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Taqsima B

L.N. 184 of 2019

PRODUCT SAFETY ACT
(CAP. 427)

Interoperability of the Rail System Regulations, 2019

IN EXERCISE of the powers conferred by articles 38 and 39 of the Product Safety Act, the Minister for Justice, Culture and Local Government on the advice of the Director General (Technical Regulations) has made the following regulations: -

Title, scope and commencement.

1. (1) The title of these regulations is the Interoperability of the Rail System Regulations, 2019.

(2) These regulations transpose Directive (EU) 2016/797 and establish the conditions to be met to achieve interoperability within the Union rail system in a manner compatible with the provisions of Directive (EU) 2016/798 in order to define an optimal level of technical harmonisation, to make it possible to facilitate, improve and develop rail transport services within the Union and with third countries and to contribute to the completion of the single European railway area and the progressive achievement of the internal market. These conditions concern the design, construction, placing in service, upgrading, renewal, operation and maintenance of the parts of that system as well as the professional qualifications of, and health and safety conditions applying to, the staff who contribute to its operation and maintenance.

(3) These regulations concern the provisions relating to, for each subsystem, the interoperability constituents, interfaces and procedures, and the conditions of overall compatibility of the Union rail system required in order to achieve its interoperability.

(4) When a public or private entity submits an official application for the purpose of building a new railway line which is to be operated in Malta in accordance with the applicability of these regulations and which will be regarded as forming part of the Union rail system with a view to its operation by one or more railway undertakings, but excluding a metro system, a tram, networks that are functionally separate from the rest of the Union rail system and any other light rail systems, Article 13, Article 14(1) to (8), (11) and (12), Article 15(1) to (9), Article 16(1), Articles 19 to 26, Articles 45, 46 and 47, Article 49(1) to (4) and Article 54 of Directive (EU) 2016/797 shall apply.

(5) These regulations shall be deemed to have come into force on 16 June 2019.

Applicability.

2. (1) The following shall be excluded from the scope of these regulations:

(a) metros;

(b) trams and light rail vehicles, and infrastructure used exclusively by those vehicles;

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

(d) privately owned railway infrastructure, including sidings, used by its owner or by an operator for the purpose of their respective freight activities or for the transport of persons for non-commercial purposes, and vehicles used exclusively on such infrastructure;

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

(f) 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; and

(g) 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.

(2) In case of tram-trains operating in the Union rail system, where there are no TSIs that apply to those tram-trains, the following shall apply:

(a) national rules or other relevant accessible measures shall be adopted in order to ensure that such tram-trains meet the relevant essential requirements;

(b) national rules may be adopted in order to specify the authorisation procedure applicable to such tram-trains. The authority issuing the vehicle authorisation shall consult the relevant national safety authority in order to ensure that mixed operation of tram-trains and heavy rail trains meet all essential

requirements as well as relevant common safety targets;

(c) by way of derogation from Article 21 of Directive (EU) 2016/797, in the case of cross-border operation, the relevant competent authorities shall cooperate with a view to issuing the vehicle authorisations. This does not apply to vehicles excluded from the scope of these regulations in accordance with regulation 2(1).

3. For the purposes of these regulations: Definitions.

"the Act" means the Product Safety Act; Cap. 427.

"accreditation" means accreditation as defined in point (10) of Article 2 of Regulation (EC) No 765/2008;

"the Agency" means the European Union Agency for Railways as established by Regulation (EU) 2016/796;

"applicant" means a natural or legal person requesting an authorisation, be it a railway undertaking, an infrastructure manager or any other person or legal entity, such as a manufacturer, an owner or a keeper; for the purpose of Article 15 of Directive (EU) 2016/797, the ‘applicant’ means a contracting entity or a manufacturer, or its authorised representatives; for the purpose of Article 19 of Directive (EU) 2016/797, the ‘applicant’ means a natural or legal person requesting the Agency's decision for the approval of the technical solutions envisaged for the ERTMS track-side equipment projects;

"authorised representative" means any natural or legal person established within the Union 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;

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

"conformity assessment body" means a body that has been notified or designated to be responsible for conformity assessment activities, including calibration, testing, certification and inspection; a conformity assessment body is classified as a ‘notified body’ following notification by the Technical Regulations Division; a conformity assessment body is classified as a ‘designated body’ following designation by a the Technical Regulations Division;

"contracting entity" means a public or private entity which orders the design and/or construction or the renewal or upgrading of a subsystem;

"design operating state" means the normal operating mode and the foreseeable degraded conditions (including wear) within the range and the conditions of use specified in the technical and maintenance files;

"ERTMS" means the European Rail Traffic Management System;

"essential requirements" means all the conditions set out in Schedule III which must be met by the Union rail system, the subsystems, and the interoperability constituents, including interfaces;

"European specification" means a specification which falls into one of the following categories:

(a) a common technical specification as defined in Annex VIII of Directive 2014/25/EU;

(b) a European technical approval as referred to in Article 60 of Directive 2014/25/EU; or

(c) a European standard as defined in point (b) of Article 2(1) of Regulation (EU) No 1025/2012;

"harmonised standard" means a European standard as defined in point (c) of Article 2(1) of Regulation (EU) No 1025/2012;

"infrastructure manager" means an infrastructure manager as defined in point (2) of Article 3 of Directive 2012/34/EU;

"interoperability" means the ability of a rail system to allow the safe and uninterrupted movement of trains which accomplish the required levels of performance;

"interoperability constituents" 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;

"keeper" means the natural or legal 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 Article 47 of Directive (EU) 2016/797;

"light rail" means an urban and/or suburban rail transport system with a crash-worthiness of C-III or C-IV (in accordance with EN 15227:2011) and a maximum strength of vehicle of 800 kN (longitudinal compressive force in coupling area); light rail systems may have their own right of way or share it with road traffic and usually do not exchange vehicles with long-distance passenger or freight traffic;

"manufacturer" means any natural or legal person who manufactures a product in the form of interoperability constituents, subsystems or vehicles, or has it designed or manufactured, and markets it under his name or trademark;

"national accreditation body" means a national accreditation body as defined in point (11) of Article 2 of Regulation (EC) No 765/2008;

