or suitability for use, whether or not accompanied by a UK(NI) indication, in relation to that interoperability constituent has been drawn up.

Assessment procedure for interoperability constituents

28.—(1) The appropriate procedures for assessing the conformity or suitability for use of an interoperability constituent are, subject to paragraph (3), the procedures indicated in the applicable TSI.

(2) If the applicable TSI requires it, those procedures must be carried out by an EU notified body or an NI notified body.

(3) Spare parts for subsystems that were placed in service before the applicable TSI came into force are not subject to the procedures referred to in paragraph (1).

EC declaration of conformity or suitability for use

29.—(1) An EC declaration of conformity or suitability for use may be drawn up in relation to an interoperability constituent by the manufacturer or manufacturer's authorised representative, but if neither has done so, the EC declaration of conformity or suitability for use in relation to that interoperability constituent must be drawn up by any person who—

(a) places that interoperability constituent on the market, or

(b) uses that interoperability constituent, or any part of it, in any other interoperability constituent that the person is manufacturing or assembling, or in any project subsystem that the person is constructing, upgrading or renewing,

before the person places the interoperability constituent on the market with a view to its use on the rail system or uses it or any part of it on the rail system.

(2) A declaration drawn up under paragraph (1) must be drawn up in accordance with the requirements of the Templates Regulation.

(3) A person must only draw up a declaration under paragraph (1) if satisfied that the interoperability constituent meets the relevant conditions—

(a) of the TSI applicable to that interoperability constituent, or

(b) of European specifications developed to comply with the conditions of the applicable TSI.

(4) If an interoperability constituent is subject to other requirements of EU legal acts covering other matters, a person may only draw up an EC declaration of conformity or suitability for use if satisfied that the interoperability constituent meets those other requirements and the person must state in the declaration that the interoperability constituent meets those other requirements.

(5) Subject to paragraph (6), where a person in Northern Ireland draws up an EC declaration of conformity or suitability for use, that declaration must be marked with a UK(NI) indication.

(6) The requirement in paragraph (5) does not apply to a person in Northern Ireland who draws up an EC declaration of conformity or suitability for use in relation to an interoperability constituent for which an EU notified body has drawn up an EC certificate of conformity.

(7) Where a person in Great Britain draws up an EC declaration of conformity or suitability for use that is to be used in Northern Ireland, that declaration must be marked with a UK(NI) indication if the relevant interoperability constituent was assessed against the TSIs by an NI notified body.

(8) In this regulation, "EC certificate of conformity" means a certificate issued by an EU notified body to confirm that an interoperability constituent, considered in isolation, meets the technical specifications set out in the relevant TSIs.

Effect of an EC declaration of conformity or suitability for use

30.—(1) An interoperability constituent in relation to which an EC declaration of conformity or suitability for use has been drawn up, whether or not the declaration is marked with a UK(NI) indication, is presumed for the purposes of these Regulations to—

(a) meet such of the essential requirements that are relevant to an interoperability constituent of that type, and

(b) conform to the applicable TSI,

unless there are reasonable grounds for believing it does not meet those requirements or it does not so conform.

(2) The presumption set out in paragraph (1) does not apply where a person fails or refuses to make available on request to the DFI the documentation, or a copy of the documentation, which the person is required to retain by the procedures set out in the applicable TSI for assessing the conformity or suitability for use of that interoperability constituent.

Duties on operators

31.—(1) Where an interoperability constituent for which there is an applicable TSI is in use on the rail system, its operator must ensure that the interoperability constituent is—

(a) correctly installed for the purpose for which it is intended to be used,

(b) not used for any purpose other than the purpose for which it was designed, and

(c) maintained in effective working order and good repair.

(2) For the purposes of this regulation, "interoperability constituent" includes a UK interoperability constituent that was made available for purchase under the 2011 Regulations with a view to its use on the UK rail system.

Recognition of assessments of EEA states

32.—(1) Nothing in these Regulations precludes any person from placing on the market any interoperability constituent that has satisfied all the requirements of any scheme in force in an EEA state or in Switzerland for the purpose of implementing the 2016 Directive.

(2) The DFI must not, in advance of any person placing an interoperability constituent on the market in accordance with paragraph (1), require checks which have already been carried out in an EEA state or in Switzerland as part of the procedure for an EC declaration of conformity or suitability for use as provided for in Article 10 of the 2016 Directive.

Notification to the European Commission of incorrect declaration

33.—(1) Where it appears to the DFI that an interoperability constituent in relation to which an EC declaration of conformity or suitability for use has been drawn up, whether or not marked with a UK(NI) indication, fails to meet the essential requirements relevant to an interoperability constituent of that type, the DFI must immediately give notice of that fact in writing to the European Commission, the European Union Agency for Railways and EEA states, and make its best efforts to give notice of that fact in writing to Switzerland.

(2) That notice must specify—

(a) if the failure to comply was due to the inadequacy of a TSI, or, where the application of a European specification is relied upon, if it was due to the inadequacy of or the incorrect application of such specification, or

(b) if it was not—

(i) the steps taken to prohibit or restrict the use of that interoperability constituent or withdraw or recall the interoperability constituent,

(ii) details of the failure of the interoperability constituent to meet the essential requirements, and

(iii) any measures taken against a person who drew up the declaration.

PART 4

Notified and designated bodies

Conformity assessment bodies

34.—(1) A person is an NI notified body if that person is notified by the Secretary of State to the European Commission and to the EEA states under paragraph (2) and no objection is raised by the European Commission or the EEA states—

(a) where the notification is accompanied by an accreditation certificate, within the period of two weeks beginning with the date of notification, or

(b) where the notification is not accompanied by an accreditation certificate, within the period of two months beginning with the date of notification.

(2) The Secretary of State may notify to the European Commission and EEA states only those persons who qualify for notification.

