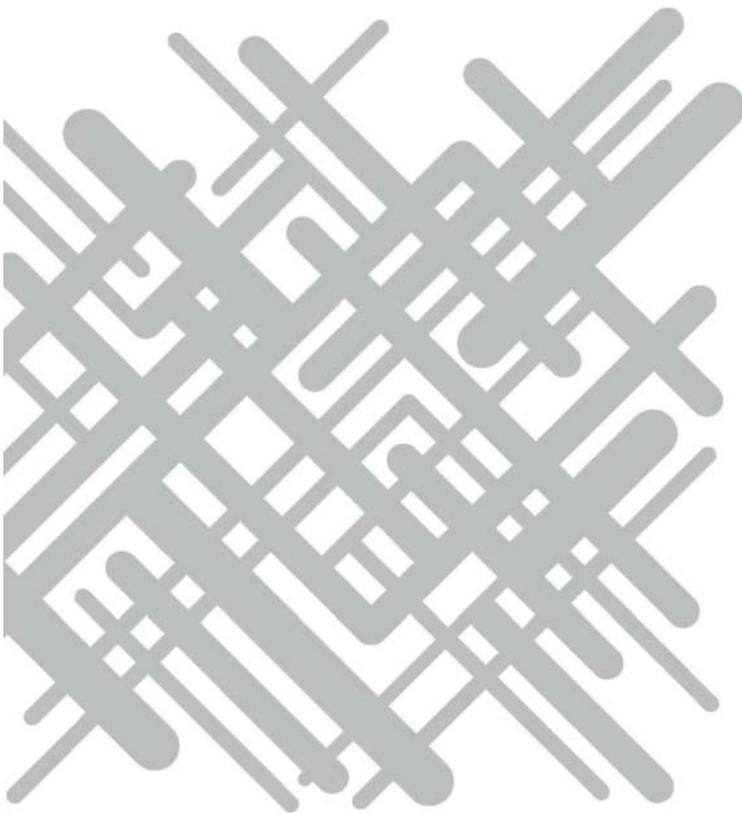


**SWEDISH  
TRANSPORT  
AGENCY**  
Railway Department

Approval

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# Approval Guidelines



## REVISION INFORMATION

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05	28/04/2009	The establishment of text in conjunction with the document's adaptations to the Transport Agency, and inserting the forms as Annex 3.	Robert Bylander Reijo Rosendal	Rune Lindberg
06	30/11/2010	Adaptation to TSFS 2010:116	Robert Bylander	Rune Lindberg

### Transport Agency safety goals for the approval of subsystems:

- Each new subsystem shall be at least as safe as existing subsystems with the same or similar function.
- There shall be preventative measures against faults so that no individual fault can cause an accident or a dangerous condition.

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## Introduction

### Instructions to reader

The guideline is to assist applicants in reading TSFS 2010:116 'The Transport Agency's approval regulations for railway subsystems'.

The guideline is designed as a commentary text to TSFS 2010:116, i.e. the first section is text in a coloured box, and under each section there are clarifications and explanations. The guideline provides examples of how to meet the approval requirements for railway vehicles in accordance with TSFS 2010:116.

### Glossary

To ease the readability of the guide, the following glossary has been added. Several definitions are taken from the Railway Act and the Railway Directive. In addition to the glossary in Section 1.1, the definitions are circular.

**User manual:** a document that describes how to operate a system.

**ATC:** Automatic Train Control – the Swedish technical system for monitoring and presentation of signal and speed information (train protection system).

**AO:** (Swedish: Anmält Organ) NB, Notified Body. The body which is responsible for assessing the interoperability constituents' conformity or suitability for use, or for processing the EC procedure for verification of the subsystems.

**Subsystem:** the result of the division of the rail system. These subsystems may be structural in nature (infrastructure, energy, control-command and signalling, rolling stock) and functional (operational and traffic management, maintenance, telematic applications for passenger and freight traffic). The subsystem is a part of the railway system.

**Operational safety and safety plan:** document which describes the applicant's planned management of reliability, availability, maintainability and safety during all phases of development. See, for example, SS-EN 50126:1999 or IEC 61508:1998.

**Interoperability:** the ability of a rail system to allow the safe and uninterrupted movement of trains which accomplish the required levels of performance, this ability rests on all the regulatory, technical and operational conditions which must be met in order to satisfy the essential requirements.

**Interoperability constituents:** any elementary constituent, group of constituent, sub-assembly or complete assembly of equipment incorporated or intended to be incorporated into a subsystem, on which the interoperability of the railway system depends either directly or indirectly; the concept of a 'constituent' covers both tangible objects and intangible objects such as software.

**EC declaration:** EC declaration of conformity or suitability for use is issued by the manufacturer (or representative) of the interoperability constituent. The declaration of conformity refers to compliance with the TSI.

**EC verification:** EC verification is the procedure whereby a notified body checks and certifies that a subsystem is in conformity with the requirements of the Directive and with the other rules of the Treaty which apply to it.

**EC declaration of verification:** the notified body responsible for EC verification shall assess the design and production of the subsystem and issue a verification certificate for the applicant, which in turn issues the EC declaration of verification intended for the supervisory authority in the Member State in which the subsystem is intended to be located and/or operate.

**ERTMS:** the European Rail Traffic Management System is a standard European signalling system for railways to permit cross-border rail traffic. Consists of ETCS and GSM-R systems.

**ETCS:** the European Train Control System is a European standard for train protection systems (see ATC), which together with GSM-R, makes the ERTMS. The ETCS main constituents are Eurobalises, radio block centres, and onboard computers.

**Approval objects:** rail infrastructure or vehicles for which approval is sought.

**GSM-R:** digital mobile telephone network adapted for railways.

**Vehicle:** a railway vehicle running on railway lines on its own wheels, with or without traction, a vehicle consists of one or more structural and functional subsystems or parts of such subsystems.

**Main track:** railway infrastructure in the form of track installations that are normally signalled and intended for train movements or single-line working. Definition in accordance with the JTF (JvSFS 2008:7): 'track designated for safe movement.'

**Infrastructure manager:** any undertaking that manages railway infrastructure and operates installations belonging to that infrastructure.

**Railway infrastructure:** the following reserved for railway traffic; track, signalling and safety systems, traffic management facilities, facilities for power supply to traffic, and other fixed facilities needed for the maintenance, operation, or use of the facilities.

**Railway System:** railway infrastructure and railway vehicles and the operation and management of the infrastructure and vehicles.

**JTF:** the Railway Board's traffic regulations (JvSFS 2008:7).

**Modernisation:** major substitution work on a subsystem or part of a subsystem which does not change the total performance of the subsystem.

**National safety constituents:** constituents of Swedish railway infrastructure or vehicles that affect safety and are not regulated in the TSI, for instance the national ATC system, signal box including object controllers, automatic block, national radio block centre, level crossing system including obstacle detector and barrier drive gear, track circuit, point motors and blade switch detection contacts, and hot box detector.

**NTR:** national technical rules, i.e. the rules that apply for an approval object when there are no rules in the TSI. The rules notified to the European Commission are called NNTR (Notified National Technical Rules).

**Remodelling:** major modification work on a subsystem or part of a subsystem which improves (changes) the total performance of the subsystem.

**RAMS:** Reliability, Availability, Maintainability and Safety. See the operational safety plan and the safety plan.

**Hazard:** a condition or set of circumstances in a system, which together with other conditions in its environment can lead to an accident causing injury to persons, property or the environment.

**Siding:** railway infrastructure which is normally intended for shunting movements of up to 30 km/h. Definition in accordance with the JTF (JvSFS 2008:7): 'Track other than the main track.'

**Safety Inspection:** inspection of the safety status of a vehicle or railway infrastructure.

**TEN:** Trans-European Network, i.e. Trans-European conventional rail system and Trans-European high-speed rail system. Which lines are included in TEN can be found in European Parliament and Council Decision 1692/96/EC, see also Annex 1.

**THR:** Tolerable Hazard Rate. Specifies how often dangerous faults may occur in a system so that goals can be met. Often given in faults/hour.

**Maintenance manual:** a document that describes corrective maintenance and preventive maintenance of a system.

**Maintenance plan:** a document that describes what maintenance is to be performed and with what frequency.

**Essential requirements:** the requirements in the areas of safety, reliability, accessibility, health, environmental protection, and technical compatibility which must be met by the rail system, the subsystems, and the interoperability constituents including interfaces.

### **What should be approved?**

A subsystem (or part of the subsystem) shall be approved by the Transport Agency before being put into service in Sweden. Similarly, substantially remodelled or modernised subsystems shall be approved before being put into service. This is regulated in the Railway Act (2004:519).

The approval regulations divide the items to be approved (approval object) into two main areas; rail infrastructure and rail vehicles. When the Transport Agency issues an approval, this approval often covers numerous subsystems. For example, 'Infrastructure,' 'Energy,' and 'CCS' (control-command and signalling subsystem) are included when a new electrified track is to be approved. The subsystems 'Rolling stock' and 'CCS' are included in the approval process of a locomotive that is equipped with ETCS or ATC.

National safety constituents are usually approved by the Transport Agency when the subsystem, in which the constituent is included, is approved. Constituents covered by the TSI (interoperability constituents) shall not be approved by the Transport Agency. However, interoperability constituents shall have an EC declaration of conformity or suitability for use as they are part of a subsystem to be approved by the Transport Agency.

Approvals issued by the Swedish Railway Inspectorate and the Swedish Rail Agency are valid and need not be repeated as long as no remodel or modernisation of a subsystem is performed. Subsystems in use when the Railway Act (2004:519) entered into force are also deemed to be approved.

Vehicles that were in use when the Railway Safety Act (1990:1157) came into force on 1 January 1991 are considered by the Transport Agency as already approved.

Figure 1 illustrates the railway system's components according to the Directive and Swedish law. The orange boxes (level 2) indicate the Railway Act's division of the railway system and the green boxes (Level 3) indicate the Railway Act and the Interoperability Directive's division of the railway system into subsystems.

