
STATUTORY INSTRUMENTS

2019 No. 837

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

PART 4

Amendments to retained direct EU legislation in respect of Great Britain

CHAPTER 3

Risk evaluation and assessment

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

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

- (2) Omit Article 1 (subject matter).
- (3) In Article 2 (scope)—
 - (a) in paragraph 1, for “a Member State”, substitute “Great Britain”;
 - (b) in paragraph 3—
 - (i) in the first place that it occurs, for “[Directive 2008/58/EC](#) applies” substitute “the Railways (Interoperability) Regulations 2011(1) apply”;
 - (ii) omit paragraph (a);
 - (iii) in paragraph (b), omit “, by virtue of Article 15(1) of [Directive 2008/57/EC](#)”;
 - (c) in paragraph 4, for “Member State concerned which”, substitute “Secretary of State who”;
 - (d) omit paragraphs 5 and 6.
- (4) For Article 3 (definitions) substitute—

“Article 3

Definitions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

‘national safety authority’ means one or both of—

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

‘notified bodies’ means the bodies which are responsible for assessing the conformity or suitability for use of the interoperability constituents or for appraising the EC procedure for verification of the subsystems, as defined in Directives 96/48/EC(2) and 2001/16/EC(3);

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

‘proposer’ means one of the following—

- (a) a railway undertaking or an infrastructure manager;
- (b) an entity in charge of maintenance;
- (c) a contracting entity or a manufacturer which invites a notified body to apply the EC verification procedure in accordance with Directive 2008/57/EC or a designated body according to Article 17(3) of that Directive;

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

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

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

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

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

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

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

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

(2) OJ No. L 191, 18.7.2008, p. 1–45.

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

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

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

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

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

‘safety’ means freedom from unacceptable risk of harm;

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

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

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

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

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

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

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

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

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

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

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

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

“Article 3A

Designated standards

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

- (a) adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory; and
 - (b) designated by the Secretary of State by publishing the reference to the standard and maintaining that publication in a manner the Secretary of State considers appropriate.
2. For the purposes of paragraph 1, a “technical specification” means a document that prescribes technical requirements to be fulfilled by a product, process, service or system and which lays down one or more of the following—
- (a) the characteristics required of a product, including—
 - (i) levels of quality, performance, interoperability, environmental protection, health, safety or dimensions; and
 - (ii) the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures; and
 - (b) production methods and processes relating to the product, where these have an effect on the characteristics of the product.
3. For the purposes of this article, a “recognised standardisation body” means any one of the following organisations—
- (a) the European Committee for Standardisation (CEN);
 - (b) the European Committee for Electrotechnical Standardisation (Cenelec);
 - (c) the European Telecommunications Standards Institute (ETSI);
 - (d) the British Standards Institution (BSI).
4. When considering whether the manner of publication of a reference is appropriate in accordance with paragraph 1(b), the Secretary of State must have regard to whether the publication will draw the standard to the attention of any person who may have an interest in the standard.
5. Before publishing the reference to a technical specification adopted by the British Standards Institution, the Secretary of State must have regard to whether the technical specification is consistent with technical specifications adopted by the other recognised standardisation bodies.
6. The Secretary of State may remove from publication the reference to a standard which has been published in accordance with paragraph 1(b).
7. Where the Secretary of State removes the reference to a standard from publication, that standard is no longer a designated standard.”.
- (6) In Article 4 (significant changes), for the first sentence of paragraph 1, substitute “The proposer shall consider the potential impact of a change on the safety of the railway system.”.
- (7) In Article 6 (independent assessment)—
- (a) in paragraph 1, omit “Union or”;
 - (b) in paragraph 3(a), for “[Directive 2004/49/EC](#)”, substitute “regulation 18A of the Railways and Other Guided Transport Systems (Safety) Regulations 2006 or paragraph 55A of the Schedule to the Channel Tunnel (Safety) (Amendment) Order 2013”;
 - (c) in paragraph 3(b), for “as defined by Article 2(j) of [Directive 2008/57/EC](#) or a body designated in accordance with Article 17 of that Directive”, substitute “a notified body or a designated body as defined in the Railways (Interoperability) Regulations 2011”;
 - (d) in paragraph 4, for “Without prejudice to Union legislation, the” substitute “The”;