(3) A person qualifies for notification if they—

(a) meet the requirements set out in Schedule 1, and

(b) have applied in writing to the Secretary of State to become an NI notified body and the application is accompanied by—

(i) a description of each of the following—

(aa) the conformity assessment activities that the person intends to carry out;

(bb) the conformity assessment module in respect of which the person claims to be competent;

(cc) the product in respect of which the person claims to be competent, and

(ii) either—

(aa) an accreditation certificate, or

(bb) the documentary evidence necessary for the Secretary of State to verify the person's compliance with the requirements set out in Schedule 1.

(4) For the purposes of paragraph (3)(a), the Secretary of State may accept an accreditation certificate provided to the Secretary of State in accordance with paragraph (3)(b)(ii)(aa) as sufficient evidence that a person meets the requirements in Schedule 1.

(5) The Secretary of State may appoint as an NI designated body a person who qualifies for appointment under paragraph (6).

(6) A person qualifies for appointment as an NI designated body if they—

(a) meet the requirements set out in Schedule 1, and

(b) have applied to the Secretary of State in writing to become an NI designated body and the application is accompanied by—

(i) a description of—

(aa) the conformity assessment activities that the person intends to carry out;

(bb) the conformity assessment module in respect of which the person claims to be competent;

(cc) the product in respect of which the person claims to be competent; and

(ii) either—

(aa) an accreditation certificate, or

(bb) the documentary evidence necessary for the Secretary of State to verify the person's compliance with the requirements set out in Schedule 1.

(7) For the purposes of paragraph 5(a), the Secretary of State may accept an accreditation certificate provided to the Secretary of State in accordance with paragraph (6)(b)(ii)(aa) as sufficient evidence that the person meets the requirements in Schedule 1.

(8) The Secretary of State must inform the European Commission and EEA states of the appointment of any NI designated body.

(9) The Secretary of State may—

(a) notify a person to the European Commission and EEA states under paragraph (2) notwithstanding that person's prior status as an EU notified body or as an NI designated body, or

(b) appoint a person as an NI designated body under paragraph (5) notwithstanding that person's prior status as an EU notified body or as an NI notified body,

and in either case the process of drawing up an EC certificate of verification may be carried out by a single body.

(10) The Secretary of State must inform the European Commission of the United Kingdom's procedures for the assessment, notification, appointment and monitoring of NI notified bodies and NI designated bodies, and any changes to those procedures.

(11) The Secretary of State must monitor each conformity assessment body with a view to verifying that it—

(a) continues to meet the requirements set out in Schedule 1;

(b) fulfills its obligations under these Regulations.

(12) In this regulation, "accreditation certificate" means a certificate issued by the UK national accreditation body appointed in accordance with regulation 34B of the 2011 Regulations, or issued in an EEA state by a national accreditation body as defined in paragraph (10) of Article 2 of RAMS, attesting that a person meets the requirements set out in Schedule 1.

Presumption of conformity for conformity assessment bodies

35.—(1) Where a conformity assessment body demonstrates its conformity with the criteria laid down in a harmonised standard or part of such a standard, the reference of which has been published in the Official Journal of the European Union, the Secretary of State is entitled to presume that the conformity assessment body meets the requirements set out in Schedule 1 relevant to a conformity assessment body covered by that standard or that part of that standard.

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

Changes to notification or appointment

36.—(1) Where, through exercise of the monitoring duty in regulation 34(11), the Secretary of State determines that an NI notified body or an NI designated body—

(a) no longer meets the requirements of Schedule 1; or

(b) is failing to meet its obligations under these Regulations,

the Secretary of State must restrict, suspend or withdraw the body's status as an NI notified body or an NI designated body under regulation 34.

(2) In deciding what action is required under paragraph (1), the Secretary of State must have regard to the seriousness of the non-compliance.

(3) Before taking action under paragraph (1), the Secretary of State must—

(a) give notice in writing to the conformity assessment body of the proposed action and the reasons for it,

(b) give the conformity assessment body an opportunity to make representations to the Secretary of State regarding the proposed action within a reasonable period from the date of the notice, and

(c) consider any such representations made by the conformity assessment body.

(4) Where the Secretary of State takes action under paragraph (1), the Secretary of State must immediately inform the European Commission and the EEA states.

(5) Where the Secretary of State has taken action in respect of a conformity assessment body under paragraph (1) or where a conformity assessment body has ceased its activity, the Secretary of State must require the conformity assessment body to—

(a) transfer its files relating to its conformity assessment activities to another conformity assessment body or to the Secretary of State, or

(b) keep its files relating to its conformity assessment activities available to the Secretary of State and the market surveillance authority for a period of ten years beginning with the date they were created.

Operational obligations of conformity assessment bodies

37. A conformity assessment body must, when carrying out each of its conformity assessment activities, meet the operational obligations set out in Schedule 2 relevant to that conformity assessment activity.

Subsidiaries and subcontractors

38.—(1) A conformity assessment body may subcontract specific conformity assessment activities, or use a subsidiary to carry out such activities, provided that—

(a) the conformity assessment body is satisfied that the subcontractor or subsidiary meets the requirements set out in Schedule 1,

(b) the conformity assessment body has informed the Secretary of State that it is satisfied that the subcontractor or subsidiary meets those requirements, and

(c) the project entity for whom the activities are to be carried out has consented to the activities being carried out by the subcontractor or subsidiary.

(2) Where a conformity assessment body subcontracts specific conformity assessment activities or uses a subsidiary to carry out such activities, the conformity assessment body remains responsible for the proper performance of those activities irrespective of where the subcontractor or subsidiary is established.

(3) Where a conformity assessment body subcontracts, or uses a subsidiary to carry out, a specific conformity assessment activity, the conformity assessment body must, for a period of ten years beginning with the day on which the activity is first carried out, keep available for inspection by the Secretary of State all documentation concerning—

(a) the assessment of the qualifications of the subcontractor or the subsidiary, and

(b) the conformity assessment activity carried out by the subcontractor or subsidiary.

(4) In this regulation, "subsidiary" has the meaning provided by section 1159(1) of the Companies Act 2006(**a**).