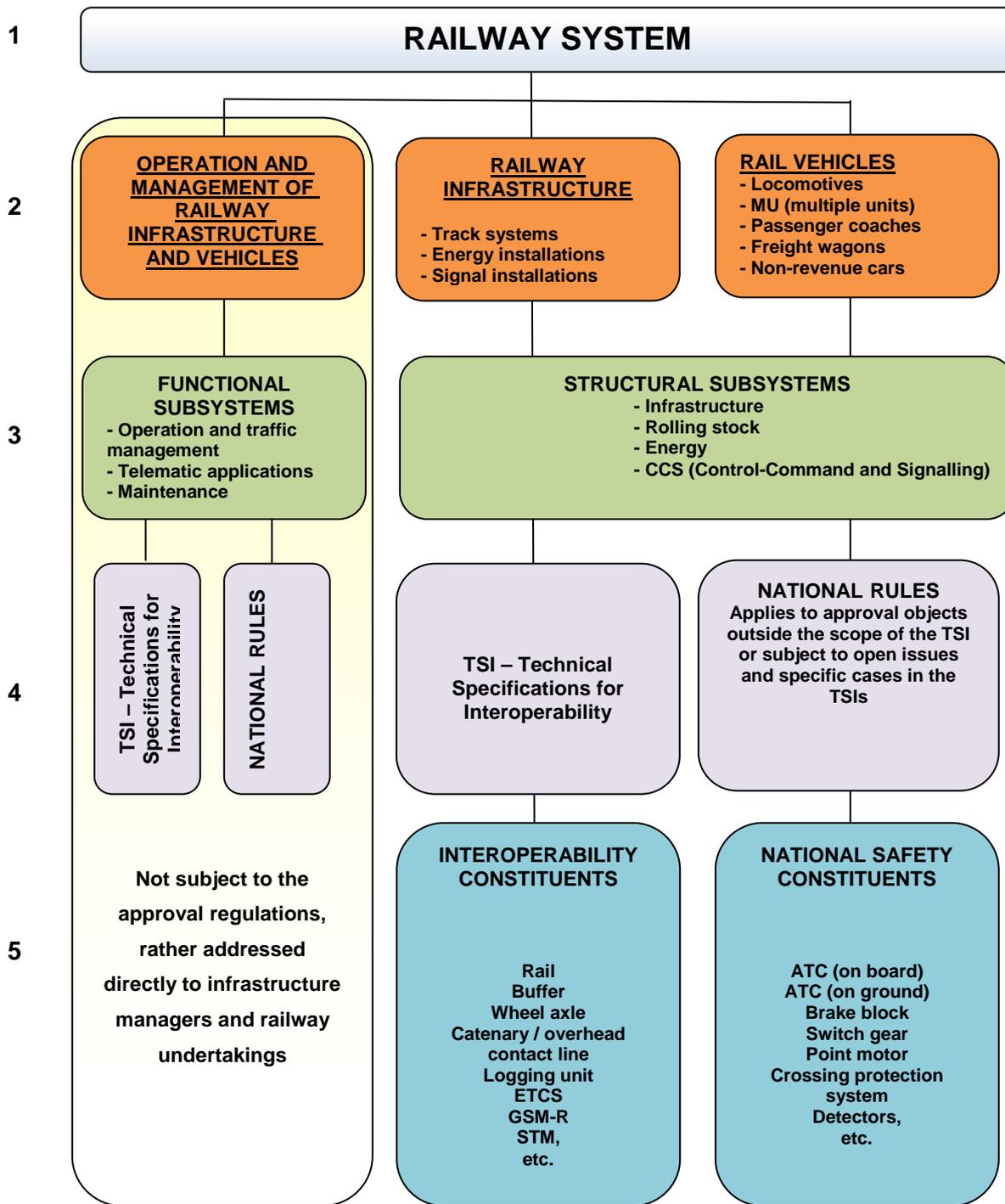


Figure 1 The railway system's components

## Which approval process applies?

The Swedish Transport Agency regulations on approval of railway subsystems consists of two different processes. One is harmonised within Europe and is applicable for approval objects which are covered by the TSI. Chapter 4 (§ 12 in TSFS 2010:116) deals with the harmonised approval process. The second process is national and is applicable for approval objects that are based on national rules (not regulated by the TSI) and approval objects that are regulated by the TSI but which have been designed, built, remodelled, or modernised before the TSI has entered into force. Chapter 5 (§§ 13-16 in TSFS 2010:116) deals with the national approval process.

The approval object is often subject to requirements that are addressed in various subsystems. These requirements can be specified in the TSIs or in national rules. This is deemed by the Transport Agency to be very common during a long transition period. The Transport Agency will then consider whether the combination of TSI requirements and national requirements are met, and thus if the combination of subsystems operate together in a safe and interoperable manner.

The following approval objects are examples of what shall be approved under the national process:

- national safety constituents;
- such items that are not yet covered by TSIs, e.g. non-revenue cars and certain railway infrastructure. (This point is only valid during a transitional period. As the new TSIs enter into force, the approval process described in Chapter 4 becomes applicable.);
- the railway infrastructure and vehicles intended solely for use with historical purposes or infrastructure which is functionally isolated from the rest of the railway system.

Figure 2 shows when the respective harmonised and national approval process shall apply.

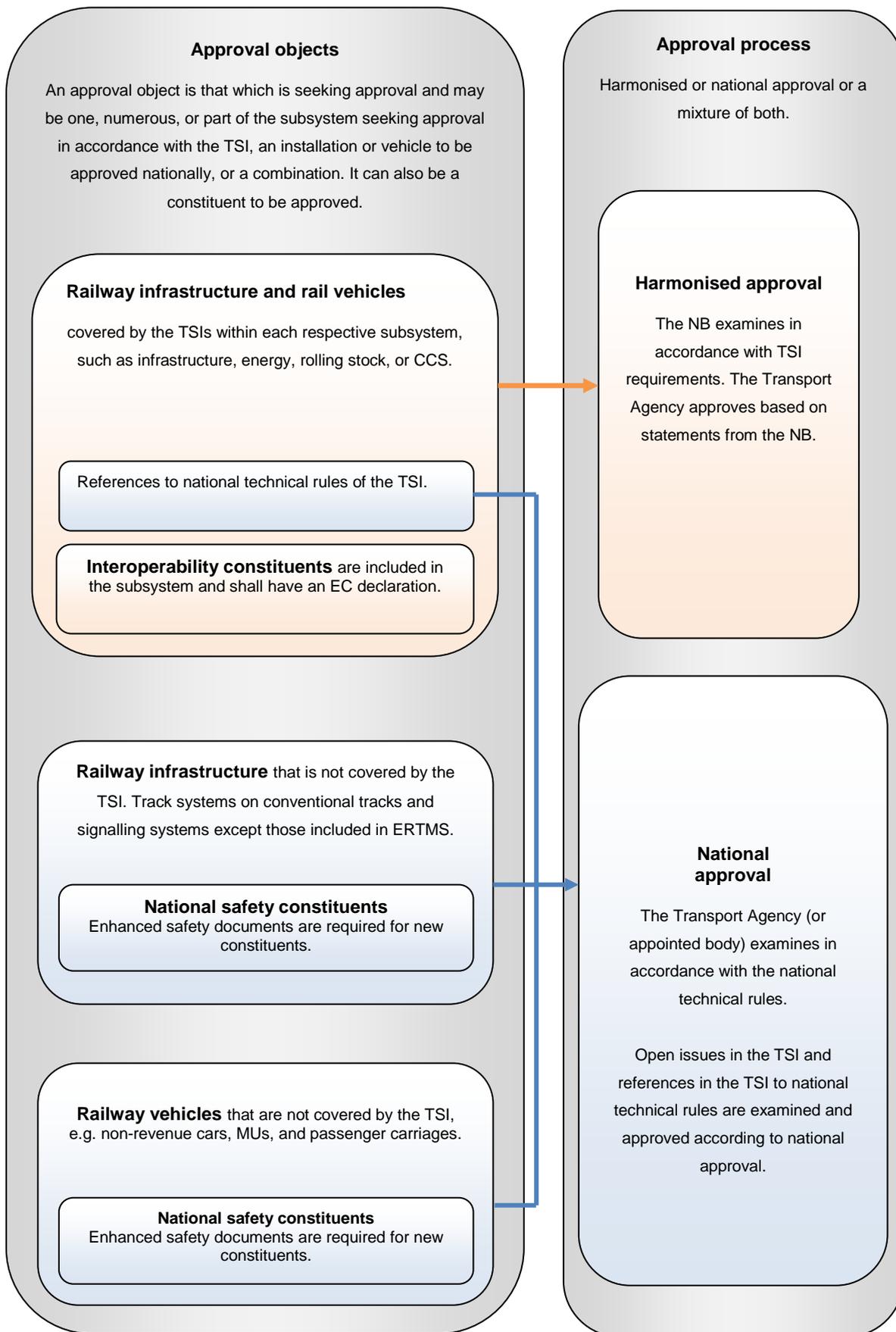


Figure 2 Processes of the approval regulations

## 1 Scope 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.

In accordance with the Railway Act, Chapter 2, §§ 13 and 13a, subsystems (new, remodelled, or modernised) shall be approved by the Transport Agency before they are put into service. These regulations govern the foundation that shall be the basis for the Transport Agency's approval. An approval decision means that the approval object in question may be used for railway operations in Sweden.

Vehicles or infrastructure for the underground and tramway are not covered by these regulations; they are regulated by TSFS 2010:115.

Chapter 6 (§ 17 TSFS 2010:116) deals with the application for exemption from the TSI.

### 1.1 Definitions

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

*specification of requirements*: document that describes the specified requirements with which the subsystem shall comply;

*intermediate EC declaration of verification*: explanation that a subsystem fulfils the requirements of Chapter 2, § 8 of the Railway Act for design and construction phases;

*independent assessor*: 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;

*risk analysis*: systematic use of all available information to identify hazards and assess risk;

*risk assessment*: the overall process comprising a risk analysis and risk valuation;

*risk valuation*: a procedure based on the risk analysis to determine if an acceptable risk level has been reached;

*safety document*: documented evidence that the product is in compliance with specified safety requirements;

*TSI – Technical Specifications for Interoperability*: Technical Specifications for Interoperability adopted by the European Commission;

*type and/or version designation*: numeric and/or letter combination for naming railway vehicles, technical systems, or constituents of the same technical design;

*validation*: testing, analysis, and assessment with the purpose of demonstrating that the resulting system meets the specified requirements;

*validation plan*: document that describes how the system's compliance with the contract documents will be proved, *the validation report*: written summary of the completed validation.

From the above definition of 'independent assessor' it is not clear that an independent assessor can perform other types of reviews than certification of a railway vehicle's safety-related interaction with the railway infrastructure or other traffic safety-affecting functions. These other reviews may be the introduction of new technology in the tracks, for example, point motor or changes in the signal safety installations, which the independent assessor shall be duly qualified for.

## 2 General information on approval

### 2.1 Limited approval

**§ 3** A subsystem may be approved for limited-time use on prescribed conditions if tests in the operating environment are needed 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.

