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Federal Department of the Environment, Transport, Energy and Communications DETEC

Federal Office of Transport FOT
Infrastructure and Safety Divisions

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Directive

Approval of rolling stock

(Type approval/operating licence)

on the basis of the Articles 6*a*, 6*b,* 7, 8 and 15*a-z* of the Ordinance on the Construction and Operation of Railways (Railways Ordinance, RailO)

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V 2.0	1 July 2013	caa/fz jow/fz eih/zr	Amendments relating to RailO revision of 1 July 2013	Draft
V 2.2	1 January 2014	caa/fz jow/fz eih/zr	Amendments from consultation procedure	Replaced
V 2.3	1 January 2016	caa/fz jow/fz eih/zr	Corrections and additions, adaptations relating to RailO revision, integration of the guidelines “Sicherheitsnachweisführung bei Änderungen an Eisenbahnfahrzeugen” (Preparing safety cases for modifications to rolling stock)	Replaced
V 2.3a	1 July 2018	jow/fz eih/zr	Administrative corrections, clarifications to approval concept, safety report, operational testing an examination, German routes on Swiss territory	Replaced
V 2.3b	1 Dec. 2019	jow/fz eih/zr	Adaptations of chapter 1 to the 4th railway package	Replaced
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V2.4	1 January 2022	jow/fz eih/zr	Adaptations to the 4th railway package and administrative corrections of ch. 1, 5.5.3, 5.7, 5.8, 6.1, 6.2, 6.4, 6.5 and annexes 2-6	Replaced
V2.5	1 July 2024	jow/fz eih/zr	Adaptation of the references to the revision RailO/IP-RailO of 1 July 2024, clarifications in chapters 4, 5.2, 5.5.2, 5.7, 5.8.2, 5.8.4.2, 5.8.5, 6.4.2 and annexes 5, 6 as well as editorial adjustments.	In force

Contents

1 Purpose and scope of the Directive

The aim of this Directive is to explain the approval procedure for railway vehicles and their components to applicants and other interested parties.

It describes the practical application of existing acts, ordinances and implementing regulations concerning the approval of railway vehicles and components.

For railway vehicles running internationally, which therefore must be approved both in Switzerland and in at least one EU member state, Directive (EU) 2016/797 and Commission Implementing Regulation (EU) 2018/545 apply under the Railways Ordinance. For these vehicles, Switzerland must be treated in principle as an EU member state for the purposes of approval processes and use of the required databases, systems and tools, such as the one-stop shop[1]. This directive is therefore not applicable to such cases. However, it is applicable for the national approval of interoperable and non-interoperable vehicles, special vehicles as well as approvals of vehicles on cross-border routes with neighbouring countries.

This Directive does not have the status of an act or ordinance, but it is more binding than a mere recommendation. Deviations are permitted, provided that the objectives of the acts, the ordinances and this Directive can be achieved in another way. Applicants who follow this Directive closely can be certain that the authorities will accept their application for consideration. Failure to do so could result in the rejection of their application.

There is a separate directive for type approvals of elements of railway systems or vehicles; this should be applied to the approval of construction components, systems and system components. This Directive “Typenzulassung für Elemente von Eisenbahnanlagen” (Type approval for elements of railway installations) is available in German on the FOT website at www.bav.admin.ch > Rechtliches > Richtlinien.

2 Legal foundations

The legal foundations for the approval of rolling stock in Switzerland are the Railways Act (RailA[2]), the Railways Ordinance (RailO[3]), in particular Art. 6*a*, 7, 8 and 15*a-z*, and the implementing provisions to the Railways Ordinance (IP-RailO[4]). The preparation of a safety case for the purpose of obtaining an operating licence is based on Art. 5*l*, 5*m* and 15*i* RailO.

The approval of rolling stock for use in international transport is also based on the Convention concerning International Carriage by Rail (COTIF[5]) and its appendices APTU[6] and ATMF[7].

Rolling stock used on the Swiss railway network must comply with the Swiss Train Operating Regulations[8] in accordance with Art.11*a* RailO. The railway undertakings must issue the necessary operating regulations for operation and maintenance in accordance with Art. 12 RailO. The operating regulations of the infrastructure managers are binding with regard to the route to be used in accordance with Art. 12, para. 4 RailO. The use of rolling stock on

[1] For legal reasons, authorisations issued by the European Railway Agency (ERA) do not currently cover Switzerland. The FOT therefore issues its own authorisations based on the ERA inspections.