Accredited in-house bodies

39.—(1) Project entities may use an accredited in-house body to carry out conformity assessment activities for the purpose of implementing the procedures set out in modules A1, A2, C1 or C2 of Annex II to Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products and repealing Council Decision 93/465/EEC as it has effect in EU law, or modules CA1 and CA2 of Annex I to Commission Decision of 9 November 2010/713/EU on modules for the procedures for assessment of conformity, suitability for use and EC verification to be used in the technical specifications for interoperability adopted under Directive 2008/57/EC of the European Parliament and of the Council as it has effect in EU law.

(2) An accredited in-house body must—

(a) constitute a separate and distinct part of the project entity,

(**a**) 2006 c. 46.

(b) be accredited in accordance with RAMS,

(c) together with its personnel, within the entity of which they form a part, be organisationally identifiable and have reporting methods which ensure their impartiality, and must provide details of the measures taken to ensure impartiality to the UK national accreditation body,

(d) together with its personnel neither—

(i) be responsible for, or participate in, the design, production, manufacture, supply, installation, operation or maintenance of the products it assesses, nor

(ii) engage in any activity that might conflict with its independence of judgement or integrity in relation to its assessment activities, and

(e) supply its services exclusively to the entity of which it forms a part.

(3) An accredited in-house body need not be notified to other relevant States or the European Commission, but information concerning its accreditation must be given, by the entity of which it forms a part or by the UK national accreditation body to the Secretary of State at the Secretary of State's request.

UK national accreditation body

40. 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 conformity assessment body meets the requirements for being an NI notified body or NI designated body;

(b) monitoring conformity assessment bodies in accordance with regulation 34.

Fees of the Secretary of State

41. The Secretary of State may charge such reasonable fee in connection with, or incidental to, carrying out the Secretary of State's functions under regulation 34 as the Secretary of State may determine.

Fees of conformity assessment bodies

42.—(1) Subject to paragraph (2), a conformity assessment body may charge such fee as it may determine in connection with, or incidental to, carrying out its functions in relation to these Regulations.

(2) Any fee charged pursuant to paragraph (1) must not exceed the sum of the following amounts—

(a) the costs incurred, or to be incurred, by the conformity assessment body in carrying out relevant work, and

(b) an amount of profit arising from the relevant work which is reasonable in the circumstances having regard to—

(i) the character and extent of the work carried out by the conformity assessment body on behalf of the person commissioning the work, and

(ii) the commercial rate normally charged on account of profit for that work or similar work.

(3) Subject to paragraph (4), the power in paragraph (1) includes the power to require the payment of a fee, or a reasonable estimate of the fee, in respect of the work commissioned in advance of carrying out that work.

(4) Unless the parties otherwise agree, an amount charged in accordance with paragraph (3) must not exceed a reasonable estimate of the fee for the work for the three months subsequent to the request for the advance payment.

PART 5

Registers

Register of infrastructure

43.—(1) The DFI, or a body appointed by it, must ensure that—

(a) a register of infrastructure stating the values of the network parameters of each subsystem or part of a subsystem concerned, as set out in the relevant TSI, is published by means of the RINF application, and

(b) that register of infrastructure is made available on request by an applicant for authorisation under these Regulations, an NI notified body, an EU notified body or an approved body.

(2) The register of infrastructure may stipulate conditions for the use of fixed installations and other restrictions.

(3) An owner of infrastructure must, in relation to its infrastructure—

(a) collate the data required to populate the fields set out in the infrastructure specifications, and

(b) ensure that data is uploaded to the register of infrastructure referred to in paragraph (1),

before any of the subsystems of which that infrastructure is constituted are placed into service.

(4) In this regulation—

"infrastructure" means any structural subsystem within the scope of the infrastructure specifications;

"the infrastructure specifications" means the specifications set out in the Annex to the Specifications Regulation;

"the RINF application" has the meaning provided by Article 2 of the Specifications Regulation;

"the Specifications Regulation" means Commission Implementing Regulation (EU) 2019/777 of 16 May 2019 on the common specifications for the register of infrastructure and repealing Implementing Decision 2014/880/EU(**a**) as it has effect in EU law.

European Vehicle Register

44.—(1) The DFI is designated as the registration entity for the purposes of Article 5(1) of the 2018 Registers Decision and must take reasonable steps to ensure the accuracy of the data registered in the European Vehicle Register.

(2) The registration entity must ensure the data that it uploads into the European Vehicle Register conforms to the specifications set out in the Annex to the 2007 Registers Decision.

(3) Subject to paragraph (4), within 14 days of placing a vehicle authorised under regulation 10 on the market, a person must submit an application to the DFI for registration of that vehicle on the European Vehicle Register.

(**a**) OJ L 139I, 27.5.2019, p. 312.

(4) Where a person has placed a vehicle authorised under regulation 10 on the market with an area of use that extends into Ireland beyond the Irish border stations, that person need not comply with the requirement in paragraph (3) if that vehicle has been registered on the European Vehicle Register by the registration entity in Ireland.

(5) A keeper of a vehicle registered on the European Vehicle Register must inform the DFI as soon as reasonably practicable if—

(a) any modification is required to the data relating to that vehicle, or

(b) if the vehicle has been destroyed or is no longer to be used in a relevant State.

(6) In the case of a vehicle authorised for the first time outside a relevant State and subsequently used in Northern Ireland, the DFI must ensure the vehicle's data, including data relating to the keeper of the vehicle, the entity in charge of maintenance assigned to it, and the restrictions on how the vehicle may be used, can be retrieved through a vehicle register or are otherwise made available without delay.

(7) In this regulation—

"2007 Registers Decision" means Commission Decision of 9 November 2007/756/EC adopting a common specification of the national vehicle register provided for under Articles 14(4) and (5) of Directives 96/48/EC and 2001/16/EC(**a**) as it had effect in EU law immediately before repeal;

"2018 Registers Decision" means Commission Implementing Decision (EU) 2018/1614 of 25 October 2018 laying down specifications for the vehicle registers referred to in Article 47 of Directive (EU) 2016/797 of the European Parliament and of the Council and amending and repealing Commission Decision 2007/756/EC(**b**)as it has effect in EU law;

"entity in charge of maintenance" has the meaning provided by regulation 2 (interpretation) of the Railways (Safety Management) Regulations (Northern Ireland) 2006;

"keeper" means the person that, being the owner of a vehicle or having the right to use it, exploits the vehicle as a means of transport and is registered as such in a vehicle register referred to in the European Vehicle Register.