"national rules" means all binding rules adopted in a Member State, irrespective of the body issuing them, which contain railway safety or technical requirements, other than those laid down by Union or international rules which are applicable within that Member State to railway undertakings, infrastructure managers or third parties;

"national safety authority" means a safety authority as defined in point (7) of Article 3 of Directive (EU) 2016/798;

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

"placing in service" means all the operations by which a subsystem is put into its operational service;

"placing on the market" means the first making available on the Union's market of an interoperability constituent, subsystem or vehicle ready to function in its design operating state;

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

"railway undertaking" means a railway undertaking as

defined in point (1) of Article 3 of Directive 2012/34/EU, and any other public or private undertaking, the activity of which is to provide transport of goods and/or passengers by rail on the basis that the undertaking is to ensure traction; this also includes undertakings which provide traction only;

"renewal" means any major substitution work on a subsystem or part of it which does not change the overall performance of the subsystem;

"specific case" means any part of the rail system which needs special provisions in the TSIs, either temporary or permanent, because of geographical, topographical or urban environment constraints or those affecting compatibility with the existing system, in particular railway lines and networks isolated from the rest of the Union, the loading gauge, the track gauge or space between the tracks and vehicles strictly intended for local, regional or historical use, as well as vehicles originating from or destined for third countries;

"subsystems" means the structural or functional parts of the Union rail system, as set out in Schedule II;

Cap. 510.

"Technical Regulations Division" means the entity as established by article 19 of the Malta Competition and Consumer Affairs Authority Act;

"technical specification for interoperability" or "TSI" means a specification adopted in accordance with Directive (EU) 2016/797 by which each subsystem or part of a subsystem is covered in order to meet the essential requirements and ensure the interoperability of the Union rail system;

"tram-train" means a vehicle designed for combined use on both a light-rail infrastructure and a heavy-rail infrastructure;

"type" means a vehicle type defining the basic design characteristics of the vehicle as covered by a type or design examination certificate described in the relevant verification module;

"the Union rail system" refers to the Elements of the Union Rail System set out in Schedule I;

"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

"vehicle" means a railway vehicle suitable for circulation on wheels on railway lines, with or without traction; a vehicle is composed of one or more structural and functional subsystems.

Non-application of TSIs.

4. (1) The Technical Regulations Division may allow the applicant not to apply one or more TSIs or parts of them in the following cases:

(a) for a proposed new subsystem or part of it, for the renewal or upgrading of an existing subsystem or part of it, or for any element referred to in Regulation 1(2) which is at an advanced stage of development or which is the subject of a contract in the course of performance on the date of application of the TSI(s) concerned;

(b) 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 shall be limited to the period before the restoration of the network;

(c) for any proposed renewal, extension or upgrading of an existing subsystem or part of it, when the application of the TSI(s) concerned would compromise the economic viability of the project and/or the compatibility of the rail system in Malta, for example in relation to the loading gauge, track gauge, space between tracks or electrification voltage;

(d) for vehicles arriving from or going to third countries the track gauge of which is different from that of the main rail network within the Union;

(e) for a proposed new subsystem or for the proposed renewal or upgrading of an existing subsystem in Maltese territory when its rail network is separated or isolated by the sea or separated as a result of special geographical conditions from the rail network of the rest of the Union.

(2) In the case referred to in sub-regulation (1)(a), Malta shall communicate to the Commission, within one year of entry into force of each TSI, a list of projects that are taking place within its territory and which, in the view of the Technical Regulations Division, are at an advanced stage of development.

(3) In the cases referred to in sub-regulation (1)(a) and (b), the

Technical Regulations Division shall communicate to the Commission its decision not to apply one or more TSIs or parts of them.

(4) In the cases referred to in sub-regulation (1) (a), (c), (d) and (e), the Technical Regulations Division shall submit to the Commission the request for non-application of the TSIs or parts of them, accompanied by a file containing the justification for the request, and specifying the alternative provisions that the Technical Regulations Division intends to apply instead of the TSIs. In the case referred to in sub-regulation (1)(e), the Commission shall analyse the request and decide whether or not to accept it on the basis of the completeness and coherence of the information contained in the file.

In the cases referred to in sub-regulation (1)(c) and (d), the Commission shall adopt its decision by means of implementing acts on the basis of such analysis. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 51(3) of Directive (EU) 2016/797. In the cases referred to in the third sub-paragraph of Article 21(6) of Directive (EU) 2016/797, the applicant shall submit the file to the Agency. The Agency shall consult the relevant safety authorities and give its final opinion to the Commission.

(5) Pending the decision of the Commission, the Technical Regulation Division may apply the alternative provisions referred to in sub-regulation (4) without delay.

Conditions for the placing on the market of interoperability constituents.

5. (1) The Technical Regulations Division shall take all necessary steps to ensure that interoperability constituents are:

(a) placed on the market only if they enable interoperability to be achieved within the Union rail system while at the same time meeting the essential requirements:

(b) used in their area of use as intended and suitably installed and maintained.

Provided that sub-regulation 1(a) and (b) shall not prevent the placing on the market of those constituents for other applications.

(2) The Technical Regulations Division shall not, in Maltese territory and on the basis of Directive (EU) 2016/797, prohibit, restrict or hinder the placing on the market of interoperability constituents for use in the Union rail system where these constituents comply with these Regulations. In particular, they shall not require checks which have already been carried out as part of the procedure for 'EC' declaration of conformity or suitability for use as provided for in

regulation 7.

Conformity or suitability for use.

6. The Technical Regulations Division and the Agency shall consider that an interoperability constituent meets the essential requirements if it complies with the conditions laid down in the corresponding TSI or the corresponding European specifications developed to comply with those conditions. The 'EC' declaration of conformity or suitability for use shall attest that the interoperability constituents have been subject to the procedures laid down in the corresponding TSI for assessing conformity or suitability for use.

Unsuitability of 'EC' declaration .

7. If the Technical Regulations Division finds that the 'EC' declaration has been drawn up improperly, it shall ensure that the interoperability constituent is not placed on the market. In such a case, the manufacturer or his authorised representative shall be required to restore the interoperability constituent to a state of conformity under the conditions laid down by the Technical Regulations Division.

Non-compliance of interoperability constituents with essential requirements.