The Transport Agency often issues approval in several stages; first, one or more temporary approvals to conduct a pilot operation, then an approval for operating experience in commercial service, and finally an approval valid until further notice. Both the temporary approval and the approval valid until further notice may include restrictions and conditions of use. Temporary approvals are given for stages of major infrastructure projects, they are not for pilot operations or operating experience in commercial service, but for normal service on a stretch which will later be integrated into the finished project.

Both pilot operations and operating experience in commercial service may be needed to gather practical experience of the approval object. Another reason for temporary approval is to allow the applicant to implement the service, although certain non-safety-affecting functions have not been shown.

The difference between pilot operations and operating experience in commercial service is that the pilot operation is performed in a 'protected environment,' e.g. the pilot operation is performed out in the field without the involvement of passengers or other vehicles. However, certain tests are carried out along with other traffic, testing the pantograph, for example. On the other hand, operating experience in commercial service involves taking the approval object into commercial service. Both the pilot operations and operating experience in commercial service are usually initiated by the applicant in order to validate certain requirements, such as availability requirements.

Examples of vehicle functions to be tested are brakes, track forces, securing loads, and profile. Passenger rail vehicles shall also have their doors and emergency and evacuation equipment tested. Certain tests will be performed both during both winter and summer conditions.

Pilot operations and operating experience shall be documented in a report. The Transport Agency accepts tests performed by competent companies in

Sweden and abroad (if conditions are equivalent to those in Sweden), as well as test reports from independent testing organisations.

For pilot operations, it is important that the railway undertaking has traffic regulations that cover trial runs and that any exemptions from the JTF (Railway Board's traffic regulations) are in order.

## 2.2 Exemptions from approval requirement

### 2.2.1 Railway vehicles

**§ 4** Approval is not needed 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. is towed.

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

The paragraph should be read so that the conditions of 20 km/h and the vehicle not being used for the transportation of passengers must always be met, and that in addition, at least one of the conditions in points 1-4 must also be satisfied. The speed of 20 km/h is chosen because the consequences of an accident or derailment are considered small.

A-SPA means that an area is given over to work that requires that no train runs may take place over the workplace. Single-line working and shunting may occur after consultation. The rules for A-SPA are found in JvSFS 2008:7 Annex 12.

Visibility movement is a movement form on the main track or siding. It means that speed must be adapted to the visibility distance (full-visibility speed, half-visibility speed, and creep speed). See JvSFS 2008:7.

Towing means that a vehicle is pulled or pushed, firmly interconnected, by another (approved) vehicle without the towed vehicle contributing in either a drive or braking capacity.

Approval is not needed for rail vehicles that are covered by the rules of mutual recognition, for example, freight wagons which fully comply with TSI Freight Wagons, foreign freight wagons that are approved under the RIV agreement, or foreign passenger coaches that are approved under the RIC agreement.

## 2.2.2 Railway infrastructure

**§ 5** Approval is not needed for railway infrastructure which:

1. services at speeds 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.

Items 1-7 must be met simultaneously. This section is primarily aimed at managers of siding as well as tracks in industrial areas. The speed of 20 km/h is chosen because the consequences of an accident or derailment are considered small.

That something 'forms the outermost section of the network to which it belongs' means that there are no tracks beyond this track (i.e. no other infrastructure managers' tracks).

### Track systems that do not require approval

Track systems that are not considered to be railway infrastructure (and which do not constitute underground or tramway) are in accordance with JvSFS 2005:2 as follows:

- amusement park facilities
- funiculars
- mining tracks intended for ore mining and which are not linked to the railway infrastructure
- track systems that are open only to pedalled inspection trolleys
- track systems which are intended only for the movement of cranes, overheads, and the like, and
- other short track systems that are only open to freight traffic and which are not linked to the railway infrastructure.

The vehicles used on these track systems do not need Transport Agency approval either.

## 2.3 Modernised or remodelled 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 if the overall safety level could be impacted.

An approval decision is valid until the subsystem is remodelled or modernised.

Modernisation and remodelling means, in accordance with the definitions of Directive 2008/57/EC, major work to substitute or modify a subsystem or part of a subsystem. Works that are of such scope that they are considered to be remodels or modernisations shall always be communicated to the Transport Agency, which determines whether a new approval is needed. A modernisation or remodel is cause for a renewed approval if the modification may impair safety, change the function, or improve performance. The use of the subsystem is a part of the approval, so if the use changes then a new approval is required.

Those who carry out a modification of an approved subsystem must work in accordance with the EC Regulation on CSM (common safety method) regarding risk valuation and assessment (352/2009).

The procedure under Regulation 352/2009 is:

1. When the Transport Agency has not indicated whether a change should be considered significant or not (see example below), the applicant should assess whether the proposed change affects safety.
2. If the change has safety implications then the applicant should, with the help of an expert opinion, assess the significance of the change. The assessment should lead to one of three conclusions:
  - 2.1 In the first situation the change is not deemed significant and the applicant should implement the change by applying its own safety method.
  - 2.2 In the second situation the change is deemed significant and the applicant should implement the change by applying Regulation 352/2009 and the Transport Agency need not be notified.
  - 2.3 In the third situation the change is deemed to be substantial and the Transport Agency shall be informed in order to issue, for example, a new approval to put a vehicle into service.

In other words, each time a modification is performed, the applicant must carry out a risk assessment. The risk assessment is an important basis for determining whether the modification has safety implications and thus requires approval of the Transport Agency or not. Changed use of the subsystem can affect safety and must be dealt with in the risk assessment of the change.

Vehicle keepers and infrastructure owners shall keep an internal record of all modifications carried out, regardless of whether they have safety implications or not. Such records shall describe all intermediate versions (known as configuration control).

If a renewed approval is required then the Transport Agency requests submission of additional documents for the modification under § 12 and/or §§ 13-16. The description of the change can be made in the form of a gap analysis / change analysis, i.e. describe the changes in relation to what was previously approved. The applicant's internal records of intermediate versions can be advantageously utilised here.

Annex 2 contains more information on risk assessment, risk valuation, and risk analysis.

The Transport Agency will determine the extent to which the modernisation /

remodel must comply with the TSI.

### **Railway vehicles**

It can be difficult to determine what changes or modifications need to be approved. Those who carry out a modification shall always perform a risk assessment which shows that the safety risks do not increase with the modified vehicle. Below are examples of vehicle modifications that are generally not considered to be remodels or modernisations within the meaning of the Railway Act. This means that such modifications do NOT require Transport Agency approval and therefore do not need a description, in accordance with § 6, to be sent if the risk assessment shows that the overall level is not adversely affected. If in doubt, contact the Transport Agency.

- The replacement of a safety-affecting detail without affecting its function or specification, such as valves, relays, sensors, bearings, springs, shock absorbers, transformers, etc.
- Installation of GSM-R for communication with traffic control on **already approved** railway vehicles.
- Replacement of details on rail vehicles that affect neither safety nor interoperability, such as a transformers.
- The replacement of interior equipment and fittings in the passenger and staff spaces on railway vehicles which do not change the rail vehicle's dynamic behaviour, or impair the fire classification, or otherwise adversely affect passenger safety. However, when replacing the entire interior of a passenger space, TSI Tunnel Safety applies and with that a new approval is required.
- Maintenance measures, both preventative and corrective.

Following are examples of vehicle remodels that require Transport Agency approval:

- A remodelled or reprogrammed ATC system. Such a system must itself be approved for installation in vehicles.
- Installation of ETCS in a vehicle.
- A new type of driver's panel or driver's safety device (DSD).
- Change of actuators, electronics, and software for control of traction and braking on rail vehicles.
- A new type of engine, bogie, axle, wheel, coupler, frame, or body.
- A new type of operating system and emergency braking system or WSP on rail vehicles.
- A new type of door control, door lock, emergency system, or fire alarm.
- Increase in performance, including increased speed, increased axle load, and changed loading gauge.
- A new use of a vehicle.

An example of a special vehicle that shall be approved is a radio locomotive, which is a common locomotive fitted with radio control and used for shunting. Basically, there should be an approval for the locomotive itself. Thereafter, an approval is required for the installation of the radio control equipment; one separate approval per locomotive.

**Note that the above lists are examples and that when a modification is planned of such scope that it is deemed to be a remodel or modernisation, a**

**description of the planned work must always be submitted to the Transport Agency.**

### **Railway infrastructure**

It can be difficult to determine what changes or modifications need to be approved. Those who carry out a modification shall always perform a risk assessment which shows that the risks do not increase with the modified infrastructure. Below are examples of infrastructure modifications that are generally not considered to be remodels or modernisations within the meaning of the Railway Act. This means that they do NOT require Transport Agency approval and therefore do not need a description, in accordance with § 6, to be sent if the risk assessment shows that the overall level is not adversely affected. If in doubt, contact the Transport Agency.

- The replacement of a safety-affecting detail without affecting its function or specification, such as sleepers, rails, cables, switch blades, and relays.
- Maintenance measures, both preventive and corrective, such as grinding, ballast washing, track straightening.
- Protection against noise.
- Removal of level crossing.
- Marginal change in track length (less than 100 m).
- Minor curve adjustment in conjunction with the existing railway embankment.
- Installation or removal of crossing protection system of proven technology that is independent from the signal box or automatic block system.
- Removal of non-signal controlled switch and associated siding(s).
- Procedure with equipment that does not have safety implications, such as control systems for signal boxes.

Following are examples of infrastructure remodels that require Transport Agency approval:

- Change in functions such as the train protection system (except for train running functions), the automatic block system, detectors, and train detection systems.
- Use of a different technical solution in relation to what has previously been known in regards to crossing protection system, signal boxes, point operating device, or other substantial part of a subsystem.
- Capacity building such as increased axle load, higher loading gauge, or increased speed.
- Procedure on the load-bearing structures of the track that significantly affect load capacity, such as new construction of a bridge, even if it is built using the same methods as the original bridge.
- Remodelling of places for the exchange of passengers, this also includes, for example, parts of travel centres that are not directly connected to the railway infrastructure.
- New communications systems or software/hardware upgrades in an existing system, such as new software in the base stations and PBX for GSM-R.
- New switch between main tracks.
- New main track.

**Note that the above lists are examples and that when a modification is planned of such scope that it is deemed to be a remodel or modernisation, a description of the planned work must always be submitted to the Transport Agency.**

## 2.4 Independent assessor

**§ 7** The functions referred to in § 15 first paragraph and § 16 first paragraph, second point, shall be assessed by an independent assessor approved by the Swedish Transport Agency. If the Swedish Transport Agency requests so, then an independent assessor shall also carry out reviews of other traffic safety-affecting functions referred to in §§ 14-16.  
If the Swedish Transport Agency requests so, then a resume of the assessor and documents which show his/her independence from the assessed object, as well a project plan for the assessment, shall be submitted to the Swedish Transport Agency.