PART 6

Appeals and enforcement

Appeals

45.—(1) Subject to paragraph (3), a person who is aggrieved by a decision of the DFI under regulation 6, 8 to 10, 12, 13, 15 or 16 may appeal under this paragraph.

(2) The model provisions set out in the Deregulation (Model Appeal Provisions) Order (Northern Ireland) 1997(**c**) apply in relation to appeals brought under paragraph (1).

(3) Where a person is aggrieved by a decision of the DFI under any of the regulations mentioned in paragraph (1) and has a right of review under regulation 9(3), 10(2) or 15(2)(a), that person must exercise that right before they may bring an appeal under paragraph (1).

(**a**) OJ L 305, 23.11.2007, p. 30.
(**b**) OJ L 268, 26.10.2018, p. 53.
(**c**) S.R. 1997 No. 269; amended by Part 1 of Schedule 18 to the Constitutional Reform Act 2005 (c. 4), paragraph 28 of Schedule 4 to the Northern Ireland Act 2009 (c. 3), paragraph 18 of Schedule 2 to the Public Service Pensions and Judicial Offices Act 2022 (c. 7) and paragraph 12 of Schedule 1 to the Department of Justice Act (Northern Ireland) 2010 (c. 3 (N.I.)).

Enforcement in Northern Ireland

46.—(1) It is the duty of the DFI to make adequate arrangements for the enforcement of these Regulations in Northern Ireland.

(2) Subject to paragraph (5), the provisions of the Health and Safety at Work (Northern Ireland) Order 1978(**a**) ("the 1978 Order") specified in paragraph (3) (the "specified provisions") apply for the purposes of the enforcement in Northern Ireland of these Regulations as if in the specified provisions—

(a) a reference to the "enforcing authority" was a reference to the Health and Safety Executive for Northern Ireland;

(b) a reference to the "relevant statutory provisions" was a reference to these Regulations and to the specified provisions;

(c) a reference to "health and safety regulations" was a reference to these Regulations.

(3) The provisions of the 1978 Order referred to in paragraph (2) are—

(a) Articles 21 and 22 (appointment and powers of inspectors), excluding Article 22(3);

(b) Articles 23 and 24 (improvement notices and prohibition notices);

(c) Article 25 (provisions supplementary to Articles 23 and 24), excluding Article 25(3);

(d) Article 26 (appeal against improvement notices and prohibition notices);

(e) Article 28 (power to indemnify inspectors);

(f) Article 30 (restrictions on disclosure of information);

(g) Articles 31(1)(c), (e) to (h), (j) to (o), 32(2) to (4), 34 (1) and (2), 34A to 38 and 39(1) to (3) (provisions as to offences).

(4) The mode of trial and maximum penalty applicable to each offence under Article 31 of the 1978 Order so applied and listed in the first column of the following table are set out opposite that offence in the subsequent columns of the table.

Offence	*Mode of trial*	*Penalty on summary conviction*	*Penalty on conviction on indictment*
An offence under Article 31(1)(c), (e), (f), (g) (k), (l), (m) or (o).	Summarily or on indictment.	Imprisonment for a term not exceeding 6 months, or a fine not exceeding £20,000, or both.	Imprisonment for a term not exceeding two years, or a fine, or both.
An offence under Article 31(1)(h).	Summarily only.	Imprisonment for a term not exceeding 6 months, or a fine not exceeding level 5 on the standard scale, or both.	
An offence under Article 31(1)(j).	Summarily or on indictment.	Imprisonment for a term not exceeding 6 months, or a fine not exceeding the statutory maximum, or both.	Imprisonment for a term not exceeding two years, or a fine, or both.
An offence under Article 31(1)(n).	Summarily only.	A fine not exceeding level 5 on the standard scale.	

(**a**) S.I. 1978/1039 (N.I. 9), amended by paragraph 27 of Schedule 29 to the Civil Partnership Act 2004 (c. 33) and S.I. 1986/1883 (N.I. 15), 1987/2049 (N.I. 20), 1988/1987 (N.I. 20), 1998/2795 (N.I. 18), 2006/1254 (N.I. 9) and 2006/3336 (N.I. 21); there are other amending instruments but none is relevant.

(5) A failure to discharge a duty placed on the Health and Safety Executive for Northern Ireland, the DFI or the Secretary of State by these Regulations is not an offence under Article 31(1)(c) of the 1978 Order.

Enforcement in Great Britain

47.—(1) It is the duty of the Office of Rail and Road(**a**) to make adequate arrangements for the enforcement of these Regulations in Great Britain.

(2) Subject to paragraph (5), the provisions of the 1974 Act specified in paragraph (3) (the "specified provisions") apply for the purposes of the enforcement of these Regulations in Great Britain as if in the specified provisions—

(a) a reference to the "enforcing authority" was a reference to the Office of Rail and Road;

(b) a reference to the "relevant statutory provisions" was a reference to these Regulations and to the specified provisions; and

(c) a reference to "health and safety regulations" was a reference to these Regulations.

(3) The provisions of the 1974 Act referred to in paragraph (2) are—

(a) sections 19 and 20 (appointment and powers of inspectors), excluding section 20(3);

(b) sections 21 and 22 (improvement and prohibition notices);

(c) section 23 (provisions supplementary to sections 21 and 22), excluding section 23(3) and (6);

(d) section 24 (appeal against improvement and prohibition notices);

(e) section 26 (power to indemnify inspectors);

(f) section 28 (restrictions on disclosure of information);

(g) sections 33(1)(c), (e) to (h), (j) to (o), 34(2) to (5), 36(1) and (2), 37 to 41 and 42(1) to (3) (provision as to offences);

(h) section 46 (service of notices).