8. (1) Where the Technical Regulations Division finds that an interoperability constituent covered by the 'EC' declaration of conformity or suitability for use and placed on the market is, when used as intended, unlikely to meet the essential requirements, the Technical Regulations Division shall take all necessary steps to restrict its field of application, prohibit its use, withdraw it from the market or recall it. The Technical Regulations Division shall forthwith inform the Commission, the Agency and the other Member States of the measures taken and give reasons for its decision, stating in particular whether the failure to conform is due to:

(a) failure to meet the essential requirements;

(b) incorrect application of European specifications where application of such specifications is relied upon;

(c) inadequacy of European specifications.

(2) Where the decision referred to in sub-regulation 1 results from an inadequacy of European specifications, the Technical Regulations Division, the Commission or the Agency, as appropriate, shall apply one or more of the following measures:

(a) partial or total withdrawal of the specification concerned from the publications containing them;

(b) if the relevant specification is a harmonised standard, restriction or withdrawal of that standard in accordance with Article 11 of Regulation (EU) No 1025/2012;

(c) review of the TSI in accordance with Article 6 of Directive (EU) 2016/797.

(3) Where an interoperability constituent bearing the 'EC' declaration of conformity fails to comply with the essential requirements, the Technical Regulations Division shall take appropriate measures against any entity which has drawn up the declaration and shall inform the Commission and the other Member States thereof.

Free movement of subsystems.

9. Without prejudice to the provisions of Chapter V of Directive (EU) 2016/797, the Technical Regulations Division shall not, in Maltese territory and on grounds relating to Directive (EU) 2016/797, prohibit, restrict or hinder the construction, placing in service and operation of structural subsystems constituting the rail system which meet the essential requirements. In particular, the Technical Regulations Division shall not require checks which have already been carried out:

(a) as part of the procedure leading to the 'EC' declaration of verification; or;

(b) in other Member Stats, before or after the entry into force of Directive (EU) 2016/797, with a view to verifying compliance with identical requirements under identical operational conditions.

Notification of national rules.

10. (1) Draft national rules and national rules referred to in paragraph 1 of Article 14 of Directive (EU) 2016/797 shall be examined by the Agency in accordance with the procedures laid down in Articles 25 and 26 of Regulation (EU) 2016/796.

(2) The Commission shall establish, by means of implementing acts, the classification of the notified national rules in different groups with the aim of facilitating cross-acceptance in different Member States and the placing on the market of vehicles, including compatibility between fixed and mobile equipment. Those implementing acts shall build on the progress achieved by the Agency in the field of cross-acceptance and shall be adopted in accordance with the examination procedure referred to in Article 51(3) of Directive (EU) 2016/797.

The Agency shall classify, in accordance with the implementing acts referred to in the first sub-paragraph, the national rules which are notified in accordance with this Article 14 of Directive (EU) 2016/797.

(3) National rules not notified in accordance with this Article 14 of Directive (EU) 2016/797 shall not apply for the purposes of these

regulations.

Non-compliance of subsystems with essential requirements.

11. (1) Technical Regulations Division shall forthwith inform the Commission of any additional checks requested and set out the reasons therefor. The Commission shall consult the interested parties.

(2) Technical Regulations Division shall state whether the failure to fully comply with these regulations is due to:

(a) non-compliance with the essential requirements or with a TSI, or incorrect application of a TSI, in which case the Commission shall forthwith inform the Technical Regulations Division where the person who drew up the 'EC' declaration of verification in error resides and shall request that Technical Regulation Division to take the appropriate measures;

(b) inadequacy of a TSI, in which case the procedure for amending the TSI as referred to in Article 6 of Directive (EU) 2016/797 shall apply.

Authorisation for the placing in service of fixed installations.

12. (1) The track-side control-command and signalling, energy and infrastructure subsystems shall be placed in service only if they are designed, constructed and installed in such a way as to meet the essential requirements, and the relevant authorisation is received in accordance with sub-regulations (3) and (4).

(2) The national safety authority shall authorise the placing in service of the energy, infrastructure and track-side control-command and signalling subsystems which are located or operated in the Maltese territory.

(3) National safety authorities shall provide detailed guidance on how to obtain the authorisations referred to in this regulation. An application guidance document describing and explaining the requirements for those authorisations and listing the documents required shall be made available to applicants free of charge. The Agency and the national safety authorities shall cooperate in disseminating such information.

(4) The applicant shall submit a request for authorisation of the placing in service of fixed installations to the national safety authority. The application shall be accompanied by a file which includes documentary evidence of:

(a) the declarations of verification referred to in Article 15 of Directive (EU) 2016/797;

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

(c) the safe integration of the subsystems, established on the basis of the relevant TSIs, national rules, and the common safety methods ('CSMs') set out in Article 6 of Directive (EU) 2016/798;

(d) in the case of track-side control-command and signalling subsystems involving European Train Control System (ETCS) and/or Global System for Mobile Communications - Railway (GSM-R) equipment, the positive decision of the Agency issued in accordance with Article 19 of Directive (EU) 2016/797; and, in the case of a change to the draft tender specifications or to the description of the envisaged technical solutions that occurred after the positive decision, the compliance with the result of the procedure referred to in Article 30(2) of Regulation (EU) 2016/796.

(5) Within one month of receipt of the applicant's request, the national safety authority shall inform the applicant that the file is complete or ask for relevant supplementary information, setting a reasonable deadline for the provision thereof.

The national safety authority shall verify the completeness, relevance and consistency of the file, and, in the case of track-side ERTMS equipment, compliance with the positive decision of the Agency issued in accordance with Article 19 of Directive (EU) 2016/797 and, where appropriate, compliance with the result of the procedure referred to in Article 30(2) of Regulation (EU) 2016/796. Following such verification, the national safety authority shall issue the authorisation for placing in service of fixed installations, or inform the applicant of its negative decision, within a pre-determined, reasonable time, and, in any case, within four months of receipt of all relevant information.