- (e) in paragraph 4(a) and (b), omit the words following “service”;
 - (f) in paragraph 4(c), omit the words following “operation”;
 - (g) in paragraph 4(d), omit the words following “framework”;
 - (h) in paragraph 4(e), omit the words following “maintenance”;
 - (i) in paragraph 4(f), omit the words following “framework”;
 - (j) in the final paragraph, omit “as referred to in Article 15(1) or Article 20 of [Directive 2008/57/EC](#)” and “in accordance with Article 18(2) of that Directive”.
- (8) In Article 7 (accreditation/recognition of the assessment body)—
- (a) omit “referred to in Article 13(1)” in both places where it occurs;
 - (b) for “under the requirement of Article 9(2)” substitute “where it fulfils the requirements set out in Annex II and the accreditation functions of the national safety authority are demonstrably independent of its other functions”.
- (9) In Article 8 (acceptance of accreditation/recognition)—
- (a) in paragraph 1, for “[Commission Regulation \(EU\) No 1158/2010](#) or [Commission Regulation \(EU\) No 1169/2010](#)”, substitute “regulation 7 or 10 of the Railways and Other Guided Transport Systems (Safety) Regulations 2006, or Chapter 3 of the Schedule to the Channel Tunnel (Safety) (Amendment) Order 2013”;
 - (b) in paragraph 2—
 - (i) for “Regulation (EU) No 445/2011”, substitute “Schedule 10 to the Railways and Other Guided Transport Systems (Safety) Regulations 2006”;
 - (ii) after “Member State”, insert “of the European Union or Northern Ireland”.
- (10) In Article 9 (types of recognition of the assessment body)—
- (a) in paragraph 1(a), after “Member State” insert “of the European Union”;
 - (b) in paragraph 1(c), omit “in conformity with Article 10 of Regulation (EU) No 445/2011”;
 - (c) in paragraph 1(d), for “by the Member State” substitute “in the United Kingdom”;
 - (d) omit paragraph 2.
- (11) In Article 10 (validity of recognition)—
- (a) in paragraph 1, for “Article 9(2)”, substitute “where the national safety authority is recognised as an assessment body”;
 - (b) in paragraph 2(a), for “harmonised format of safety certificates provided in Annex I to [Commission Regulation \(EC\) No 653/2007](#)”, substitute “safety certificates in the form provided in Part 2 of Schedule 8 to the Railways and Other Guided Transport Systems (Safety) Regulations 2006”;
 - (c) in paragraph 3(a), for “harmonised format of certificates for entities in charge of maintenance provided in Annex V, or Annex VI where relevant, of Regulation (EU) No 445/2011”, substitute “certificates in the forms provided in Part 1 or Part 4 of Schedule 9 to the Railways and Other Guided Transport Systems (Safety) Regulations 2006, as appropriate”.
- (12) Omit Article 12 (relaxed criteria where a significant change is not to be mutually recognised), Article 13 (provision of information to the Agency) and Article 14 (support from the Agency to accreditation or recognition of the assessment body).
- (13) In Article 15 (safety assessment reports), in paragraph 3, for “Without prejudice to Article 16 of [Directive 2008/57/EC](#), the”, substitute “The”.
- (14) In Article 17 (risk control management and audits)—

- (a) in paragraph 1, for “Article 9 of [Directive 2004/49/EC](#)”, substitute “regulations 5 and 6 of the Railways and Other Guided Transport Systems (Safety) Regulations 2006 or paragraphs 22 to 26 of the Schedule to the Channel Tunnel (Safety) (Amendment) Order 2013”;
 - (b) in paragraph 2, for “Article 14a(3) of [Directive 2004/49/EC](#)”, substitute “regulation 18A of the Railways and Other Guided Transport Systems (Safety) Regulations 2006 or paragraphs 55A and 55B of the Schedule to the Channel Tunnel (Safety) (Amendment) Order 2013”;
 - (c) in paragraph 3—
 - (i) for “As part of the tasks defined in Article 16(2)(e) of [Directive 2004/49/EC](#), the” substitute “The”;
 - (ii) for “Regulation (EU) No 445/2011”, substitute “Schedule 10 to the Railways and Other Guided Transport Systems (Safety) Regulations 2006”;
 - (d) in paragraph 4, for “Article 7(1) of Regulation (EU) No 445/2011”, substitute “paragraph 7(1) of Schedule 10 to the Railways and Other Guided Transport Systems (Safety) Regulations 2006”.
- (15) In Article 18 (feedback and technical progress)—
- (a) in paragraph 1, for “referred to in Article 9(4) of [Directive 2004/49/EC](#)”, substitute “pursuant to regulation 20(1) of the Railways and Other Guided Transport Systems (Safety) Regulations 2006 or paragraph 16 of the Schedule to the Channel Tunnel (Safety) (Amendment) Order 2013”;
 - (b) omit paragraph 2;
 - (c) in paragraph 3—
 - (i) for “point I(7)(4)(k) of Annex III to Regulation (EU) No 445/2011”, substitute “paragraph 7(4)(k) of Part 4 of Schedule 10 to the Railways and Other Guided Transport Systems (Safety) Regulations 2006”;
 - (ii) omit the final sentence;
 - (d) omit paragraphs 4, 5 and 6.
- (16) Omit Article 19 (repeal).
- (17) In Article 20 (entry into force and application), omit the last two sentences.
- (18) In Annex I (general principles applicable to the risk management process)—
- (a) in point 1.1.4(a), for “Article 10(2)(a) or Article 11(1)(a) of [Directive 2004/49/EC](#)”, substitute “regulation 7(4)(b)(i) or regulation 10(1)(b)(ii) of the Railways and Other Guided Transport Systems (Safety) Regulations 2006 or paragraphs 22 to 26 of the Schedule to the Channel Tunnel (Safety) (Amendment) Order 2013”;
 - (b) in point 1.1.5, for “Member States”, substitute “United Kingdom”;
 - (c) in point 2.3.3, omit “by [Directive 2008/57/EC](#)”;
 - (d) in point 2.4.2(a), for “and would therefore still qualify for approval in the Member State where the change is to be introduced”, substitute “in the United Kingdom”;
 - (e) in point 2.5.2, for “Union legislation” substitute “legislation in Great Britain”;
 - (f) in points 2.5.5 to 2.5.8, omit “harmonised” in each place it occurs;
 - (g) in point 2.5.6—
 - (i) omit “They shall be the most demanding design targets that can be required for mutual recognition.”;
 - (ii) omit “of a Member State”;

(h) omit point 2.5.10;

(i) in point 2.5.11—

(i) for “Member State where the system is being used” substitute “United Kingdom”;

(ii) for “harmonised design target”, substitute “design target”;

(iii) omit “of the harmonised one”.

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