[2] SR **742.101**

[3] SR **742.141.1**

[4] SR **742.141.11**, available in German at: www.bav.admin.ch > Rechtliches > Ausführungsbestimmungen zur EBV (AB-EBV)

[5] SR **0.742.403.12,** www.otif.org

[6] Uniform Rules concerning the Validation of Technical Standards and the Adoption of Uniform Technical Prescriptions applicable to Railway Material intended to be used in International Traffic

[7] Uniform Rules concerning the Technical Admission of Railway Material used in International Traffic

[8] SR **742.173.001**, available in German at: www.bav.admin.ch > Rechtliches > Fahrdienstvorschriften (FDV)

German and Austrian routes on Swiss territory is subject to the relevant German or Austrian operating regulations.

The current status of the regulations at the time when the specification is approved, if the approval has been applied for, or at the time when the application for approval is submitted is the definitive status. If new, safety-related findings come to light between the approval of the specification or the submission of the application for approval and the commissioning of the vehicle, the FOT can, in justified cases, apply more recent regulations to the application procedures that are already in progress.

3 Terms and definitions

This Directive uses the following terms:

a) Applicant: The manufacturer, the owner or the keeper of rolling stock or its authorised representative, the railway undertaking, and the infrastructure manager can submit an application for approval to the FOT.

b) Approval: Generic term for the operating licence and/or type approval of a railway vehicle or component (cf. Annex 1).

c) Approval procedure: Process from submitting the application to obtaining approval (cf. 5).

d) Approval concept: The approval concept defines the scope and procedure for preparing a safety case to meet the requirements for a vehicle approval. It includes information about the evidence to submit, the planned project schedule, the required project stages, the organisation and the responsibilities of the experts tasked with preparing the safety case (cf. 5.8).

e) Safety case: Documentary evidence supplied by the applicant on the basis of the regulations and the current state of technology (see Art. 2 RailO) showing that the vehicle or component concerned meets all the specified safety requirements in accordance with the applicable safety regulations and the requirements of the safety case preparation process.

f) Approval of specification and drawing: Confirmation by the FOT (with conditions or reservations, as applicable) that the specification and drawing of the vehicle or component concerned meet the requirements of the Railways Ordinance (RailO) and its implementing provisions (IP-RailO).

g) Type approval: Decision by the FOT that the vehicle type or component concerned have been examined from both a technical and an operational point of view and are suitable for use for a specific purpose under specific conditions and, if applicable – that their interoperability is assured. In the case of vehicles, approval is normally granted when an operating licence for the first vehicle (prototype) in a series is issued.

h) Operating licence: Decision by the FOT that the vehicle or component concerned have been examined from both a technical and an operational point of view and are suitable for use for a specific purpose under specific conditions and, if applicable, that their interoperability is assured. If a type approval already exists, the operating licence also specifies the conformity with the type concerned.

i) Independent expert: Specialist from outside the regulatory authority who has the required expertise to inspect functions, in accordance with the FOT Directive “Unabhängige Prüfstellen Eisenbahnen” (Independent Railway Inspection Bodies)[9].

[9] Available in German at: www.bav.admin.ch > Rechtliches > Richtlinien

j) *Safety report:* Verification based on a safety analysis that shows the risks that could arise from the construction and operation of the vehicle and also defines the measures to counteract these risks (Art. 5*m* RailO).

k) *Lack of retroactive effects*: Evidence that the modifications made have an effect only on the affected systems, components or functions, including interfaces, in accordance with the description of the modification. This evidence can be provided in the form of an analysis or of tests (for example, regression tests).

l) *Substantial modification:* A safety-related modification to a vehicle which requires a new operating licence in accordance with Art. 8 para. 1bis RailO.

m) *Modification with high safety relevance*: A modification which is substantial and which, because of its high safety relevance, must be assessed by an independent expert (Art. 5*l* para. 3 RailO).