(6) In the event of renewal or upgrading of existing subsystems, the applicant shall send a file describing the project to the national safety authority. Within one month of receipt of the applicant's request, the national safety authority shall inform the applicant that the file is complete or ask for relevant supplementary information, setting a reasonable deadline for the provision thereof. The national safety authority, in close cooperation with the Agency in the case of track-side ERTMS projects, shall examine the file and shall decide whether a new authorisation for placing in service is needed, on the basis of the following criteria:

(a) the overall safety level of the subsystem concerned may be adversely affected by the works envisaged;

(b) it is required by the relevant TSIs;

(c) it is required by the national implementation plans established by Malta; or

(d) changes are made to the values of the parameters on the basis of which the authorisation was already granted.

The national safety authority shall take its decision within a predetermined, reasonable time, and, in any case, within four months of receipt of all relevant information.

(7) A decision refusing a request for an authorisation for the placing in service of fixed installations shall be duly substantiated by the national safety authority. The applicant may, within one month of receipt of the negative decision, submit a request that the national safety authority review its decision. The request shall be accompanied by a justification. The national safety authority shall have two months from the date of receipt of the request for review in which to confirm or reverse its decision. If the negative decision of a national safety authority is confirmed, the applicant may bring an appeal before the appeal body designated by Malta under Article 18(3) of Directive (EU) 2016/798.

Designation of notifying authority. Cap. 510.

13. The Technical Regulations Division established by article 19 of the Malta Competition and Consumer Affairs Authority Act shall be the notifying authority for the purposes of articles 27, 28 and 29 of the Directive (EU) No. 2016/797

Conformity assessment bodies. S.L. 427.45.

14. (1) The procedures for assessment and notification of conformity assessment bodies, and the monitoring of notified bodies shall be those prescribed in the Method for Designating Conformity Assessment bodies Regulations. In addition, a conformity assessment body shall meet the requirements laid down in these regulations.

(2) The Technical Regulations Division shall notify the bodies responsible for carrying out the procedure for the assessment of conformity referred to in sub-regulation (1), to the Commission and the other Member States using the electronic notification tool developed and managed by the Commission and in accordance with the provisions of Article 37 of Directive (EU) 2016/797.

(3) A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by the relevant TSI and in relation to which it has been notified, whether those tasks are

carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of product in relation to which it has been notified, a conformity assessment body shall have at its disposal:

(a) the necessary personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

(b) the relevant descriptions of procedures in accordance with which conformity assessment is to be carried out, ensuring the transparency and the ability to apply those procedures. It shall have in place appropriate policies and procedures that distinguish between tasks it carries out as a notified conformity assessment body and other activities;

(c) the proper procedures for the performance of 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 mass or serial nature of the production process.

It shall have the means necessary to perform in an appropriate manner the technical and administrative tasks concerned with the conformity assessment activities and shall have access to all necessary equipment or facilities.

(4) Conformity assessment bodies shall participate in, or ensure that their assessment personnel are informed of, the relevant standardisation activities and the activities of the notified conformity bodies ‘coordination group established under the relevant Union Law, and shall apply as a general guidance the administrative decisions and documents produced as a result of the work of that group.

(5) Conformity assessment bodies that are notified for track-side and/or on-board control-command and signalling subsystems shall participate in, or shall ensure that their assessment personnel are informed of, the activities of the ERTMS group referred to in Article 29 of Regulation (EU) 2016/796. They shall follow the guidelines produced as a result of the work of that group. In the event that they consider it inappropriate or impossible to apply them, the conformity assessment bodies concerned shall submit their observations for discussion to the ERTMS group for the continuous improvement of the guidelines.

(6) Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Articles 30 to 32 of Directive (EU) 2016/797 and shall inform the Technical Regulations Division accordingly.

(7) Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established. Activities of notified bodies may be subcontracted or carried out by a subsidiary only with the agreement of the client.

(8) Notified bodies shall keep at the disposal of the Technical Regulations Division the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under the relevant TSI.

(9) A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products which they assess, or the authorised representative of any of those parties. This shall not preclude the use of assessed products that are necessary for the operations of the conformity assessment body or the use of such products for personal purpose.

(10) A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacturer or construction, marketing, installation, use or maintenance of those products, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgment or integrity in relation to conformity assessment activities for which they are notified. This prohibition shall apply, in particular, to consultancy services.

(11) Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

Presumption of conformity of a conformity assessment body.

15. Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof, the references of which have been published in the Official Journal of the European Union, it shall be presumed to comply with the requirements set out in Articles 30 to 32 of Directive (EU) 2016/797, in so far as the applicable harmonised standards cover

those requirements.

Accredited in-house bodies.

16. (1) Applicants 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 laid down in Annex II to Decision No 768/2008/EC and modules CA1 and CA2 laid down in Annex I to Decision 2010/713/EU. That body shall constitute a separate and distinct part of the applicant concerned and shall not participate in the design, production, supply, installation, use or maintenance of the product it assesses.

(2) An accredited in-house body shall meet the following requirements:

(a) it shall be accredited in accordance with Regulation (EC) 765/2008;

(b) the body and its personnel shall, within the undertaking of which they form a part, be organisationally identifiable and have reporting methods which ensure their impartiality, and shall demonstrate it to the competent national accreditation body;

(c) neither the body nor its personnel shall be responsible for the design, manufacture, supply, installation, operation or maintenance of the products they assess, nor shall they engage in any activity that might conflict with their independence of judgement or integrity in relation to their assessment activities;

(d) the body shall supply its services exclusively to the undertaking of which it forms a part.

(3) An accredited in-house body shall not be notified to the Member States or the Commission, but information concerning its accreditation shall be given by the undertaking of which it forms a part or by the national accreditation body to the Technical Regulations Division at request.

Changes to notifications.

17. (1) Where the Technical Regulations Division has ascertained or has been informed that a notified body no longer meets the requirements laid down in Articles 30 to 32 of Directive (EU) 2016/797, or that it is failing to fulfil its obligations, the Technical Regulations Division shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly

(2) In the event of restriction, suspension or withdrawal of

notification, or where the notified body has ceased its activity, the Technical Regulations Division shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

Challenges to the competence of notified bodies.

18. The Technical Regulations Division shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the body concerned.

Operational obligations of notified bodies.

19. (1) Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in the relevant TSI.

(2) Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Notified bodies, when performing their activities, shall 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 mass or serial nature of the production process.

In so doing, they shall nevertheless operate with the aim of assessing the compliance of the product with these regulations.

(3) Where a notified body finds that requirements laid down in the relevant TSI or corresponding harmonised standards or technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a conformity certificate.