(4) The mode of trial and maximum penalty applicable to each offence under section 33 of the 1974 Act so applied and listed in the first column of the following table are set out opposite that offence in the subsequent columns of the table.

Offence	*Mode of trial*	*Penalty on summary conviction*	*Penalty on conviction on indictment*
An offence under section 33(1)(c), (e), (f), (g), (j), (k), (l), (m) or (o).	Summarily or on indictment.	Imprisonment for a term not exceeding 3 months, or a fine not exceeding level 5 on the standard scale as it has effect from time to time (as if the offence was triable only summarily), or both.	Imprisonment for a term not exceeding two years, or a fine, or both.
An offence under section 33(1)(h).	Summarily only.	Imprisonment for a term not exceeding 3 months, or a fine not exceeding level 5 on the standard scale as it has effect from time to time, or both.	

(**a**) Established under section 15 of the Railways and Transport Safety Act 2003 (c. 20).

An offence under section 33(1)(n).	Summarily only.	A fine not exceeding level 5 on the standard scale as it has effect from time to time.	

(5) A failure to discharge a duty placed on the Office of Rail and Road or the Secretary of State by these Regulations is not an offence under section 33(1)(c) of the 1974 Act.

(6) In this regulation, the "1974 Act" means the Health and Safety at Work etc. Act 1974(**a**).

Notices relating to interoperability constituents not meeting the essential requirements

48.—(1) If the Health and Safety Executive for Northern Ireland is of the opinion that an interoperability constituent in use in Northern Ireland or intended for use in Northern Ireland is unlikely when used as intended to meet the essential requirements relating to it, the Health and Safety Executive for Northern Ireland may serve a notice in writing on any person who is using or intending to use that interoperability constituent in a project subsystem—

(a) prohibiting the use of, or restricting the area of use of, that interoperability constituent, or

(b) where there is a serious safety risk, requiring the recall or withdrawal of that interoperability constituent.

(2) A notice served under paragraph (1) must contain the following information—

(a) a statement that the Health and Safety Executive for Northern Ireland is of the opinion referred to in paragraph (1);

(b) the reasons for that opinion;

(c) a direction that the interoperability constituent to which that notice relates must not be used, or that its area of use shall be restricted, or that it must be recalled or withdrawn;

(d) the date by which the person must comply with the notice.

(3) Any notice served under paragraph (1) may be withdrawn by the Health and Safety Executive for Northern Ireland by serving notice of the withdrawal on the person.

(4) If the Health and Safety Executive for Northern Ireland intends to serve a notice under paragraph (1) or withdraw a notice under paragraph (3), it must—

(a) inform the DFI in writing at least seven days before it intends to either serve or withdraw the notice, and

(b) provide the DFI with particulars of the relevant failure or alleged failure by an interoperability constituent to meet the essential requirements.

(5) Where a notice has been served on a person ("P") in accordance with paragraph (1), P must—

(a) comply with that notice, and

(b) notify the person, if any, who supplied P with the interoperability constituent in relation to which the notice under paragraph (1) was served—

(i) that a notice under paragraph (1) has been served,

(ii) what the notice says, and

(iii) that P requires that person in turn to notify the supplier, if any, of the same information contained in the notice from P.

(**a**) 1974 c. 37.

(6) If a notice has been served on a person ("P") under paragraph (1) and that notice has not been withdrawn, P must restore the relevant interoperability constituent to a state of conformity with the essential requirements before drawing up a new EC declaration of conformity or suitability for use in contemplation of placing the interoperability constituent on the market.

(7) For the purposes of this regulation, "interoperability constituent" includes interoperability constituents in relation to which an EC declaration of conformity or suitability for use has been drawn up, whether or not they bear a UK(NI) indication, and UK interoperability constituents made available for purchase with a view to their use on the UK rail system under the 2011 Regulations.

Defence of due diligence

49.—(1) Subject to the following provisions of this regulation, if proceedings are brought against a person ("P") for an offence under these Regulations, it is a defence for P to show that P took all reasonable steps and exercised all due diligence to avoid committing the offence.

(2) Where P's defence involves an allegation that the commission of the offence was due to—

(a) the act or default of another, or

(b) reliance on information given by another,

P is not, without the leave of the court, entitled to rely on the defence unless, within a period ending at least seven days before the commencement of the hearing of the proceedings, P has served a notice under paragraph (3) on the person bringing the proceedings.

(3) A notice under this paragraph must give such information identifying, or assisting in the identification of, the person who committed the act or default or gave the information as is in the possession of P serving the notice at the time it is served.

(4) P is not entitled to rely on the defence provided by paragraph (1) by reason of P's reliance on information supplied by another, unless P shows that it was reasonable in all the circumstances to have relied on the information, having regard in particular—

(a) to the steps which P took, and those which might reasonably have been taken, for the purpose of verifying the information, and

(b) to whether P had any reason to disbelieve the information.

PART 7

Supplementary provision relating to railways interoperability in Northern Ireland

National Technical Specification Notice (Northern Ireland)

50. The National Technical Specification Notice published by the Secretary of State for Transport on 12th June 2025 pursuant to regulation 3B (publication of National Technical Specification Notices) of the 2011 Regulations relating to Northern Ireland ceases to have effect(**a**).

Transitional arrangements

51.—(1) Where a fixed installation consists of structural subsystems that were authorised to be placed in service on the rail system in accordance with regulation 7 (authorisation decision) of

(**a**) The National Technical Specification Notice may be found at https://www.gov.uk/government/publications/ntsn-northern-ireland.

the 2011 Regulations and that authorisation has not been revoked, the fixed installation is deemed to have been authorised to be placed in service under regulation 9.

(2) Where a vehicle consists of structural subsystems that were authorised to be placed in service on the rail system in accordance with regulation 7 (authorisation decision) of the 2011 Regulations and that authorisation has not been revoked, the vehicle is deemed to have been authorised to be placed on the market under regulation 10.