### 2.4.1 General

The Transport Agency may request certain traffic safety-affecting functions to be assessed by one or more independent assessors. These independent assessors shall be approved by the Transport Agency for each respective approval object. For Transport Agency approval, the assessor is required to be independent and impartial in relation to the object that is to be assessed, and also to have adequate competence to complete the task.

Independent assessors should be involved early in the process in order to have continuous feedback from the work being carried out and to prevent deficiencies that can be difficult to manage at a later stage.

### Several independent assessors

An approval object may consist of several combined elements, each of which is separately assessed by different independent assessors. It is incumbent upon the applicant to present to the Transport Agency a clear overview of all component parts and which parts are covered by each respective assessment. Note that all independent assessors must normally be approved by the Transport Agency.

### Completed independent reviews

In some cases, parts of an approval object may have already been assessed by an independent assessor for foreign approval, for example. Such reviews can normally be reused if the assessment is properly conducted and documented.

In the case above, the independent assessor is obviously not approved by the Transport Agency and greater responsibility falls on the independent assessor for the approval object of which the part is included. The independent assessor must then check and evaluate the competence, independence, and impartiality of the previous independent assessor and that their report meets the other requirements for an independent assessment (see Chapter 2.4.5). The valuation of this check, and how the valuation is performed, shall be clearly stated in the report for the approval object.

## 2.4.2 Railway vehicles

There are different types of independent assessments for railway vehicles, there is an assessment of the vehicle's interaction with the infrastructure, but also of the constituents and functions of the vehicle.

Functions in points a) - i) in § 15 and § 16 apply to the vehicles' interaction with the infrastructure and shall always be assessed by independent assessors. When introducing a completely new vehicle, all relevant (determined by the Transport Agency) points shall be assessed. For approval of remodels, upgrades, or modernisation, only the functions affected (determined by the Transport Agency) are assessed again by independent assessors.

The independent assessment for foreign vehicles may be the foreign approval, if the approval makes clear what was assessed. For more information, please refer to the Transport Agency's guidelines '*Review of railway vehicle interaction with Swedish railway infrastructure*' at [www.transportstyrelsen.se](http://www.transportstyrelsen.se).

'Other traffic safety-affecting functions' refers to advanced braking and door systems, for example, which are not functions that relate to interaction with the infrastructure. These are handled in the same way as the development of new signal boxes, see Chapter 2.4.3.

## 2.4.3 Railway infrastructure

Currently, the Transport Agency does not normally require an independent assessor for changes to a track system or energy installation. However, an independent assessor may be required following the introduction of new technologies to the track, such as point motors.

The Transport Agency always requires an independent assessor for changes in signal safety devices. However, the independent assessor's duties may vary

depending on the scope of the approval.

For reengineering of items such as signal boxes, the Transport Agency requires compliance with SS-EN 50126 (or upon agreement with the Transport Agency, equivalent standard to provide the intended SIL level of the product) and documentation in a safety certificate according to SS-EN 50129. The safety certificate is then evaluated by an independent assessor (ISA – Independent Safety Assessor).

The purpose of an independent assessment can be divided into two parts, these are:

- To verify that the applicant is working with a process that enables the implementation of a coherent strategy for managing reliability, availability, maintainability and safety.
- To verify that the results of applying the above process are relevant to the proposed work and sufficient to show that the implementation of the work achieves standards of safety requirements.

For changes in existing signal installations, there are often in-house process descriptions for the independent assessor's work such as the Swedish Transport Administration's *'Technical safety management, work with signalling systems, BVF 544.94001'* or SL's *'Global Security Governance SÄK-0410, Safety Management for work on signalling.'*

#### **2.4.4 Requirements for the independent assessor**

The requirements for an independent assessor will vary depending on the scope of the task, but it is generally required that he/she have extensive expertise in the area(s) to be examined, as well as that an overall perspective of the approval object is utilised. Furthermore, the independent assessor shall not be in a position of dependence or conflict of interest to the particular object(s) to be subjected to independent assessment.

Therefore, the Transport Agency does not normally accept independent assessors that belong to the same company as the manufacturer.

A CV (Curriculum Vitae) of the independent assessor is required as basis for the Transport Agency's acceptance.

The Transport Agency may also require a plan for the independent assessment to be presented. The minimum that the plan should include:

- Scope of the task
  - o What products or functions are included in the assessment.
  - o What parts of the life cycle (according to SS-EN 50126) are included in the assessment.
  - o The purpose of the independent assessment.
  - o Relations to other independent assessments.
- Method
  - o Working methods
  - o Planned audits
- Organisation

- Time schedule
- Deliveries

#### **2.4.5 Requirements for the report content**

The report shall clearly state what has been assessed, why, how, at what level the assessment was conducted, and if the approval object or change to the approval object meets or does not meet the stipulated requirements (the degree of compliance required may vary). If the requirements can not be satisfied in full, the independent assessor shall specify what consequences it entails and, if possible, indicate what measures should be taken prior to an approval.

## 3 Application for subsystem approval

### 3.1 General information

These help guidelines and the application forms in the guideline annexes are to assist in the approval application process. The submitted documentation may be more or less detailed depending on the complexity of the approval object. It's always a good idea to consult with the Transport Agency in conjunction with application submission.

Initial contact can be made in the most simple manner, for example, by phone, e-mail ([jarnvag@transportstyrelsen.se](mailto:jarnvag@transportstyrelsen.se)) or a letter in which the applicant notifies that it intends to develop something new or remodel an existing item. The case is assigned to an administrator at the Transport Agency who will contact the applicant and supply a case number.

If the approval is in regards to a vehicle, it is possible for the applicant to make a preliminary application directly in the rolling stock register, [www.transportstyrelsen.se](http://www.transportstyrelsen.se). If the applicant does not have a user account in the rolling stock register, then one can be applied for with the Transport Agency. However, the information required for the rolling stock register is entered by the administrator in conjunction with the approval.

#### 3.1.1 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.

It is important that the applicant contacts the Transport Agency at an early stage to discuss how the continued process should be implemented. For approval cases in which the TSI applies, it is recommended that a notified body is engaged right from the design stage.

By contacting the Transport Agency early, the opportunity is provided to be informed on current laws, regulations, and regulatory requirements, including those in adjoining areas such as the environment, working environment, and electrical safety.

The Transport Agency and the applicant should keep an ongoing dialogue during the project in order to create good continuity in the approval process. This makes the work easier for both the applicant and the Transport Agency and also shortens processing times.

The Transport Agency recommends that the requested documents are sent in as they are completed during the development phase. The applicant submits the finished document to the Transport Agency, which can thus work in parallel with the applicant. In this way, the processing time prior to approval for the object being put into service is shortened. Any updates to submitted information are sent again to the Transport Agency so that the basis for the decision is final.

### 3.1.2 Basic information

- § 9** An approval application shall 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.

The applicant may be a railway undertaking, manufacturer, importer, infrastructure manager, or other interested party. Several parties are sometimes involved in an application and they should agree on who shall formally stand as the applicant. He or she who stands as the application assumes a coordinating role with the Transport Agency and is responsible for all necessary information being provided to the Transport Agency.

#### **Railway infrastructure**

The description of the railway infrastructure should include layout drawings and technical specifications such as horizontal projections and cross-sectional drawings, track geometry, design factors (maximum permitted speed, greatest permitted axle load, track radii, maximum slope – in particular slope towards other infrastructure), signal safety devices, etc. The description shall also indicate which approved national safety constituents are included in the installation, such as signal boxes and ATC systems.

#### **Railway vehicles**

The description shall include a general description of the vehicle, overall design, construction, and performance. Basic functions shall be specified, e.g. maximum permitted speed, greatest permitted axle load, loading gauge, brakes, placement in the train, any software for the control of safety-affecting functions, etc.

The Transport Agency determines the type designation and vehicle number of the vehicle(s), however, the applicant may submit proposals. TSI Traffic Operation and Management – Annex P is used for the vehicle number.

### 3.1.3 Railway vehicles of the same technical design

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

Type and individual approval is used for vehicles. For a new or modified vehicle of an approved type, the Transport Agency applies a simplified approval. If an application relates to production vehicles, approval shall be sought for all vehicles in the series. The Transport Agency conducts a review of the first vehicle in the series before entry into service and decides on the approval of the vehicle type and all vehicles. Simplified approval is subsequently applied in conjunction with the putting into service of each individual vehicle of the series.

Something that the Transport Agency requests from the applicant is a statement of conformity with the type approved. In this the applicant certifies that the production vehicles are identical to the approved vehicle type. The Transport Agency may also request documentation showing how it is ensured that production vehicles are identical to the first approved vehicle.

For vehicles of types included in the European Register of Authorised Types of Vehicles (ERATV), the approval process is conducted in accordance with Chapter 4 (§ 12 in TSFS 2010:116).

#### **3.1.4 Modernised or remodelled subsystems**

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

Generally, modernisations and remodels will need only the changed parts of the approval object to meet applicable requirements. However, in the various TSIs, there are implementation strategies that describe when a TSI should apply for modernised and remodelled subsystems.

Also see Chapter 2.3.

## 4 Subsystems that are wholly or partially regulated by the TSI

### 4.1 General

The applicant shall engage a notified body (NB) when the application is for a subsystem covered by the TSI. The notified body should follow the entire development of the approval object from project initiation to its being put into service and assess compliance with the requirements of the TSI with a focus on safety and interoperability. Initiation of a project for an infrastructure system means the project initiation document phase, while for a vehicle it means the specification phase.

The notified body may be accredited in any EU country, as well as Norway and Switzerland. Accredited NBs are listed on the official EU website.

The Transport Agency makes an assessment of the necessary documents that the applicant shall submit (in accordance with § 12). The assessment consists of:

- a verification that the NB is duly accredited,
- a check of any open issues and Swedish special circumstances in the TSI (special circumstances are national deviations as specified in the TSI),
- a determination of possible granted (temporary) exemptions from complying with the requirements of the TSI,
- a verification that the approval object is compatible with the system that it is integrated in. For vehicles this means that they are checked against Swedish infrastructure and the Swedish climate, and
- a verification that the included subsystems of the approval object are compatible with each other.

Amendment efforts of the TSI content is ongoing. It is estimated that approximately every three to five years each TSI will be updated. In the meantime, there is a need to quickly introduce changes for reasons such as shortcomings and deficiencies that have a negative impact on interoperability. Such changes are handled by a specific process within the EU Commission. For this reason, changed requirements may be adopted in the TSI which are not included in the official Swedish version of the TSI. Information on such adopted changes is found on the Transport Agency home page.