(4) Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that a product no longer complies with the relevant TSI or corresponding harmonised standards or technical specifications, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.

(5) Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

Obligation of notified bodies to provide information.

20. (1) Notified bodies shall inform the notifying authority of the following:

(a) any refusal, restriction, suspension or withdrawal of a certificate;

(b) any circumstances affecting the scope of, and conditions for, notification;

(c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;

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

The competent national safety authorities shall also be informed of any refusal, restriction, suspension or withdrawal of a certificate under sub-regulation (1)(a).

(2) Notified bodies shall provide the other bodies notified under Directive (EU) 2016/797 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.

(3) Notified bodies shall provide the Agency with 'EC' certificates of verification of subsystems, 'EC' certificates of conformity of interoperability constituents and 'EC' certificates of suitability of use of interoperability constituents.

Coordination of notified bodies.

21. Bodies notified by the Technical Regulations Division shall participate in the work of sectoral groups of notified bodies as established by the Commission under Directive (EU) 2016/797, directly or by means of designated representatives. The Agency shall support the activities of notified bodies in accordance with Article 24 of Regulation (EU) 2016/796.

Other transitional provisions. S.L. 427.31.

22. (1) Schedules IV, V, VII and IX to the Interoperability of the Rail System Regulations shall apply until the date of application of the corresponding implementing acts referred to in Article 7(5), Article 9(4), Article 14(10) and Article 15(9) of Directive (EU) 2016/797.

(2) Directive 2008/57/EC shall continue to apply in relation to ERTMS track-side projects which are to be placed before 16 June 2019.

(3) Projects which have completed the tendering or contracting phase prior to 16 June 2019 are not subject to the pre-authorisation by the Agency referred to in Article 19 of Directive (EU) 2016/797.

(4) Until 16 June 2031 options included in contracts which were signed before 15 June 2016 shall not be subject to the pre-authorisation by the Agency referred to in Article 19 of Directive (EU) 2016/797, even if they are exercised after 15 June 2016.

(5) Before authorising the placing in service of any ERTMS track-side equipment which was not subject to the pre- authorisation by the Agency referred to in Article 19 of Directive (EU) 2016/797, national safety authorities shall cooperate with the Agency in order to ensure that the technical solutions are fully interoperable, in accordance with Articles 30(3) and 31(2) of Regulation (EU) 2016/ 796.

23. The penalties and proceedings applicable for infringement of any of the provisions of these regulations shall be those provided for in Part IV of the Product Safety Act.

Penalties and Proceedings Cap. 427.

24. The Interoperability of the Rail System Regulations shall be repealed with effect from 16 June 2020.

Repeal of S.L. 427.31.

SCHEDULE I

ELEMENTS OF THE UNION RAIL SYSTEM

1. Network

For the purposes of these regulations, the Union's network shall include the following elements:

(a) specially built high-speed lines equipped for speeds generally equal to or greater than 250 km/h;

(b) specially upgraded high-speed lines equipped for speeds of the order of 200 km/h;

(c) specially upgraded high-speed lines which have special features as a result of topographical, relief or town-planning constraints, to which the speed must be adapted in each case. This category includes interconnecting lines between high-speed and conventional networks, lines through stations, accesses to terminals, depots, etc. travelled at conventional speed by ‘high-speed’ rolling stock;

(d) conventional lines intended for passenger services;

(e) conventional lines intended for mixed traffic (passengers and freight);

(f) conventional lines intended for freight services;

(g) passenger hubs;

(h) freight hubs, including intermodal terminals;

(i) lines connecting the above-mentioned elements.

This network includes traffic management, tracking and navigation systems, technical installations for data processing and telecommunications intended for long-distance passenger services and freight services on the network in order to guarantee the safe and harmonious operation of the network and efficient traffic management.

2. Vehicles

For the purposes of these regulations, Union vehicles shall comprise all vehicles likely to travel on all or part of the Union's network:

— locomotives and passenger rolling stock, including thermal or electric traction units, self-propelling thermal or electric passenger trains, and passenger coaches;

— freight wagons, including low-deck vehicles designed for the entire network and vehicles designed to carry lorries;

— special vehicles, such as on-track machines

This list of vehicles shall include those which are specially designed to operate on the different types of high-speed lines described in point 1.

SCHEDULE II

SUBSYSTEMS

1. List of subsystems

For the purposes of these regulations, the system constituting the Union rail system may be broken down into the following subsystems, either:

(a) structural areas:

— infrastructure,

— energy,

— track-side control-command and signalling,

— on-board control-command and signalling,

— rolling stock; or

(b) functional areas:

— operation and traffic management,

— maintenance,

— telematics applications for passenger and freight services.

2. Description of the subsystems

For each subsystem or part of a subsystem, the list of constituents and aspects relating to interoperability is proposed by the Agency at the time of drawing up the relevant draft TSI. Without prejudging the choice of aspects and constituents relating to interoperability or the order in which they will be made subject to TSIs, the subsystems include the following:

2.1. Infrastructure

The track, points, level crossings, engineering structures (bridges, tunnels, etc.), rail-related elements of stations (including entrances, platforms, zones of access, service venues, toilets and information systems, as well as their accessibility features for persons with disabilities and persons with reduced mobility),

safety and protective equipment.

2.2. Energy

The electrification system, including overhead lines and the trackside electricity consumption measuring and charging system.

2.3. Trackside control-command and signalling

All the trackside equipment required to ensure safety and to command and control movements of trains authorised to travel on the network.

2.4. On-board control-command and signalling

All the on-board equipment required to ensure safety and to command and control movements of trains authorised to travel on the network.

2.5. Operation and traffic management

The procedures and related equipment permitting coherent operation of the various structural subsystems, during both normal and degraded operation, including in particular train composition and train driving, traffic planning and management.

The professional qualifications which may be required for carrying out any type of railway service.

2.6. Telematics applications

In accordance with Schedule I, this subsystem comprises two elements:

(a) applications for passenger services, including systems which provide passengers with information before and during the journey, reservation and payment systems, luggage management and management of connections between trains and with other modes of transport;

(b) applications for freight services, including information systems (real-time monitoring of freight and trains), marshalling and allocation systems, reservation, payment and invoicing systems, management of connections with other modes of transport and production of electronic accompanying documents.