(3) Where, immediately before the coming into force of these Regulations, a body had been appointed as a designated body under regulation 31 (appointment of approved bodies and designated bodies) of the 2011 Regulations and that appointment had not been terminated (a "UK designated body"), it is deemed to be a body appointed as an NI designated body under regulation 34(5), and regulation 34(8) applies.

(4) Where an approved body or a UK designated body was engaged before the coming into force of these Regulations to carry out a UK verification assessment procedure or a part thereof in relation to one or more subsystems, the work carried out by that approved body or UK designated body before the coming into force of these Regulations is treated as work undertaken pursuant to regulation 20(3)(b) and regulation 21.

(5) Where an approved body or a UK designated body was engaged before the coming into force of these Regulations to carry out an assessment procedure or part thereof in relation to an interoperability constituent, the work carried out by that approved body or UK designated body is treated as work undertaken pursuant to regulation 27(b) and regulation 28.

(6) Where an application for a decision by the DFI as to whether an authorisation is required was made pursuant to regulation 13 of the 2011 Regulations in respect of a fixed installation and the application was not determined before the coming into force of these Regulations—

(a) it is treated as an application made under regulation 16, and

(b) any reference in the application to NTSNs or parts of NTSNs is treated as a reference to the equivalent TSIs or equivalent parts of TSIs.

(7) An exemption granted from an NTSN or part of an NTSN by the DFI in accordance with regulations 14 and 14A of the 2011 Regulations before the coming into force of these Regulations is treated as a derogation granted by the DFI in accordance with regulation 18 from the equivalent TSI or equivalent part of a TSI.

(8) Where an application to the DFI for an exemption from an NTSN or part of it under regulations 14 and 14A of the 2011 Regulations was made and the application had not been determined at the coming into force of these Regulations, it is treated as an application under regulation 18 for a derogation from the equivalent TSI or equivalent part of a TSI.

(9) Where work undertaken prior to the coming into force of these Regulations is deemed to be work done under these Regulations under paragraphs (4) and (5), work done with reference to an NTSN is to be considered work done with reference to the equivalent TSI, if any.

(10) In this regulation, "NTSN" and "UK verification assessment procedure" have the meaning provided by regulation 2 (interpretation) of the 2011 Regulations.

Consequential amendments

52.—(1) In paragraph (5) of regulation 13 (network statement) of the Railways Infrastructure (Access, Management and Licensing of Railway Undertakings) Regulations (Northern Ireland) 2016(**a**), for "regulation 35 of the Railways (Interoperability) Regulations 2011", substitute

(**a**) S.R. 2016 No. 420, amended by S.I. 2019/826.

"regulation 43 of the Railways (Interoperability in Northern Ireland) (Convention on International Carriage by Rail) (Amendment) Regulations 2026".

(2) In Commission Implementing Regulation (EU) No 402/2013 of 30 April 2013 on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009(**a**)—

(a) in Article 2 (scope)—

(i) in paragraph 3, for "Railways (Interoperability) Regulations 2011", substitute "Railways (Interoperability in Northern Ireland) (Convention on International Carriage by Rail) (Amendment) Regulations 2026";

(ii) in paragraph 4, in the first sentence, for NTSNs, substitute "TSIs" and omit the second sentence;

(b) in Article 3 (definitions)—

(i) in the definition of "designated body", for "in regulation 2 of the Railways (Interoperability) Regulations 2011", substitute "by "NI designated body" in regulation 2 of the Railways (Interoperability in Northern Ireland) (Convention on International Carriage by Rail) (Amendment) Regulations 2026";

(ii) in the definition of "EU notified body", for "Railways (Interoperability) Regulations 2011" substitute "Railways (Interoperability in Northern Ireland) (Convention on International Carriage by Rail) (Amendment) Regulations 2026";

(iii) in the definition of "national rule", for "NTRs as defined in regulation 2 of the Railways (Interoperability) Regulations 2011", substitute "notified national rules as defined in regulation 2 of the Railways (Interoperability in Northern Ireland) (Convention on International Carriage by Rail) (Amendment) Regulations 2026";

(iv) in the definition of "proposer", for sub-paragraph (c), substitute—

"(c) a contracting entity or manufacturer which invites an EU notified body, an NI notified body or an NI designated body to apply the EC verification assessment procedure in accordance with regulation 20 of the Railways (Interoperability in Northern Ireland) (Convention on International Carriage by Rail) (Amendment) Regulations 2026;".

Amendment to the Railways (Interoperability) Regulations 2011

53.—(1) The 2011 Regulations are amended as follows.

(2) In regulation 2 (interpretation)—

(a) for the definition of "Competent Authority", substitute—

""Competent Authority" means the Secretary of State;";

(b) in the definition of "rail system", for "the United Kingdom", substitute "Great Britain";

(c) for the definition of "Safety Authority", substitute—

""Safety Authority" means the Office of Rail and Road, except in relation to the Channel Tunnel System, where it means the Intergovernmental Commission;".

(3) In regulation 3 (application)—

(a) in paragraph (1)(b), for "the United Kingdom", substitute "Great Britain";

(b) omit paragraph (7).

(**a**) EUR 2013/402, amended by S.I. 2019/837.

(4) In regulation 3B (publication of National Technical Specification Notices), in paragraph (1), for "may", substitute "may, in relation to Great Britain,".

(5) In regulation 3C (publication of a list of National Technical Rules), in paragraphs (1) and (5), for "may", substitute "may, in relation to Great Britain,".

(6) In regulation 5 (application for authorisation), omit paragraph (7).

(7) In regulation 29 (notification to the European Commission of incorrect declaration), in paragraph (1), for "European Commission", substitute "DFI, European Commission".

(8) In regulation 36 (national vehicle register), in paragraph (11)—

(a) omit "and in Northern Ireland the DFI";

(b) for "the United Kingdom", substitute "Great Britain".

(9) In regulation 37 (appeals in Great Britain), omit paragraph (10).