Current information on which TSIs are available, applicable, and their content, can be found on the Transport Agency home page, [www.transportstyrelsen.se](http://www.transportstyrelsen.se).

## 4.2 Application

**§ 12** An application for approval of subsystems that are wholly or partially regulated by the TSI, 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 of verification, intermediate EC declaration of verification, or other evidence with technical documentation of the subsystem.
3. EC declarations on interoperability constituents 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 circumstances with explicit reference to national rules, then the application shall be accompanied by the documents under §§ 13-16 which the Swedish Transport Agency requests.

The application and accompanying documents should be written in Swedish or English, but Danish and Norwegian can also be accepted for less extensive applications.

The applicant (contracting entity or the manufacturer, or their authorised ombudsman) shall issue an EC declaration of verification for the subsystem. The EC declaration of verification shall be based on the certificate of verification that the NB shall issue for the subsystem in question.

Instead of the EC declaration of verification, an EC intermediate statement of verification is issued in cases where the subsystem is not in compliance with all prescribed requirements. Prior to certain approvals, it may instead be necessary to have other documents issued to confirm the safety of the subsystem, this is covered by so-called 'other certificates,' see 4.2.1.

Similarly, the manufacturer of an interoperability constituent shall issue an EC declaration of conformity or suitability for putting the constituent into service. The EC declaration of conformity or suitability for putting into service shall in most cases be based on a certificate issued by an NB. There must be an EC declaration for each interoperability constituent included in the approval object that is to be approved. The NB for the subsystem is responsible for compiling these EC declarations.

If the applicant has obtained an exemption from complying with the requirements of the TSI, then the Transport Agency checks that the approval item meets the obligations which have been communicated in the exemption application (for example, regarding which standards are met instead). If the chosen solution is time-limited, then the approval decision will be time-limited (for no longer than up to the date on which the applicant has undertaken to comply with the TSI requirements).

For such that is not yet covered by the TSI, but where the only regulatory framework available is national, the approval shall be in accordance with national rules, i.e. in accordance with §§ 13-16 in TSFS 2010:116.

Most TSIs contain so-called open issues, i.e. identified areas that remain to be specified. Such open issues refer to national rules while requirements of the TSI are pending .

Special circumstances entered in the TSI are national deviations for each Member State. They are deviations from the TSI which shall continue to apply temporarily or until further notice. Sweden has a number of such special circumstances which shall be met, where applicable. By reading the relevant TSI, the applicant can check which special circumstances apply in Sweden.

An approval object may be put into service only if designed, constructed, installed, and operated in such a way as not to hinder satisfaction of the essential requirements concerning them when integrated into the Swedish railway system.

The Transport Agency is responsible for this control, which is partly performed by following up on the work performed by the NB in regards to verifying the approval object's interface in relation to the system into which it is integrated, and partly by following up on an independent assessor's work on the parts that are outside of the TSI. In some cases, verification is performed by testing the subsystem in its operating environment, and the application shall then include a document certifying that the test was conducted.

### **Railway vehicles**

For vehicles not intended to be put into service or to undergo operating experience, such as the development of new technologies, and where the only issue is approval to implement the vehicle test, the manufacturer/applicant may choose not to assess the vehicle in accordance with the TSI. Note that a time-limited approval for the test through a national approval process can not replace an NB's work for an EC verification certificate.

### **Railway infrastructure**

A track section covered by the TSI needs to be approved in accordance with § 12 TSFS 2010:116 only when *the entire* track section is completed (i.e., when the final stage is put into service). Each prior commissioning (during the construction period) will be treated as an approval under §§ 13-16 in TSFS 2010:116, which are time-limited pending approval of the track section in its entirety. After 01-01-2011, the stages shall also be approved under § 12.

#### **4.2.1 Other certificates**

The Interoperability Directive 2008/57/EC states in Article 18.4 that: *'The NB may issue intermediate reports to cover certain stages in the assessment process or certain parts of the subsystem.'* This means that an ISV<sup>1</sup> can be written even when there is not full compliance with the TSI.

For development projects which gradually develop, for example, a vehicle or an

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<sup>1</sup> 'Intermediate statement of verification' is mentioned in Directive 2001/16/EC.

ERTMS system, there is no intention to require full compliance for the individual stages, only for the final stage. However, the Transport Agency considers the NBs to be responsible for assessing the approval object and to express an opinion. A solution is the issuing of an ISV (intermediate statement of verification) in which the NB gives their opinion on the subsystem or interoperability constituent.

Because the approval object does not contain all functions or meet all the requirements of the TSI, it is required that one carefully specifies what is included and the system intended use. With this document as a basis, the NB then assesses whether the approval object is fit for Intended use and documents this in the ISV. The ISV focuses mainly on safety, but depending on its use, other essential requirements may need to be inspected.

The ISV and the document on intended use are then the basis for the Transport Agency's approval. Use of the method above should be communicated to the Transport Agency.

## 5 Subsystems that are not regulated by the TSI

### 5.1 General information

Approval objects not covered by the TSI are approved entirely according to national rules (NTR). No NB is involved in the approval process, but rather the Transport Agency administrator has an equivalent role in monitoring the safety management from project initiation to approval.

The life-cycle perspective is important, i.e. the assessment involves both the chosen technical choices and specifications, construction, validation, and installation. For new technologies, additional documentation is also required describing the operation and maintenance. The Transport Agency checks if the applicant has worked methodically with the safety risks during all phases of the life cycle, i.e. structured and well documented. A development process in accordance with SS-EN 50126 is a good reference for safety management; see Figure 3. SS-EN 50126 is the basis for § 13-16 in TSFS 2010:116.

**Life cycle model in accordance with SS-EN 50126**

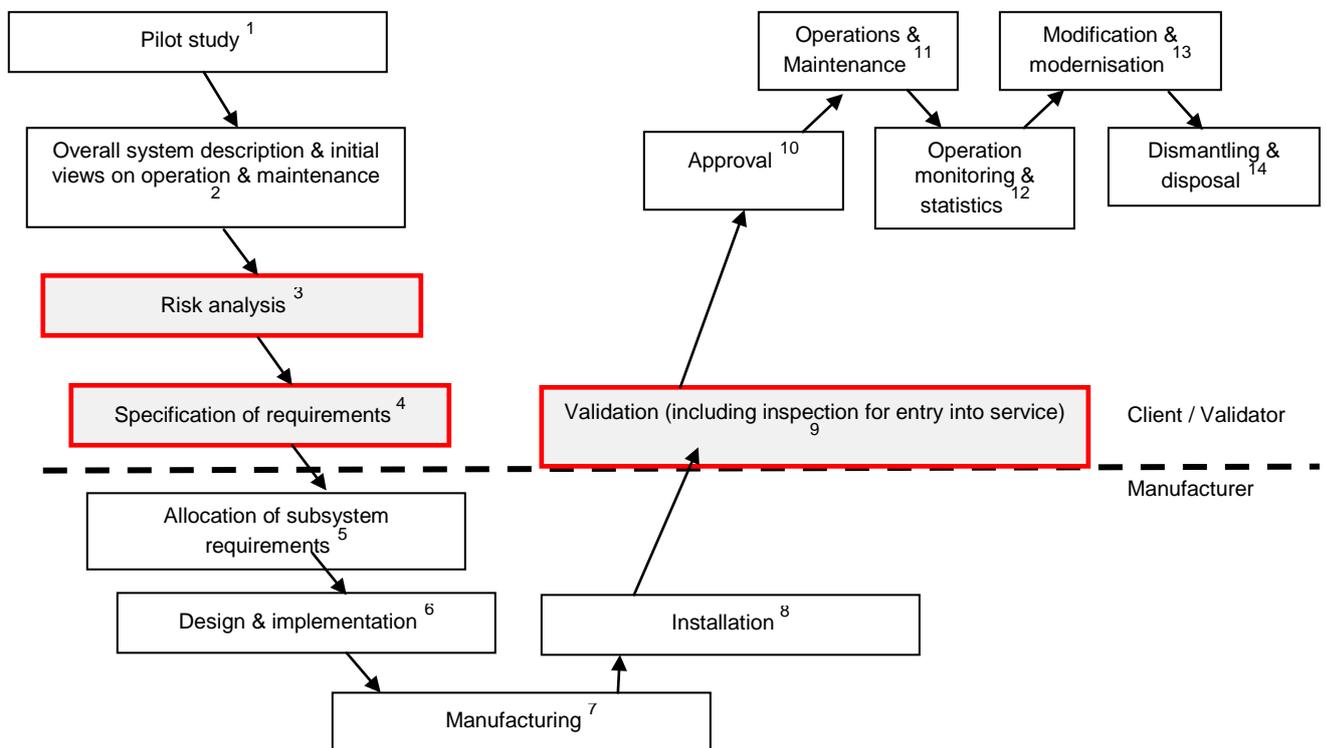


Figure 3: Development process – the life cycle divided into 14 phases. Phases 3, 4, and 9 are marked red because the quality of the information produced in these phases reveals much about the conditions for the implementation of a safe product.

## 5.2 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.

The Transport Agency has different criteria depending on the scope of complexity in the technical and safety systems. This then has an indirect influence on what requirements are set for documentation of system safety by the Transport Agency. For this reason, the Transport Agency has separated the requested documents for approval into two parts; that which is always requested and that which is requested in cases of major safety implications. More extensive documentation is required for the approval of new technical solutions and signal boxes, ATC and STM, as well as for vehicle functions. Less extensive documentation is required for the approval of modifications (only in regards to the difference from the previously approved version of the approval object). § 13 states that which is always requested in some form.

**The risk assessment** and more information about it is described in a separate annex (Annex 2). The risk assessment shall focus on traffic safety risks. The results of the risk assessment shall form the basis for which requirements are specified for the approval object, design decisions, and the need for manuals or new procedures. The risk assessment shall have the result that a number of measures are taken to minimise the risks. The risk assessment for modifications shall show that the overall risk is reduced, or just as small, for the subsystem after modification.

A **specification of requirements** is basically a detailed description of what is to be developed or modified. The specification of requirements is often drawn up by the client or the manufacturer themselves. The specification of requirements should be drawn up following completion of the risk assessment, but before construction begins. As a recommendation it should express functional requirements, not specify technical solutions. It should also include requirements for performance, environmental durability, interface, standards to be followed, design requirements, validation including testing, and related documentation and manuals. A specification of requirements can either be written with regular sentence structure, mathematical/logical expressions, or in the form of a drawing. Specification of requirements for infrastructure are often provided by the construction documents.