n) *Significant modification:* A modification of high safety relevance and high complexity or innovation. Typically, a modification of this kind is outside the current state of technology and outside the standards. Therefore, it requires a risk management process and an assessment by a risk assessment body (Art. 5*m* RailO).

o) *Running behaviour:* Characteristic of a vehicle or running gear relating to the interaction between the vehicle and the railway infrastructure. The following items are included in the term “running behaviour”:

- Driving safety
- Stresses on the railway infrastructure
- Vibration characteristics

4 Registration of rolling stock

Rolling stock used on the Swiss normal gauge network must be registered in the national register of rolling stock and must be labelled with a 12-digit TSI number. This does not apply to road-rail vehicles, demountable vehicles or similar vehicles.

First approvals in Switzerland will be included in the national register of rolling stock. If approval is sought for several countries, the applicant can choose the country in which it will apply for the first approval and registration.

In order to make an entry in the national register of rolling stock, the FOT requires an application[10] from the vehicle keeper stating the type of vehicle, the Vehicle Keeper Marking (VKM) if one exists, the most important technical properties of the vehicle and the number of vehicles to be approved. If a VKM does not yet exist, the FOT will issue one and refer it to OTIF[11] for registration throughout Europe, provided that the company has its headquarters in Switzerland. The VKM can subsequently be used for registering vehicles in other countries as well.

VKMs registered by foreign companies in their own country can also be used to enter vehicles in the Swiss national register of rolling stock.

Further information can be found at www.rollingstockregister.ch.

[10] E-Mail: fahrzeugregister@bav.admin.ch

[11] Intergovernmental Organisation for International Carriage by Rail

5 Approval procedure

5.1 Introduction

Every vehicle operating in Switzerland requires a valid approval (cf. 3) in the form of an operating licence (Art. 8 para. 1bis RailO).

Recognised applicants for an operating licence are:

- The manufacturer of a vehicle or its authorised representative,
- The owner or keeper of a vehicle or its authorised representative,
- Railway undertakings or infrastructure managers.

The operating licence is generally issued to the vehicle keeper. Depending on the complexity, scope of use and type of the planned vehicle, further approvals, for example temporary operating licences for operational testing or type approvals for components used, can be applied for until an operating licence is obtained. The process and the necessary steps are agreed by the applicant and the FOT and specified in the form of an approval concept.

Under Art. 7 RailO, the FOT can, on request, issue an approval for vehicles in the form of a type approval, provided that this is a suitable way of simplifying the procedure for obtaining an operating licence. Type approval generally applies to larger series from a single manufacturer, who is also the applicant.

5.2 Stages of the approval procedure

The approval procedure consists of the following stages:

- Application for approval (type approval/operating licence) (cf. 5.5);
- Agreement on the approval concept (cf. 5.6);
- Preparation of the safety case in accordance with the approval concept (cf. 5.8);
- Submission of the safety case in accordance with the approval concept and inspections by the FOT (cf. 5.9);
- Issuing of the approval.

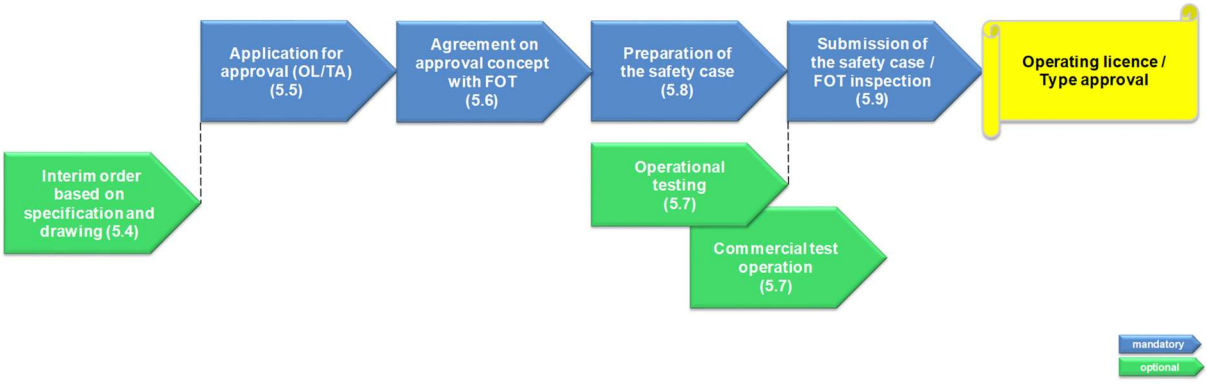

Figure 1: Stages of the approval procedure

Before applying for approval, the applicant has the option of having the specification and drawing approved in the form of an interim order (cf. 5.4).