(10) Omit regulation 38 (appeals in Northern Ireland).

(11) In regulation 41 (notices relating to interoperability constituents not meeting the essential requirements)—

(a) omit "or the Health and Safety Executive for Northern Ireland" in each place it occurs;

(b) in paragraph (1), after "interoperability constituent" in the first place it appears, insert "in use in Great Britain or intended for use in Great Britain".

(12) In regulation 42 (notice of improper drawing up of the EC or UK declaration of conformity or suitability for use for an interoperability constituent)—

(a) for paragraph (1), substitute—

"(1) Where the Office of Rail and Road has reasonable grounds for suspecting—

(a) that an EC declaration of conformity or suitability for use has not been drawn up in accordance with the requirements of relevant EU law and that declaration relates to an interoperability constituent in use or intended to be used in Great Britain, or

(b) a UK declaration of conformity or suitability for use has not been drawn up in accordance with the requirements of regulation 25 and Schedule 7,

it may give notice in writing to any person who made the declaration.";

(b) in paragraph (2)—

(i) in sub-paragraph (a), omit "or the Health and Safety Executive for Northern Ireland";

(ii) in sub-paragraph (c)(ii), omit "or the Health and Safety Executive for Northern Ireland, as the case may be".

(13) In regulation 46 (dispensations), in paragraph (3), omit "or the Rail Vehicle Accessibility Regulations (Northern Ireland) 2001".

(14) In Schedule 4 (UK verification assessment procedure for subsystems), in sub-paragraph 2.4(e), omit "or the Railways (Safety Management) Regulations (Northern Ireland) 2006".

(15) In Schedule 8 (minimum criteria which must be taken into account by the Secretary of State when approving bodies), in paragraph 2, omit "or the Railways Infrastructure (Access, Management and Licensing of Railway Undertakings) Regulations (Northern Ireland) 2016" and "or the Railways (Safety Management) Regulations (Northern Ireland) 20006".

PART 8

Convention concerning International Carriage by Rail

Amendment to the Railways (Convention on International Carriage by Rail) Regulations 2005

54.—(1) The Railways (Convention on International Carriage by Rail) Regulations 2005(**a**) are amended as follows.

(2) In regulation 2 (interpretation), in paragraph (2), in the definition of "the Convention", for "Appendices A to G", substitute "Appendices A to D and F to H".

Signed by authority of the Secretary of State for Transport

Minister of State
Department for Transport

We consent

Two of the Lords Commissioners of His Majesty's Treasury

(**a**) S.I. 2005/2092.

SCHEDULES

SCHEDULE 1

Regulation 34(3)

Requirements for conformity assessment bodies

1. A conformity assessment body must participate in, or ensure that its personnel who are responsible for carrying out the conformity assessment activities are informed of, the relevant standardisation activities and the activities of any notified conformity assessment body coordination group established under the 2016 Directive and must apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

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

3. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment activities must be neither the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products that they assess, nor the representative of any of those parties.

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

(a) sound technical and vocational training, covering all conformity assessment activities in relation to which the conformity assessment body has been notified;

(b) satisfactory knowledge of the requirements of the assessment which the conformity assessment body carries out, and adequate authority to carry out those assessments;

(c) in the case of the personnel of NI notified bodies, appropriate knowledge and understanding of the essential requirements of any harmonised standards and any applicable provisions of the 2016 Directive, and the relevant TSIs, and in the case of the personnel of NI designated bodies, appropriate knowledge and understanding of relevant domestic law and notified national rules;

(d) the ability to draw up certificates, records and reports demonstrating that the assessments have been carried out.

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

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

(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment activities,

(b) descriptions of procedures in accordance with which conformity assessment activities are to be carried out, ensuring the transparency of, and the ability to, apply those procedures,

(c) appropriate policies and procedures in place that distinguish between activities it carries out as a conformity assessment body and other activities, and

(d) procedures for the performance of conformity assessment activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the scale or complexity of the production process.

7. A conformity assessment body must have the means necessary to perform the technical and administrative activities connected with the conformity assessment activities in an appropriate manner and must have access to the necessary equipment or facilities.

8. A conformity assessment body must have, and must satisfy the Secretary of State that it has, adequate civil liability insurance in respect of its activities.

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

10. Paragraph 9 does not prevent the personnel from providing the information to the Secretary of State.

11. Conformity assessment bodies that are notified for trackside or on-board control-command and signalling subsystems must—

(a) participate in or ensure that their assessment personnel are informed of the activities of the ERTMS group referred to in Article 29 of the Agency Regulation;

(b) follow the guidelines produced as a result of the work of that group, unless they consider it inappropriate or impossible to apply the guidelines in which case they must submit their observations for discussion by the ERTMS group.

SCHEDULE 2

Regulation 37

Operational obligations of conformity assessment bodies

1. In this Schedule—

"certificate of conformity" means a certificate issued by an NI notified body to confirm that an interoperability constituent, considered in isolation, meets the technical specifications set out in the relevant TSIs;

"certificate of suitability for use" means a certificate delivered for an interoperability constituent by the relevant NI notified body of the suitability for use of an interoperability constituent considered within its railway environment.

2. A conformity assessment body must carry out conformity assessment activities in accordance with the conformity assessment procedures provided for in the relevant TSI or the relevant national rules.

3. A conformity assessment body must carry out the conformity assessment activities referred to in paragraph 1—

(a) in a proportionate manner, and

(b) avoiding unnecessary burdens on economic operators.

4. A conformity assessment body when carrying out activities must take due account of—

(a) the size of the undertaking,

(b) the structure of the undertaking,

(c) the sector in which it operates,

(d) the degree of complexity of the product technology in question, and

(e) the scale and complexity of the production process,

but nevertheless, operate with the aim of assessing the compliance of the product with the 2016 Directive.

5. Where a conformity assessment body finds that the requirements laid down in—

(a) the relevant TSI,

(b) corresponding harmonised standards,

(c) a relevant national rule, or

(d) other relevant technical specifications,

have not been met by a manufacturer, it must require the manufacturer to take appropriate corrective measures and, where appropriate, must not issue an EC declaration of conformity or suitability for use.