**The validation plan** describes how compliance with the specification of requirements for the vehicle, the infrastructure, or the technical system will be evidenced. Which method or methods will be used (tests, mathematical analysis, assessment). Preferably, the validation plan is written in parallel with the drawing up of the specifications of requirements, as this raises the quality of requirements' formation. The validation plan often covers several steps, such as first testing in the

factory, then testing in the field, and finally a plan for operating experience. It is particularly important during functionality testing to remember the odd situations and to test several sequences of commands, for example: run backwards, change direction, change the command during execution of another command, and the like.

The validation plan shall be adapted to Swedish conditions and show that, for example, test runs can be conducted in a manner that does not require traffic safety to be dependent upon the functions being tested. For infrastructure such as tracks and switches, it is intended that a technical verification or inspection be conducted prior to commissioning and which ensures design compliance with required standards and construction documents.

**The validation report** shall describe the activities carried out *before* entry into service in order to determine which requirements are met and which ones are not, based on the validation plan. Documentation of the tests / factory tests shall describe the test environment and specify the version of the vehicle / system that has been tested, since testing is often performed repeatedly and in several steps. To demonstrate that an installation was properly performed, it shall be documented in a record specifying the version. Any deviations from the specified requirements shall be stated and include a description of the consequences. If the client deems the deviations acceptable then an explanation shall be given. The Transport Agency may accept deviations if there is a good explanation and they do not have a negative impact on safety. Analyses which show compliance with requirements shall state the conditions for analysis such as operational environment and technical documentation.

The validation report may be, for example, a record of completed ATC simulation or factory tests. It can also be a report from a completed contract inspection of the infrastructure (the track). The report / record shall indicate who performed the inspection, the result, and the number of re-tests (if any).

Record from the railway infrastructure inspection shall show any inspection results regarding issues of traffic safety. The record must also state that the issues have been resolved with the date and a signature. In the case of a newly constructed or modified catenaries, the Transport Agency verifies that there is documentation showing that the catenary does not interfere with the clearance gauge.

### 5.3 Railway infrastructure

Individual approvals are generally granted for rail infrastructure such as tracks, switches, and signalling systems, i.e. each approval object is separately approved.

The background to the individual approvals is that the nature of such objects usually has a unique geographic adjustment. If this is not the case, for example, as with certain mass-produced national safety constituents such as point motors and blade switch detection contacts, the Transport Agency tests the first safety constituent of the series and then all subsequent identical safety constituents may be put into service without separate approval.

Note that railway infrastructure covers much more than just the actual track system, for example, the catenary and technical systems as well as signal box systems and

automatic block systems.

Building a new track section is usually a project that takes several years to complete and is done in phases. A difficulty arises in how such projects shall be regarded. The Transport Agency deems that when a planned track section consists of a number of legs which are commissioned separately, each leg must be separately approved by the Transport Agency.

**§ 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 certificate.

Additional documentation to supplement the safety certificate is mainly requested for new technical solutions or modified signal box systems and/or automatic block systems. The Transport Agency requires the applicant to hire an independent assessor for a safety assessment of such objects.

The additional documentation can be:

- 1) A description of the methodology of how to produce and test an individual installation on the basis of the basic version.
- 2) Information on which norms are the basis for the technical design.
- 3) Operational safety and safety plan.
- 4) User manual.
- 5) Maintenance and installation manuals.
- 6) A document that describes the history of the version designations.
- 7) Logbook of hazards.
- 8) Report from independent assessors.
- 9) Record from inspection for entry into service.
- 10) Document verifying the test in an operational environment.
- 11) Safety case.

**A description of the methodology** of how to produce and test an individual installation is relevant only in conjunction with reengineering of signal boxes and serial delivery. It deals with the process drawn up by the supplier to plan a specific installation. This information shall show that the applicant has taken measures to minimise the risks associated with the planning and testing of individual installations.

#### **Information on which norms are the basis for the technical design**

is a subset of information that is specified in the specifications of requirements.

**A Risk Assessment Management System (RAMS-plan)** is relevant only in conjunction with reengineering of technical systems and describes the applicant's management of reliability, availability, maintainability, and safety during all phases of development. For example, how will a need for change be handled in the operational phase (such as updating the safety document or the approval object itself). Which process is applicable for necessary future modifications. If an accident occurs, how information about it is disseminated to other owners. The RAMS plan need not be *one* document, rather it can be advantageously divided into

a safety plan and an operational plan. Compare the requirements of SS-EN 50126:1999 or IEC 61508:1998.

**Manuals** for installation, operation, and maintenance shall be available in the language used by the users. Manuals shall be independently assessed, by the end user for example. There should be an assurance that the manuals are usable and safe.

Documents which describe the **history of the version designations** are about version control. It is important that the applicant can demonstrate traceability and track completed changes to files and documents during various phases of the life cycle.

A **Hazard Log** is relevant only in conjunction with reengineering or further development of signal boxes and shall follow the approach of SS-EN 50129:2003. The document includes all identified hazards from the risk analysis and is filled in with potential hazards that occur during the life cycle or that have been experienced in closely related projects. The document shall state what decisions have been made for actions to be taken, as well as risk mitigation measures that have been taken.

**One or more reports from independent assessors** shall describe in detail what has been assessed (each and every element), what criteria he/she has had for each controlled element, and the outcome for each element. There shall be conclusions in the form of a statement. There are often several reports for a signal box connected to different sections of the safety certificate for various phases.

**Record from inspection for entry into service** describes the outcome of the actual entry into service and the record of field tests performed.

**Documents verifying the test in an operational environment** are only relevant in conjunction with reengineering or further development of objects such as signal boxes and may be, for example, a report on operating experience conducted in order to validate the availability requirements for switchgear.

A **safety certificate** in accordance with EN 50129, for example, shall be drawn up for signal-related equipment such as computerised signal boxes or a new type of point motor. However, no safety certificate is necessary for railway infrastructure associated with track installations and energy installations. The manufacturer (or the applicant) shall certify that the approval object meets the safety requirements and that it is developed in a structured and controlled manner. The safety certificate is often divided into three separate parts (to allow re-use and cross-acceptance): platform, general functionality, and specific application. Read more in Chapter 5 of SS-EN 50129:2003, which gives very specific guidelines for the design of the safety certificate. The safety certificate shall contain six elements: description of the item, description of the company's quality management, description of the company's safety management, description of the object's technical safety, description of related safety certificates, and conclusion.

### 5.3.1 National safety constituents

Signal boxes, ATC, crossing protection systems, detectors, point motors, etc. are called national safety constituents in this document. A national

safety constituent is often approved in conjunction with the entry into service of the subsystem in which it is included. For example, the introduction of a new type of point motor is a safety-affecting modification of the 'infrastructure' subsystem and therefore requires Transport Agency approval prior to entry into service.

Certain national safety constituents are individual, i.e. they are characterised by a unique geographic adjustment (signal boxes, for example). Individual approval is therefore applied to signal boxes regardless of whether the application concerns a new type of signal box or a modification of an existing installation.

Other national safety constituents are mass produced and lack geographic adjustment, such as point motors or blade switch detection contacts. Such safety constituents may be put into service without new approval by the Transport Agency as long as proven technology is used. However, if the applicant intends to introduce new technical solutions, then the first safety constituent put into service shall be approved by the Transport Agency while all subsequent safety constituents may be put into service without Transport Agency approval.

Note that the Transport Agency does not issue retroactive approvals because subsystems containing national safety constituents that have been in service for a long time are considered approved. These include existing switches, point motors, blade switch detection contacts, track circuits, fortifications, insulated rail joints, mechanical signal boxes, electrical signal boxes, relay signal boxes, computerised signal boxes, ATC, automatic block systems, level crossing protection systems, obstacle detectors, barrier drive gear, hot box detectors, and landslide warning systems.

However, note that if these national safety constituents are modified and the modification has safety implications, then the modified subsystem requires approval!

### **5.3.2 Catenary that does not affect the clearance gauge**

In the case of a newly constructed or modified catenary, the Transport Agency verifies technical compatibility. This means that the applicant for these objects shall show that they do not interfere with the clearance gauge.

## **5.4 Railway vehicles**

There are no fundamental differences in regards to approval of different vehicle types such as locomotives, MUs, and freight wagons. The information requested is needed to assess the vehicle's traffic safety and interoperability. However, there are large differences, both technically and in terms accident consequences, between a non-revenue car and an MU train which is carrying many passengers. In general the more complex the vehicle is and the higher the operating speed is of the vehicle, the more detailed documentation is required.

**§ 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 certificate.

The documentation certifying the vehicle's safety-related interaction with the infrastructure shall always be independently assessed and certified by the assessor. What is accepted as certification and which compliance requirements apply for points a-i can be found in greater detail in the Transport Agency's guidelines 'Review of railway vehicle interaction with Swedish railway infrastructure,' which is available at [www.transportstyrelsen.se](http://www.transportstyrelsen.se).

Often, additional documentation to supplement the safety certificate is only requested for new vehicles or remodels that are on a scale comparable to new construction or when the approval object has a great affect on safety, such as vehicle braking systems or when completely untested technology is to be introduced. The Transport Agency can require the applicant to hire an independent assessor for such projects.

The additional documentation can be:

- 1) A description of the methodology of how to produce and test an individual production vehicle.
- 2) Operational safety and safety plan.
- 3) User manual.
- 4) Maintenance manual.
- 5) Maintenance plan.
- 6) Logbook of hazards.
- 7) Report from independent assessors.
- 8) Record from safety inspection.
- 9) Document verifying the test in an operational environment.
- 10) Safety certificate.
- 11) Crash card.

A **description** of how an individual production vehicle is produced and tested . The

methodology should be common to all vehicles in the series inasmuch as possible. Reference to the company's quality system is something which guarantees that the vehicles are identical or that differences are documented.

**A Risk Assessment Management System (RAMS-plan)** describes the applicant's management of reliability, availability, maintainability, and safety during all phases of development. For example, how will a need for change be handled in the operational phase (such as updating the safety document or the approval object itself). Which process is applicable for necessary future modifications. If an accident occurs, how information about it is disseminated to other owners. The RAMS plan need not be *one* document, rather it can be advantageously divided into a safety plan and an operational plan. Compare the requirements of SS-EN 50126:1999 or IEC 61508:1998.

**Manuals** for operation and maintenance shall be available in the language used by the users. Manuals shall be assessed by end users or by independent assessors. There should be an assurance that the manuals are usable and safe.

**Maintenance plan** shall show how to maintain safety throughout the life cycle of the system and, for example, indicate how often safety inspections and functional checks are to be performed during the operating period.

