
Swedish Transport Agency regulations on approval of railway subsystems;

TSFS 2010:116

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The Swedish Transport Agency stipulates¹ by virtue of Chapter 1, § 2 and Chapter 2, §§ 14b, 15, and 16 of the Railway Regulation (2004:526), the following.

RAILWAY

Scope of application and definitions

§ 1 These regulations contain provisions concerning the approval of the subsystems under Chapter 2, §§ 13 and 13a of the Railway Act (2004:519) and the application for exemption from the technical specifications for interoperability in accordance with Chapter 2, § 11 of the Railway Act.

§ 2 The terminology used in these regulations have the same meanings as in the Railway Act (2004:519), the Railway Regulation (2004:526) and Railway Board's Traffic Regulations (JvSFS 2008:7). In addition the following apply:

Specification of requirements a document that describes the specified requirements with which the subsystem shall comply;

Interim EC declaration a declaration that a subsystem fulfils the requirements of Chapter 2, § 8 of the Railway Act for design and construction phases;

¹See Directive 2004/49/EC of the European Parliament and of the Council of 29 April 2004 on safety on the Community's railways and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on the allocation of infrastructure capacity and the levying of charges for use of railway infrastructure and safety certification (Railway Safety Directive) (OJ L 220, 21.6.2004, p. 16, Celex 32004L0049) and Directive 2004/50/EC of the European Parliament and of the Council of 29 April 2004 amending Council Directive 96/48/EC on the interoperability of the trans-European high-speed rail system and Directive 2001/16/EC of the European Parliament and of the Council on the interoperability of the trans-European conventional rail system (OJ L 220, 21.6.2004, p. 40, Celex 32004L0050).

<i>Independent reviewer</i>	natural or legal person independent from the applicant and duly qualified for the task of certifying a railway vehicle's safety-related interaction with the railway infrastructure or other traffic safety-affecting functions;
<i>Risk analysis</i>	systematic use of all available information to identify hazards and assess risk;
<i>Risk Assessment</i>	the overall process comprising a risk analysis and risk valuation;
<i>Risk valuation</i>	a procedure based on the risk analysis to determine if an acceptable risk level has been reached;
<i>Safety document</i>	documented evidence that the product is in compliance with specified safety requirements;
<i>TSI – Technical Specifications for Operational Compatibility</i>	Technical Specifications for Operational Compatibility adopted by the European Commission;
<i>Type and/or version designation</i>	numeric and/or letter combination for naming railway vehicles, technical systems, or components of the same technical design;
<i>Validation</i>	testing, analysis, and review with the purpose of demonstrating that the resulting system meets the specified requirements;
<i>Validation plan</i>	a document that describes how the system's conformity with the required specifications will be proven;
<i>Validation report</i>	written summary of the completed validation.

General information on approval

Limited approval

§ 3 A subsystem may be approved for limited-time use on prescribed conditions if tests in the operating environment are required and if operational experience is required in order to show that a subsystem meets the requirements of the Railway Act (2004:519).

In other cases besides those specified in the first paragraph, an approval may be for a limited-time or subject to other conditions or be both limited-time and subject to other conditions.

Exemptions from approval requirement

Railway vehicles

§ 4 Approval is not required for rail vehicles which operate at no more than 20 kilometres per hour and which are not engaged for the carriage of passengers, if the rail vehicle:

1. is used within an A-SPA (special protection area closed to traffic due to work in progress);
2. is used within an area where other traffic is conducted exclusively by low-speed cautious movement;
3. does not have rail-mounted wheels with significance for propulsion or braking; or
4. are towed.

Railway vehicles authorised in a foreign country, under the international agreements on mutual recognition, may be used without Swedish Transport Agency approval.

Railway infrastructure

§ 5 Approval is not required for railway infrastructure which:

1. travels at a speed no greater than 20 kilometres per hour;
2. is not engaged for the carriage of passengers;
3. is not engaged for the transport of dangerous goods covered by the provisions of the Swedish Civil Contingencies Agency (MSB) Regulations (MSBFS 2009:3) on the Transport of Dangerous Goods by Rail (RIDS) or regulations which have replaced them;
4. is not simultaneously served by more than one vehicle motion;
5. has neither bridges nor tunnels nor level crossings crossed by a street or road that is open to general traffic;
6. forms the outermost section of the network to which it belongs; and
7. is equipped with technical protection that prevents rail vehicles from rolling out onto adjoining operational tracks.

Modernised or upgraded subsystems

§6 The description that, according to Chapter 2, § 13a of the Railway Act (2004:519), must be submitted to the Swedish Transport Agency shall include a risk assessment which should make clear whether the overall safety level could be affected.

Independent reviewer

§ 7 The functions referred to in § 15 first paragraph and § 16 first paragraph, second point, shall be reviewed by an independent reviewer approved by the Swedish Transport Agency. If the Swedish Transport Agency requests so, then an independent reviewer shall also carry out reviews of other traffic safety-affecting functions referred to in §§ 14-16.

If the Swedish Transport Agency so requests, then a resume of the reviewer and documents which show his/her independence from the reviewed object, as well a project plan for the review, shall be submitted to the Swedish Transport Agency.

Application for subsystem approval

General information

Deadline for submission of application documents

§ 8 Application documents for subsystem approval may, upon agreement with the Swedish Transport Agency, may be submitted as they are quality-assured and determined.