2.7. Rolling stock

Structural body, command and control system for all train equipment, electric current collection devices, traction and energy conversion units, on-board equipment for electricity consumption measuring and charging, braking, coupling and running gear (bogies, axles, etc.) and suspension, doors, man/machine interfaces (driver, on-board staff and passengers, including accessibility features for persons with disabilities and persons with reduced mobility), passive or active safety devices and requisites for the health of passengers and on-board staff.

2.8. Maintenance

The procedures, associated equipment, logistics centres for maintenance work and reserves providing the mandatory corrective and preventive maintenance to ensure the interoperability of the Union rail system and guarantee the performance required.

B 1450

SCHEDULE III

ESSENTIAL REQUIREMENTS

1. General requirements

1.1. Safety

1.1.1. The design, construction or assembly, maintenance and monitoring of safety-critical components, and more particularly of the components involved in train movements, must be such as to guarantee safety at the level corresponding to the aims laid down for the network, including those for specific degraded situations.

1.1.2. The parameters involved in the wheel/rail contact must meet the stability requirements needed in order to guarantee safe movement at the maximum authorised speed. The parameters of brake equipment must guarantee that it is possible to stop within a given brake distance at the maximum authorised speed.

1.1.3. The components used must withstand any normal or exceptional stresses that have been specified during their period in service. The safety repercussions of any accidental failures must be limited by appropriate means.

1.1.4. The design of fixed installations and rolling stock and the choice of the materials used must be aimed at limiting the generation, propagation and effects of fire and smoke in the event of a fire.

1.1.5. Any devices intended to be handled by users must be designed in such a way as not to impair the safe operation of the devices or the health and safety of users if used in a foreseeable manner, albeit not in accordance with the posted instructions.

1.2. Reliability and availability

The monitoring and maintenance of fixed or movable components that are involved in train movements must be organised, carried out and quantified in such a manner as to maintain their operation under the intended conditions.

1.3. Health

1.3.1. Materials likely, by virtue of the way they are used, to constitute a health hazard to those having access to them must not be used

in trains and railway infrastructures.

1.3.2. Those materials must be selected, deployed and used in such a way as to restrict the emission of harmful and dangerous fumes or gases, particularly in the event of fire.

1.4. Environmental protection

1.4.1. The environmental impact of establishment and operation of the rail system must be assessed and taken into account at the design stage of the system in accordance with Union law.

1.4.2. The materials used in the trains and infrastructures must prevent the emission of fumes or gases which are harmful and dangerous to the environment, particularly in the event of fire.

1.4.3. The rolling stock and energy-supply systems must be designed and manufactured in such a way as to be electromagnetically compatible with the installations, equipment and public or private networks with which they might interfere.

1.4.4. The design and operation of rail system must not lead to an inadmissible level of noise generated by it:

— in areas close to railway infrastructure, as defined in point (3) of Article 3 of Directive 2012/34/EU, and

— in the driver's cab.

1.4.5. Operation of the rail system must not give rise to an inadmissible level of ground vibrations for the activities and areas close to the infrastructure and in a normal state of maintenance.

1.5. Technical compatibility

The technical characteristics of the infrastructure and fixed installations must be compatible with each other and with those of the trains to be used on the rail system. This requirement includes the safe integration of the vehicle's subsystem with the infrastructure.

If compliance with these characteristics proves difficult on certain sections of the network, temporary solutions, which ensure compatibility in the future, may be implemented.

1.6. Accessibility

1.6.1. The ‘infrastructure’ and ‘rolling stock’ subsystems must be

accessible to persons with disabilities and persons with reduced mobility in order to ensure access on an equal basis with others by way of the prevention or removal of barriers, and by way of other appropriate measures. This shall include the design, construction, renewal, upgrade, maintenance and operation of the relevant parts of the subsystems to which the public has access.

1.6.2. The ‘operations’ and ‘telematics applications for passengers’ subsystems must provide for the necessary functionality required to facilitate access for persons with disabilities and persons with reduced mobility on an equal basis with others by way of the prevention or removal of barriers, and by way of other appropriate measures.

2. Requirements specific to each subsystem

2.1. Infrastructure

2.1.1. Safety

Appropriate steps must be taken to prevent access to, or undesirable intrusions into, installations.

Steps must be taken to limit the dangers to which persons are exposed, particularly when trains pass through stations.

Infrastructure to which the public has access must be designed and made in such a way as to limit any human safety hazards (stability, fire, access, evacuation, platforms, etc.). Appropriate provisions must be laid down to take account of the particular safety conditions in very long tunnels and viaducts.

2.1.2. Accessibility

Infrastructure subsystems to which the public has access must be accessible for persons with disabilities and persons with reduced mobility in accordance with point 1.6.

2.2. Energy

2.2.1. Safety

Operation of the energy-supply systems must not impair the safety either of trains or of persons (users, operating staff, track-side dwellers and third parties).

2.2.2. Environmental protection

The functioning of the electrical or thermal energy-supply systems must not interfere with the environment beyond the specified limits.

2.2.3. Technical compatibility

The electricity/thermal energy-supply systems used must:

— enable trains to achieve the specified performance levels,

— in the case of electricity energy-supply systems, be compatible with the collection devices fitted to the trains.

2.3. Control-command and signalling

2.3.1. Safety

The control-command and signalling installations and procedures used must enable trains to travel with a level of safety which corresponds to the objectives set for the network. The control-command and signalling systems must continue to provide for safe passage of trains permitted to run under degraded conditions.

2.3.2. Technical compatibility

All new infrastructure and all new rolling stock manufactured or developed after adoption of compatible control-command and signalling systems must be tailored to the use of those systems.

The control-command and signalling equipment installed in the train drivers' cabs must permit normal operation, under the specified conditions, throughout the rail system.

2.4. Rolling stock

2.4.1. Safety

The rolling-stock structures and those of the links between vehicles must be designed in such a way as to protect the passenger and driving compartments in the event of collision or derailment.

The electrical equipment must not impair the safety and functioning of the control-command and signalling installations.

The braking techniques and the stresses exerted must be compatible with the design of the tracks, engineering structures and signalling systems.

Steps must be taken to prevent access to electrically-live constituents in order not to endanger the safety of persons.