**Hazard Log.** The document includes all identified hazards from the risk analysis and is filled in with potential hazards that occur during the life cycle or that have been experienced in closely related projects. The document shall state what decisions have been made for actions to be taken, as well as risk mitigation measures that have been taken. See the template in SS-EN 50129:2003.

**A report from independent assessors** shall describe in detail what has been assessed (each and every element), what criteria the assessor has had for each controlled element, and the outcome for each element. There shall be conclusions.

**A record of the safety inspection** shall include reference to which instructions were used for the inspection (e.g. BVF 528.2622 and BVH 528.2622) and include both signed and printed name. It shall be clear if the vehicle has remarks or not.

**Documents verifying that the vehicle is tested in its operational environment** can entail test reports of new locomotives and MUs in the winter environment. The Transport Agency normally requires that new types of locomotives and MUs are tested for 4 weeks in winter conditions before they are approved for traffic.

In **the safety certificate**, the manufacturer (or the applicant) shall certify that the vehicle meets the safety requirements on a technical level and that it is developed in a structured and controlled manner. Read more in Chapter 5 of SS-EN 50129:2003, which gives very specific guidelines for the design of the safety certificate. The safety certificate shall contain six elements: description of the system, description of the company's quality management, description of the company's safety management, description of the system's technical safety, description of related safety certificates, and conclusion.

**Crash card** describes how actions will be conducted in an accident with the vehicle and is requested for vehicles intended for passenger transport. See Transport Agency guideline *'Development of crash cards passenger transport vehicles'* available at [www.transportstyrelsen.se](http://www.transportstyrelsen.se).

## 5.5 Rail vehicles approved in another state within the EEA or Switzerland

These paragraphs of TSFS 2010:116 apply to railway vehicles approved in another country and which are not approved in accordance with the TSI for rolling stock.

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

1. A copy of the other country's valid approval 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) 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 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 certificate.

The Transport Agency's testing of foreign vehicles is the same as for domestic vehicles. The difference is that foreign vehicles have foreign approval and the Transport Agency applies cross-acceptance of the other country's approval. This means that the Transport Agency accepts the safety certificate issued abroad, insofar as possible. Requested documentation from the applicant shall demonstrate how the foreign test was conducted.

The documentation certifying the vehicle's safety-related interaction with the infrastructure shall always be independently assessed and certified by the assessor. What is accepted as certification and which compliance requirements apply for points a-i can be found in greater detail in the Transport Agency's guidelines

'Review of railway vehicle interaction with Swedish railway infrastructure,' which is available at [www.transportstyrelsen.se](http://www.transportstyrelsen.se).

Further documentation to supplement the safety certificate basically means documentation which verifies that the vehicle meets the specific Swedish requirements; requirements that are not assessed in the country of origin. For example, analysis of THR (Tolerable Hazard Rate) for an MU braking system.

## 6 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 to which that the exemption request relates.

Exceptions are deviations from the TSI for specific subsystems.

An applicant is entitled to apply for exemption from complying with the requirements of a TSI in the following cases and in the following circumstances:

- a) In cases of proposed new sub-systems, for the modernising or remodel of an existing subsystem and which, when the TSIs are published, are well advanced or covered by an agreement already in place or prepared for implementation.
- b) For any project concerning the modernising or remodel of an existing subsystem where the loading gauge, track gauge, space between the tracks, or electrification voltage in these TSIs is not compatible with those of the existing subsystem.
- c) In cases of a proposed new subsystem or a proposed modernising or remodel of an existing subsystem in Sweden, and on the railway network in Sweden, which as a result of the sea or special geographical conditions is isolated from the rail network in the rest of the European Community.
- d) In cases of proposed modernisation, extension, or remodel of an existing subsystem if the application of these TSIs would compromise the economic viability of the project and/or the compatibility of the Swedish rail system.
- e) If conditions for the rapid restoration of the railway network following an accident or a natural disaster do not economically or technically allow for partial or total application of the relevant TSIs.

The applicant shall provide information to the Transport Agency under paragraph b) of Annex IX in Directive 2008/57. The Directive also available on the Transport Agency website, [www.transportstyrelsen.se](http://www.transportstyrelsen.se).

Projects receiving financial assistance from the EU to incorporate the requirements of the TSI should not apply for exemption from complying with the TSI (such exemptions are only granted under very special circumstances).

Applications for exemption of vehicles and infrastructure not covered by TEN are unilaterally decided on by the Transport Agency. However, if the request is for exemption of vehicles and infrastructure which are included in TEN, the Transport Agency may only decide on an exemption after notification to the EU Commission. The European Commission will respond to the submitted application within six months. An absence of a response is considered to mean that exemption application is granted.

Exemption applications for subsystems that are not covered by TEN should preferably be received by the Transport Agency in conjunction with the approval application.

TEN is divided into high-speed lines respective lines for conventional trains. In Sweden, about half of all infrastructure is comprised of TEN. Annex 1 shows which routes are classified as TEN routes in Sweden.

## 7 Exemptions from the regulations

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

TSFS 2010:116 is essentially an implementation regulation which specifies the documents that shall be submitted to the Transport Agency in order to apply certain provisions of the Railway Act.

In rare cases, the Transport Agency under § 18, can decide on exemptions from any of the provisions of TSFS 2010:116. For example, the Transport Agency can decide that an application for approval of a subsystem need not contain a certain document that is mandatory in accordance with a provision.

However, § 18 can not be used to provide an exemption from the Railway Act. Applications for exemption from complying with the requirements of a TSI are referred to Chapter 6.

## References

Requirements and guidelines for the approval of rail vehicles and railway infrastructure is based on following provisions, laws, directives, and standards:

- |      |   |  |
|------|---|--|
| [1]  | The Railway Act: 2004:519   | *  |
| [2]  | The Railway Ordinance: 2004:526   | *  |
| [3]  | Swedish Transport Agency provisions on approval of railway subsystems: TSFS 2010:116  | *  |
| [4]  | Specification of reliability, operational reliability, operational safety, availability, maintainability, and safety (RAMS): SS-EN 50126:1999 | <a href="http://www.sis.se">www.sis.se</a> |
| [5]  | Data transfer and railway control – electronic signalling systems relevant to safety: SS-EN 50129:2003  | <a href="http://www.sis.se">www.sis.se</a> |
| [6]  | IEC 61508:1998  | <a href="http://www.sis.se">www.sis.se</a> |
| [7]  | Council Directive on the interoperability of the Trans-European high-speed rail system: 96/48/EC  | *  |
| [8]  | European Parliament and Council Directive on the interoperability of the railway system within the Community: 2008/57/EC                      | *  |
| [9]  | Technical specifications for interoperability (TSIs), numerous documents  | *  |
| [10] | Commission Regulation (EC) No 352/2009 – Common safety method regarding risk valuation and risk assessment                                    | *  |

\* [www.transportstyrelsen.se](http://www.transportstyrelsen.se)

Annex 1: TEN – Extract from Directive 1692/96/EC



LEITSCHEMA DES TRANSEUROPAISCHEN VERKEHRSNETZES (Horizont 2020)  
 TRANS-EUROPEAN TRANSPORT NETWORK OUTLINE PLAN (2020 horizon)  
 SCHÉMA DU RÉSEAU TRANSEUROPEEN DE TRANSPORT (horizon 2020)

EISENBAHNEN  
 RAILWAYS  
 CHEMINS DE FER

2/2004

SVERIGE



- Hochgeschwindigkeitsstrecken
  - High-speed lines
  - Lignes à grande vitesse
  - Konventionelle Strecken
  - Conventional lines
  - Lignes conventionnelles
- - - Ausbaustrecken für Hochgeschwindigkeitsverkehr
  - Upgraded high-speed lines
  - Lignes aménagées à grande vitesse
- - - Geplante Hochgeschwindigkeitsstrecken, entsprechend Richtlinie 96/48/EG
  - Planned high-speed lines, following Directive 96/48/EC
  - Lignes planifiées à grande vitesse, selon la Directive 96/48/EC
  - - - Geplante Konventionelle Strecken
  - Planned conventional lines
  - Lignes conventionnelles planifiées



## Annex 2 Risk assessment

### Introduction

Risk assessment is the overall process comprising a risk analysis and a risk valuation, where risk analysis is the systematic use of all available information to identify hazards and assess risk to people, property, or the environment and where risk valuation is a procedure based on the risk analysis to determine if an acceptable risk level has been reached. The risk assessment shall be seen as a tool for the applicant to address safety risks during the operation and maintenance phases. It should therefore be done early, before service orders are written. An applicant is then well equipped to include in the service order those measures that must be taken to minimise the identified risks, whether they be through structural engineering or through manuals, procedures, or rules.

The risk assessment is essentially of a list of possible risks and an accompanying plan of what measures are intended to be taken to minimise the risks. The results of the risk assessment shall form the basis for which requirements are specified for the approval object, design decisions, and the need for manuals or new procedures.

Risk analysis methods and the depth of these varies depending on what is to be analysed. The greater the risk associated with a system or a remodel, the harder the requirements of the risk assessment. The introduction of new technical solutions therefore calls for a more thorough analysis than, for example, modifications to existing technology.

A risk assessment is preceded by a preliminary hazard analysis, with the aim of answering the question whether an activity (new construction or modification) has safety implications or not. If the preliminary hazard analysis shows that the activity has safety implications, then a more in-depth analysis shall be conducted.

A risk assessment shall be performed in the following cases (examples):

- During the reengineering of vehicles, traffic management systems, or infrastructure.
- In conjunction with safety-affecting modifications to existing vehicles, traffic management systems, and infrastructure.
- New or modified traffic safety instructions (TRI) and training plans or safety-affecting changes in existing organisation<sup>2</sup>.
- Other safety-affecting untested solutions.

It is the applicant who is responsible for having a risk analysis conducted and that steps are taken to minimise hazards. When the Transport Agency issues an approval, permit, or conducts supervision, the risk assessments are assessed. The Transport Agency's assessment will determine whether the presented risk assessment is sufficiently wide in scope and depth and, if necessary, can request clarifications and additions.

### Vehicles

The subsystems of a vehicle which the Transport Agency requires risk

---

<sup>2</sup> This is verified by the Transport Agency within the framework for permits, not approvals.

assessments for are: brakes, running gear, driver's cab design, safety system in the vehicle, coupling, and mechanical stability. The Transport Agency would also like to see analyses of securing loads on freight wagons. The door functions, fire hazards, emergency and alarm systems, and evacuation shall be analysed for passenger vehicles.

In principle, the analysis shall demonstrate that there are barriers against dangerous brake failure, derailments, uncoupling, loss of cargo, or seriously injured passengers. It shall also demonstrate that the risks do not increase due to modification of a vehicle.