Basic information

§ 9 An approval application must include the following:

1. The applicant's name, address and organisation number.
2. Description of the subsystem and how it is to be used.
3. Indication on when the subsystem is intended to be put into operation.
4. Proposals for any possible type and/or version number.

Railway vehicles of the same previously approved technical design

§ 10 If the Transport Board has previously approved the technical design of the rail vehicle, then the application only needs, beyond what is set out in § 9, contain information about the previous decision and the documents requested by the Swedish Transport Agency.

Modernised or upgraded subsystems

§ 11 An application for new approval pursuant to Chapter 2, § 13 of the Railway Act (2004:519) shall contain only the documents according to § 9 and § § 13-15 which are relevant to the modernisation or upgrade.

Subsystems that are wholly or partially regulated by the TSI

§ 12 An application for approval of subsystems that are wholly or partially regulated by the TSI, in the event that § 10 does not apply, in addition to what is stated in § 9, shall include the following:

1. . Indication of which TSI(s) govern the subsystem(s).
2. Where relevant, EC declaration, interim EC declaration, or other evidence with technical documentation of the subsystem.
3. EC declarations on operational compatible components incorporated into the subsystem.
4. Where applicable, reference to the exemption decision from the TSI in accordance with Chapter 2, § 11 of the Railway Act (2004:519).

If the subsystem is only partially regulated by the TSI, or if a TSI contains special cases with explicit reference to national rules, then the application shall be accompanied by the documents under § § 13-16 which the Swedish Transport Agency requests.

Subsystems that are not regulated by the TSI

Contents

§ 13 An application for approval of subsystems that are not regulated by the TSI, in addition to the provisions of § 9, shall include the following:

1. Risk assessment.
2. Specification of requirements.
3. Preliminary timetable indicating the dates of construction and validation.
4. Validation plan.
5. Validation report.

Railway infrastructure

§ 14 An application for approval of rail infrastructure beyond what is stated in § 9 and § 13, shall contain information on the geographic placement with precise control points.

An application shall, when requested by the Swedish Transport Agency, be supplemented by additional documentation to supplement the safety case.

Railway vehicles

§ 15 An application for approval of railway vehicles shall, in the event that § 10 or § 16 are not applicable, beyond what is stated in § 9 and § 13, shall contain documentation certifying the railway vehicle's safety-related interaction with the railway infrastructure. The documentation must include a report containing information on:

- a) detectability in terms of signal safety,
- b) interaction with the train protection systems,
- c) the railway infrastructure scanning for defective railway vehicles,
- d) communication between the railway vehicle and traffic management,
- e) dynamic interaction with the track,
- f) dynamic and static profile,
- g) electromagnetic compatibility with the surroundings, excluding the energy system,
- h) current collection and interaction with the energy system of the infrastructure, and
- i) towing, lifting/rescue.

The application shall, when requested by the Swedish Transport Agency, be supplemented by additional documentation to supplement the safety case.

Rail vehicles approved in another state within the EEA or Switzerland

§ 16 An application for approval of railway vehicles referred to in Chapter 2, § 14b Railway Regulation (2004:526), beyond what is stated in § 9, need only to include the following:

1. A copy of the other country's valid authorisation decisions.
2. Documentation certifying the rail vehicle's safety-related interaction with Swedish railway infrastructure. The documentation must include a report containing information on:
 - a) interaction with the train protection systems,
 - b) the technical monitoring of speed,
 - c) the railway infrastructure scanning for defective railway vehicles,
 - d) communication between the railway vehicle and traffic management,
 - e) dynamic interaction with the track,
 - f) dynamic and static profile,

- g) electromagnetic compatibility with the surroundings, excluding the energy system,
- h) current collection and interaction with the energy system of the infrastructure, and
- i) towing, lifting/rescue.

The application shall, when requested by the Swedish Transport Agency, be supplemented by the following.

1. A list of which documents were the basis for the other country's approval.
2. Manuals and instructions in the language used during the installation, operation, and maintenance of the railway vehicle.
3. Documents showing the results of rail vehicle tests in its operating environment.
4. Additional documentation to supplement the safety case.

Application for exemption from TSI

§ 17 An approval for exemption from TSI must include the following:

1. The applicant's name, address and organisation number.
2. A description of the work to be performed, geographic location, and functional and technical scope.
3. Information on which parts of the TSI that the exemption request relates to.
4. Presentation of the reasons (technical, administrative, or economic) that are the basis for the exemption request.
5. Presentation of the corresponding technical specifications which the applicant intends to implement.

An application for exemption shall, when requested by the Swedish Transport Agency, be supplemented by an action plan of the measures the applicant is taking and will take in order to eventually achieve compliance with the part(s) of the TSI that the exemption request relates to.

Exemption from the regulations

§ 18 Exemptions from these regulations are communicated by the Swedish Transport Agency.

Entry into force and transitional provisions

1. These regulations shall enter into force on 1 August 2010.
2. These regulations suspend the Swedish Rail Agency Regulations (JvSFS 2006:1) for approval of sub-systems in railways, etc.
3. The Swedish Transport Agency's decision which is in force when this statute comes into force is still valid after the entry into force of this statute. The decision communicated by the Swedish Rail Agency shall be deemed to have been communicated by the Swedish Transport Agency and is in force until the Swedish Transport Agency communicates a new decision or the period of validity for the decision expires.

For the Swedish Transport Agency

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