In the event of danger, devices must enable passengers to inform the driver and accompanying staff to contact them.

The safety of passengers boarding and alighting from trains must be ensured. The access doors must incorporate an opening and closing system which guarantees passenger safety.

Emergency exits must be provided and indicated.

Appropriate provisions must be laid down to take account of the particular safety conditions in very long tunnels.

An emergency lighting system having a sufficient intensity and duration is an absolute requirement on board trains.

Trains must be equipped with a public address system which provides a means of communication to the public from on-board staff.

Passengers must be given easily understandable and comprehensive information about rules applicable to them both in railway stations and in trains.

2.4.2.Reliability and availability

The design of the vital equipment and the running, traction and braking equipment as well as the control- command system must, in a specific degraded situation, be such as to enable the train to continue without adverse consequences for the equipment remaining in service.

2.4.3.Technical compatibility

The electrical equipment must be compatible with the operation of the control-command and signalling installations.

In the case of electric traction, the characteristics of the current-collection devices must be such as to enable trains to travel under the energy-supply systems for the rail system.

The characteristics of the rolling stock must be such as to allow it to travel on any line on which it is expected to operate, taking account of relevant climatic conditions.

2.4.4.Controls

Trains must be equipped with a recording device. The data collected by that device and the processing of the information must be harmonised.

2.4.5.Accessibility

Rolling-stock subsystems to which the public has access must be accessible for persons with disabilities and persons with reduced mobility in accordance with point 1.6.

2.5. Maintenance

2.5.1.Health and safety

The technical installations and the procedures used in the centres must ensure the safe operation of the subsystem and not constitute a danger to health and safety.

2.5.2.Environmental protection

The technical installations and the procedures used in the maintenance centres must not exceed the permissible levels of nuisance with regard to the surrounding environment.

2.5.3.Technical compatibility

The maintenance installations for rolling stock must be such as to enable safety, health and comfort operations to be carried out on all stock for which they have been designed.

2.6. Operation and traffic management

2.6.1.Safety

Alignment of the network operating rules and the qualifications of drivers and on-board staff and of the staff in the control centres must be such as to ensure safe operation, bearing in mind the different requirements of cross-border and domestic services.

The maintenance operations and intervals, the training and qualifications of the maintenance and control centre staff and the quality assurance system set up by the operators concerned in the control and maintenance centres must be such as to ensure a high level of safety.

2.6.2.Reliability and availability

The maintenance operations and periods, the training and qualifications of the maintenance and control centre staff and the quality assurance system set up by the operators concerned in the control and maintenance centres must be such as to ensure a high level of system reliability and availability.

2.6.3.Technical compatibility

Alignment of the network operating rules and the qualifications of drivers, on-board staff and traffic managers must be such as to ensure operating efficiency on the rail system, bearing in mind the different requirements of cross-border and domestic services.

2.6.4.Accessibility

Appropriate steps must be taken to ensure that operating rules provide for the necessary functionality required to ensure accessibility for persons with disabilities and persons with reduced mobility.

2.7. Telematics applications for freight and passengers

2.7.1.Technical compatibility

The essential requirements for telematics applications guarantee a minimum quality of service for passengers and carriers of goods, particularly in terms of technical compatibility.

Steps must be taken to ensure:

— that the databases, software and data communication protocols are developed in a manner allowing maximum data interchange between different applications and operators, excluding confidential commercial data,

— easy access to the information for users.

2.7.2. Reliability and availability

The methods of use, management, updating and maintenance of these databases, software and data communication protocols must guarantee the efficiency of these systems and the quality of the service.

2.7.3. Health

The interfaces between these systems and users must comply with the minimum rules on ergonomics and health protection.

2.7.4. Safety

Suitable levels of integrity and dependability must be provided for the storage or transmission of safety-related information.

2.7.5. Accessibility

Appropriate steps must be taken to ensure that telematics applications for passenger subsystems provide for the necessary functionality required to ensure accessibility for persons with disabilities and persons with reduced mobility.

B 1458

SCHEDULE IV

‘EC’ VERIFICATION PROCEDURE FOR SUBSYSTEMS

1. GENERAL PRINCIPLES

‘"EC" verification’ means a procedure carried out by the applicant within the meaning of Article 15 to Directive (EU) 2016/797 to demonstrate that the requirements of the relevant Union law and any relevant national rules relating to a subsystem have been fulfilled and the subsystem may be authorised to be placed in service.

2. CERTIFICATE OF VERIFICATION ISSUED BY A NOTIFIED BODY

2.1. Introduction

For the purpose of these regulations, the verification by reference to TSIs is the procedure whereby a notified body checks and certifies that the subsystem complies with the relevant technical specifications for interoperability (TSI).

This is without prejudice to the obligations of the applicant to comply with the other applicable legal acts of the Union and any verifications by the assessment bodies required by the other rules.

2.2. Intermediate statement of verification (ISV)

2.2.1 Principles

At the request of the applicant the verifications may be done for parts of a subsystem or may be limited to certain stages of the verification procedure. In these cases, the results of verification may be documented in an ‘intermediate statement of verification’ (ISV) issued by the notified body chosen by the applicant. The ISV must provide reference to the TSIs with which the conformity has been assessed.

2.2.2 Parts of the subsystem

The applicant may apply for an ISV for any part into which he decides to split the subsystem. Each part shall be checked at each stage as set out in point 2.2.3.

2.2.3 Stages of the verification procedure

The subsystem, or certain parts of the subsystem, shall be checked at each of the following stages:

(a) overall design;

(b) production: construction, including, in particular, civil-engineering activities, manufacturing, constituent assembly and overall adjustment;

(c) final testing.

The applicant may apply for an ISV for the design stage (including the type tests) and for the production stage for the whole subsystem or for any part into which the applicant decided to split it (see point 2.2.2).

2.3. Certificate of verification

2.3.1. The notified bodies responsible for the verification assess the design, production and final testing of the subsystem and draw up the certificate of verification intended for the applicant who in turn draws up the 'EC' declaration of verification. The certificate of verification must provide reference to the TSIs with which the conformity has been assessed.