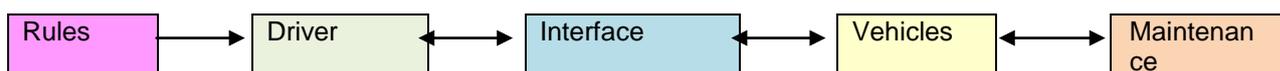
### Railway infrastructure

Risk assessments are required for all newly built infrastructure and safety affecting remodels of infrastructure.

Examples of railway infrastructure subsystems that the Transport Agency requires risk assessments for (e.g. changes in technology) are: point motors, blade switch detection contacts, track circuits, signal boxes, automatic blocks, level crossing systems, obstacle detectors, hot box detectors, and landslide warning systems.

### Interoperability

Administration of a system, which includes operations, maintenance, and modifications, entails risk for faulty manipulation and hazardous situations. Risk assessments must therefore evaluate the interaction between system and human (man-machine interface, MMI). The figure schematically shows some examples of possible interactions between systems (both operational and functional):



### Analytical methods

When the technical solution and construction of an approval object is known to the manufacturers, for example, there are a variety of established and structured methodologies such as FTA (Fault Tree Analysis) to evaluate the effect of multiple errors and FMECA (Failure Modes and Effects Critical Analysis). Read more about this in SS-EN 50129:2003 Table E6 (a railway standard for safety certificates and approval) or in Annex B of SS-EN 50128:2001 ('Software for railway control and protection systems,' a railway standard for development of safety critical software).

DMI (Driver Machine Interface) analysis is a method that is suitable for the analysis of new and modified driver's cabs and control blocks.

### Annex 3 Application for approval of vehicles

Title: .....

(Write the vehicle's designation and the applicant's reference number)

Your reference ..... Date .....

#### Applicant

• Name of operator:

Contact person:

(Name, title / function)

- Telephone: .....

- Email: .....

Postal address: .....

Postal code and city: .....

Visitor's address: Organisation number: .....

Telephone: ..... Fax: .....

Homepage: ..... Email: .....

Railway undertaking / client: .....

(Indicate whether these are different from the applicant and if these are determined)

#### The application regards:

- Locomotive       Multiple unit       Freight wagon       Passenger car  
 Non-revenue car       Other:
- 

#### Vehicle Information:

Vehicle designation / machine type:

Vehicle number / serial number: .....

- New build
- Remodel
- Existing foreign

Comments:.....

Version designation: .....

Type designation (proposed): .....

Manufacturer: .....

Year of manufacture: .....

Intended for type of traffic: .....

**The application regards driving:**

- |                                   |              |
|-----------------------------------|--------------|
|                                   | Speed (km/h) |
| <input type="checkbox"/> Active:  |              |
| <input type="checkbox"/> Passive: |              |

**Preliminary entry into service date:** .....

**Previous approvals:**

- Previous vehicle approvals:  
(by the Transport Agency / Rail Agency / Railway Inspectorate)
- Foreign vehicle approvals

(Date / ref. number)

Registered  
country:.....

**Proposal of independent assessor:**

.....

.....

.....

**Indicate the attachments sent with this application.**

.....  
.....  
.....

**Billing address (if different from address of applicant):**

.....  
.....  
.....

## Annex 4 Application for approval of subsystems that are regulated by the TSI, Fixed installations

### Form G3

Title: .....

(Write the approval object's designation and the applicant's reference number)

– see Guidelines for approval, Chapter 4.

Date: .....

### Applicant

• Name of operator: .....

Contact person: .....

(Name, title / function)

- Telephone: .....

- Email: .....

Postal address: .....

Postal code and city:.....

Visitor's address:.....

Organisation number: .....

Telephone:..... Fax: .....

Homepage: ..... Email: .....

### Billing Address (if different from address of applicant):

.....  
 .....  
 .....

### The application regards:

- |   |   |   |
|---|---|---|
| <input type="checkbox"/> Railway infrastructure | <input type="checkbox"/> Energy                                 | <input type="checkbox"/> CCS (control-command and signalling) |
| <input type="checkbox"/> Tunnel safety          | <input type="checkbox"/> Needs of persons with reduced mobility |   |

Preliminary entry into service date: .....

### Previous approvals:

Previous approval:  
(By the Transport Agency / Rail Agency / Railway  
Inspectorate)

(Date / ref. number)

Exemption from compliance with requirements  
of the TSI:  
(By the Transport Agency / Rail Agency)  
(Date / ref. number)

### Overview description

#### Railway infrastructure:

Town or section<sup>\*)</sup> : .....

Any designation: .....

Brief description<sup>\*)</sup>.....

Intended use (freight /  
passenger / mixed traffic):.....

Average number of cars per month: .....

<sup>\*)</sup> Required information

#### Other:

Any approval objects that are not covered by the requirements of the TSI: .....

(It shall be stated if TSI applies for part of the subsystem and national rules apply to other parts. In addition, the relevant form for the subsystems that are not regulated by the TSI are to be completed, G8.)

### **Plan for the submission of supporting documents (annexes to form G3)**

Indicate the annexes sent in this application and indicate an estimated timeframe when the documents will be submitted.

<b>Id</b>	Mark with a cross	<b>Attachment No.</b>	<b>Prelim. timeframe</b>
	<b>With the application (in conjunction with initiation of development, construction document, or specification), or at least 4 months prior to entry into service:</b>		
A	Description, e.g. - What subsystem it is, - how the subsystem shall be used, - which TSIs apply, - when the subsystem shall be put into service, - proposals for any type or version designations.		
B	Information on who will be engaged as a notified body.		
C	Any Transport Agency decision on TSI exemption		
	<b>At least 2 months before entry into service:</b>		
F	EC declaration of verification for the subsystem.		
G	NB's certificates of conformity or suitability of the subsystem.		
H	EC declarations for the interoperability constituents included in the system.		
	<b>After tests in the operating environment:</b>		
I	Documents certifying that the subsystem is tested in its operating environment.		

# Annex 5 Application for approval of railway infrastructure that is not regulated by the TSI,

## Form G8

Title: .....

(Write the approval object's designation and the applicant's reference number)

- - see Guidelines for approval, Chapter 5.3.

Date: .....

### Applicant

• Name of operator: .....

Contact person: .....

(Name, title / function)

- Telephone: .....

- Email: .....

Postal address: .....

Postal code and city: .....

Visitor's address: .....

Organisation number: .....

Telephone: ..... Fax: .....

Homepage: ..... Email: .....

### Billing Address (if different from address of applicant):

.....  
.....  
.....  
.....

### The application regards:

Tracks

Sidings

CCS (control-command and signalling)

If the application concerns the introduction of new technical solutions or modifications to signal boxes and/or automatic block systems, then an independent assessor is engaged by the applicant. This shall be approved by the Transport Agency for each approval item!

- Any independent assessor for this task is accepted by TA (which the independent assessor shall indicate)

Preliminary entry into service date: .....

### Overview description:

Town or section: .....

Any designation: .....

Contractor / build manager : .....

Inspection manager: .....  
(regards tracks and signals, not electricity)

Brief description: .....

(can also be attached

Safety-affecting functions shall be particularly described, e.g. safety-affecting

separately)

electronics, computers / software, mechanical constituents, electrical subsystems and communication systems.

Intended use (freight / passenger / mixed traffic): .....

Average number of cars per month: .....

Dangerous

goods:

Dangerous goods present

Dangerous goods not present

The following information only needs to be provided when the approval object is a signal box:

Signal box type:

Any version designation:.....

**Technical information:**Track length<sup>33</sup> (m): .....

- of which street tracks (tramway): .....

- of which special embankment: .....  
(tramway)

Number of switches: .....

Rail weight (in kg/m): .....

Aggregates (e.g. gravel, macadam): .....

Fortification (e.g. Pandrols,  
heyback):

Type of sleepers: .....

Maximum permissible axle load: .....

Maximum permissible speed: .....

Minimum curve radius: .....

Maximum slope: .....

 Slope towards other infrastructure (e.g. siding sloping towards main track)

Loading gauge:

Any level crossings, type, and location: .....

Tunnels, number, and location: .....

Bridges, number, and location:

Platforms, number, and location:

Catenary (yes/no): .....

---

<sup>33</sup> State any future or removed tracks and switches.

### **Plan for the submission of supporting documents (annexes to form G8)**

Indicate the attachments sent with this application and indicate an estimated timeframe when the documents will be submitted.

<b>Id</b>	Mark with a cross	<b>Attachment No.</b>	<b>Prelim. timeframe</b>
	<b>With the application (in conjunction with construction document or specification)</b>		
A	Description of infrastructure installations, for example: - geographic location with precise control points. - intended use. - entry into service date. - any version designation.		
B	Risk analysis		
	<b>Before design and construction begins:</b>		
C	Specification of requirements		
D	Information on who performs the design, drawing examination, and inspection for entry into service.		
E	Information on which norms are the basis for the technical design.		
F	Preliminary timetable indicating the dates of design, construction, and validation.		
	<b>Before validation is started:</b>		
G	Validation plan		
	<b>At least two weeks before entry into service:</b>		
H	<b>Validation report</b> (e.g. report of construction inspection carried out before entry into service or report from ATC simulation or review protocol).		
I	<b>Safety Case</b> (relates only to signal-related equipment such as computerised signal boxes or a new type of point motor. Not relevant for track).		
	<b>After entry into service:</b>		
J	Record from inspection for entry into service		
	<b>After test in the operating environment:</b>		
K	Documents certifying that the subsystem is tested in its operating environment. <sup>*)</sup>		

### More application forms for new technical solutions or signal boxes and/or automatic block

These application forms are sent upon request of the Transport Agency. It is needed for approval objects with large safety implications such as new or modified signal boxes or new technical solutions for national safety constituents.

Id	Mark with a cross	Annex
	<b>If the Transport Agency so requests</b>	
L	A description of the methodology of how to produce and test an individual installation on the basis of the basic version. <sup>*)</sup>	
M	Information on who is proposed to be engaged as an independent assessor.	
N	Operational safety and safety plan. <sup>*)</sup>	
O	Logbook of hazards. <sup>*)</sup>	
P	A document that describes the history of the version designations. <sup>*)</sup>	
Q	User manual. <sup>*)</sup>	
R	Maintenance and installation manuals. <sup>*)</sup>	
S	Report(s) from the independent assessor with statement.	

<sup>\*)</sup> Only relevant to the introduction of new technical solutions.

**SWEDISH  
TRANSPORT  
AGENCY**  
Railway Department

# Guidelines