6. Where a conformity body becomes aware in the course of the monitoring of conformity following the issue of a certificate of conformity that an interoperability constituent no longer complies with—

(a) the relevant TSI,

(b) corresponding harmonised standards,

(c) relevant national rules, or

(d) other relevant technical specifications,

it must require the manufacturer to take appropriate corrective measures and must, if necessary, suspend or withdraw a certificate of conformity.

7. Where a conformity assessment body has required a manufacturer to take corrective measures and the manufacturer has failed to take such measures, or those measures have not had the required effect, the conformity assessment body must, as appropriate, restrict, suspend or withdraw any certificate of conformity.

8. Where a conformity assessment body intends to refuse to issue a certificate of conformity, or to restrict, suspend or withdraw a certificate of conformity, the conformity assessment body must provide the applicant for the certificate of conformity or the holder of the certificate of conformity with—

(a) a notice in writing giving reasons for the intended decision and an opportunity to make written representations within 28 days, beginning with the day the notice was received;

(b) where the intention is to restrict, suspend or withdraw a certificate of conformity, the date on which the restriction, suspension or withdrawal is to take effect;

and take account of any representations made under sub-paragraph (a) before making its decision.

9. A conformity assessment body must inform the Secretary of State and the DFI of any refusal, restriction, suspension or withdrawal of a certificate of conformity, and must additionally inform the Secretary of State of—

(a) any circumstances affecting the scope of or conditions for notification,

(b) any request for information which it has received from the market surveillance authority regarding conformity assessment activities, and

(c) on request, any conformity assessment activities performed within the scope of its notification and any other activity performed, including cross-border activities and subcontracting.

10. A conformity assessment body must provide the European Union Agency for Railways with a copy of each EC certification of verification, certificate of conformity or certificate of suitability of use that it issues.

11. A conformity assessment body must provide other bodies notified under these Regulations or the 2016 Directive which are carrying out similar conformity assessment activities covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (O.J. No. L 138, 26.5.2016, p. 44) (the "2016 Directive") for Northern Ireland, making technical provision for the placing on the market, putting into service and free movement of railway products. The 2016 Directive is a recast of Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 (O.J. No. L 191, 18.7.2008, p. 1), which was transposed for Great Britain and Northern Ireland by way of the Railways (Interoperability) Regulations 2011 (S.I. 2011/3066). These Regulations replace that regime for Northern Ireland in line with the UK's obligations pursuant to Article 5(4) and Annex II of the Windsor Framework.

Additionally, these Regulations amend the Railways (Convention on International Carriage by Rail) Regulations 2005 (S.I. 2005/2092) (the "COTIF Regulations"), which bring the 1999 Protocol to the Convention concerning International Carriage by Rail 1980 (Cm 4873) ("COTIF") into effect in domestic law. COTIF is an intergovernmental Convention concerning international carriage of passengers and goods by rail, administered by the Intergovernmental Organisation for International Carriage by Rail ("OTIF"). The UK made a notification to OTIF in 2017 that it would disapply Appendix E to the Convention, and in 2018 a new Appendix H to the Convention was adopted by OTIF. The amendments to the COTIF Regulations bring these changes into effect.

Part 1 provides for the application of the Regulations, including provision for part of the rail system to be excluded from the scope of the Regulations.

Part 2 restricts the placing in service or placing on the market (in both cases, "putting into use") of fixed installations or vehicles that are new or have undergone renewal or upgrade. Only those fixed installations or vehicles that have been authorised by the Department for Infrastructure in Northern Ireland (the "DFI") under regulations 9 and 10 or do not require authorisation (pursuant to regulation 16 or 17) may be put into use. Regulations 6 to 10 outline the process for authorisation of a fixed installation or vehicle and regulation 26 provides that a fee may be charged.

Regulation 12 provides that the DFI must issue an authorisation of vehicle type that describes the basic design characteristics of the vehicle for which an authorisation has been issued, and allows for an applicant to apply for an authorisation of type for a vehicle in other cases. Once an authorisation of vehicle type has been issued the applicant may rely on a declaration of conformity to type when making an application for authorisation to place a vehicle on the market.

Regulation 15 provides that the DFI may revoke an authorisation to place a vehicle on the market and the process for making a revocation decision.

Part 3 concerns interoperability constituents, which are components of a subsystem that must satisfy specific requirements to be placed on the market for use on the rail system. Regulations 27 to 33 make provision for the placing on the market of interoperability constituents and how their conformity with the essential requirements should be assessed, as well as for ongoing duties on operators of interoperability constituents and the consequences of non-compliance.

Part 4 concerns the bodies responsible for assessing conformity of subsystems and interoperability constituents to the relevant standards. Conformity assessment bodies in Northern Ireland consist of NI notified bodies, for assessment against European standards, and NI designated bodies, for

assessment against notified national rules. Provision for the recovery of fees by NI notified bodies, designated bodies and the Secretary of State are contained in regulations 41 and 42.

Part 5 contains provisions for the keeping of registers of infrastructure (regulation 43) and data to be included in a European Vehicle Register (regulation 44).

Part 6 contains enforcement and appeal provisions.

Part 7 makes transitional and consequential provisions. It also concludes the operation of a National Technical Specification Notice issued by the Secretary of State for Northern Ireland on 12th June 2025, as that notice made interim arrangements intended to regularise the regime in Northern Ireland in the period before these Regulations were brought into force.

Regulation 53 narrows the substantive application of the Railways (Interoperability) Regulations 2011 to Great Britain and makes consequential and transitional amendments to those Regulations.

Part 8 makes the required amendment to the definition of "the Convention" in the COTIF Regulations to disapply Appendix E and apply Appendix H in domestic law.

Schedules 1 and 2 detail the obligations and requirements imposed upon conformity assessment bodies.

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 and a de minimis assessment have been prepared and are available alongside this instrument at www.legislation.gov.uk.

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