Where a subsystem has not been assessed for its conformity with all relevant TSI(s) (e.g. in the case of a derogation, partial application of TSIs for upgrade or renewal, transitional period in a TSI or specific case), the certificate of verification shall give the precise reference to the TSI(s) or their parts whose conformity has not been examined by the notified body during the verification procedure.

2.3.2. Where ISV have been issued, the notified body responsible for the verification of the subsystem takes these ISV into account, and, before issuing its certificate of verification:

(a) verifies that the ISV cover correctly the relevant requirements of the TSI(s);

(b) checks all aspects that are not covered by the ISV; and

(c) checks the final testing of the subsystem as a whole.

2.3.3. In the case of a modification to a subsystem already covered by a certificate of verification, the notified body shall perform only those examinations and tests that are relevant and necessary, i.e. assessment shall relate only to the parts of the subsystem that are

changed and their interfaces to the unchanged parts of the subsystem.

2.3.4 Each notified body involved in the verification of a subsystem shall draw up a file in accordance with Article 15(4) of Directive (EU) 2016/797 covering the scope of its activities.

2.4. Technical file accompanying the 'EC' declaration of verification.

The technical file accompanying the 'EC' declaration of verification shall be assembled by the applicant and must contain the following:

(a) technical characteristics linked to the design including general and detailed drawings with respect to execution, electrical and hydraulic diagrams, control-circuit diagrams, description of data-processing and automatic systems to the level of detail sufficient for documenting the verification of conformity carried out, documentation on operation and maintenance, etc., relevant for the subsystem concerned;

(b) a list of interoperability constituents, referred to in point (d) of Article 4(3) of Directive (EU) 2016/797, incorporated into the subsystem;

(c) the files referred to in Article 15(4) of Directive (EU) 2016/797, compiled by each of the notified bodies involved in the verification of the subsystem, which shall include:

— copies of the 'EC' declarations of verification and, where applicable, 'EC' declarations of suitability for use established for interoperability constituents referred to in point (d) of Article 4(3) of Directive (EU) 2016/797 and accompanied, where appropriate, by the corresponding calculation notes and a copy of the records of the tests and examinations carried out by the notified bodies on the basis of the common technical specifications,

— where available, the ISV that accompany the certificate of verification, including the result of verification by the notified body of the ISV validity,

— the certificate of verification, accompanied by corresponding calculation notes and signed by the notified body responsible for the verification, stating that the subsystem complies with the requirements of

the relevant TSI(s) and mentioning any reservations recorded during performance of the activities and not withdrawn; the certificate of verification should also be accompanied by the inspection and audit reports drawn up by the same body in connection with its task, as specified in points 2.5.2 and 2.5.3;

(d) certificates of verification issued in accordance with other legal acts of the Union;

(e) when verification of safe integration is required pursuant to point (c) of regulation 12(4) and point (c) of Article 21(3) of Directive (EU) 2016/797, the relevant technical file shall include the assessors' report(s) on the CSMs on risk assessment referred to in Article 6(3) of Directive 2004/49/EC.

2.5. Surveillance by notified bodies.

2.5.1. The notified body responsible for checking production must have permanent access to building sites, production workshops, storage areas and, where appropriate, prefabrication or testing facilities and, more generally, to all premises which it considers necessary for its task. The notified body must receive from the applicant all the documents needed for that purpose and, in particular, the implementation plans and technical documentation concerning the subsystem.

2.5.2. The notified body responsible for checking implementation must periodically carry out audits in order to confirm compliance with the relevant TSI(s). It must provide those responsible for implementation with an audit report. Its presence may be required at certain stages of the building operations.

2.5.3. In addition, the notified body may pay unexpected visits to the work-site or to the production workshops. At the time of such visits the notified body may conduct complete or partial audits. It must provide those responsible for implementation with an inspection report and, if appropriate, an audit report.

2.5.4. The notified body shall be able to monitor a subsystem on which an interoperability constituent is mounted in order to assess, where required by the corresponding TSI, its suitability for use in its intended railway environment.

2.6. Submission

A copy of the technical file accompanying the 'EC' declaration of verification must be kept by the applicant throughout the service life of the subsystem. It must be sent to any Member State or the Agency, upon request.

The documentation submitted for an application for an authorisation for placing in service shall be submitted to the authority where the authorisation is sought. The national safety authority or the Agency may request that part(s) of the documents submitted together with the authorisation is/are translated into its own language.

2.7. Publication

Each notified body must periodically publish relevant information concerning:

(a) requests for verification and ISV received;

(b) request for assessment of conformity and suitability for use of ICs;

(c) ISV issued or refused;

(d) certificates of verification and 'EC' certificates for suitability for use issued or refused;

(e) certificates of verification issued or refused.

2.8. Language

The files and correspondence relating to the 'EC' verification procedure must be written in Maltese or English.

3. CERTIFICATE OF VERIFICATION ISSUED BY A DESIGNATED BODY

3.1. Introduction

In the case where national rules apply, the verification shall include a procedure whereby the body designated pursuant to Article 15(8) of Directive (EU) 2016/797, (the designated body) checks and certifies that the subsystem complies with the national rules notified in accordance with Article 14 of Directive (EU)

2016/797 for each Member State in which the subsystem is intended to be authorised to be placed in service.

3.2. Certificate of verification

The designated body draws up the certificate of verification intended for the applicant.

The certificate shall contain a precise reference to the national rule(s) whose conformity has been examined by the designated body in the verification process.

In the case of national rules related to the subsystems composing a vehicle, the designated body shall divide the certificate into two parts, one part including the references to those national rules strictly related to the technical compatibility between the vehicle and the network concerned, and the other part for all other national rules.

3.3. File

The file compiled by the designated body and accompanying the certificate of verification in the case of national rules must be included in the technical file accompanying the 'EC' declaration of verification referred to in point 2.4 and shall contain the technical data relevant for the assessment of the conformity of the subsystem with those national rules.

3.4. Language

The files and correspondence relating to the 'EC' verification procedure must be written in Maltese or English.

4. VERIFICATION OF PARTS OF SUBSYSTEMS IN ACCORDANCE WITH ARTICLE 15(7) OF DIRECTIVE (EU) 2016/797

If a certificate of verification is to be issued for certain parts of a subsystem, provisions for this Schedule shall apply *mutatis mutandis* for those parts.

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