During the preparation of the safety case, test drives can be necessary as part of operational testing and/or commercial test operations. The prerequisite for commercial test operations is a largely completed safety case.

The applicant must submit to the FOT an appropriate application for an operating licence for operational testing and/or commercial test operations and provide the necessary evidence (cf. 5.7).

5.3 Scope

5.3.1 Normal gauge

Normal gauge routes in Switzerland are generally regarded as part of the interoperable network. The exceptions are a few defined sections of the line that are exclusively regional (Annex 5 RailO).

For the approval of interoperable normal gauge rolling stock, the certificates of conformity for the TSI[12] that apply in Switzerland must be submitted (Art. 15*k* RailO). The national part of the approval comprises the Swiss Notified National Technical Rules (NNTRs, cf. 5.8.2). In principle, approvals apply to Switzerland's interoperable normal gauge network.

5.3.2 Metre gauge and special gauges

Metre gauge and special gauge routes in Switzerland generally have a regional focus. The rolling stock is built, approved and operated in accordance with the existing national regulations.

The Swiss state requirements for metre gauge and special gauge rolling stock are laid down in the RailO and the IP-RailO, and are updated regularly. Wherever sensible and possible, technical rules from the interoperability sector are applied. Therefore, it is possible to carry out a voluntary partial inspection under TSI rules (for example, a safety case for vehicle software) in order to have a special gauge vehicle approved.

5.4 Specification and drawing

Before construction begins and during construction, the FOT can, on request, examine the specification and drawing of the planned vehicle or component and issue an interim order (Art. 6*a* RailO).

The specification and the drawing will be approved if they are eligible. This gives the applicant planning security at an early stage.

5.5 Application for approval (type approval/operating licence)

5.5.1 Duties of the applicant

The applicant has the following duties:

- To construct, convert, operate, maintain and dispose of the vehicles or their components in a way that complies with the statutory requirements;
- To define the operating conditions;
- To provide the safety case (cf. 5.8).

Only the applicant (cf. 3) can act as the other party in the approval procedure.

5.5.2 Information

The application signed by the applicant must contain at least the following **general details**:

- The title "Application for operating licence, type approval …";

[12] Technical specifications for interoperability, see Annex 6 IP-RailO.

- The name and address of the applicant and the vehicle keeper;
- A technical description of the purpose, use and model of the vehicle or component;
- The 12-digit vehicle number (incl. NID_ENGINE for vehicles with ETCS equipment) of each vehicle to be authorised or the technical identification of components;
- The country code and the vehicle keeper marking (VKM) of the vehicles;
- Details concerning the origin of the vehicle or component;
- The type of use and conditions of use under which the approval is to apply;
- Details concerning any existing approvals (including by foreign authorities);
- The safety case (cf. 5.8), if already available;
- A draft of the schedule for the approval procedure.

These general details must be supplemented with the **specific details** stipulated in Annexes 2, 3 or 4 or Annex 5 for operational testing.

5.5.3 Addresses

Applications for the approval of rolling stock and their components as well as relevant documents must be submitted via the website www.bav.admin.ch as electronic applications[13].

In exceptional cases and after prior consultation with the FOT, Approvals and Rules Section, signed applications and documents may be submitted by e-mail to approval@bav.admin.ch. Postal mailing is not necessary. For any information please use the same e-mail address.

Postal address (exceptional case):

Federal Office of Transport
Approvals and Rules Section
3003 Bern
SWITZERLAND

5.5.4 Examining the application

The FOT ascertains whether the application is complete and contains all the necessary information for carrying out a substantive inspection. After receiving the application, it initiates the approval procedure, requests more information from the applicant or rejects the application.

5.6 Approval concept

In the approval concept (cf. 3), the applicant specifies in which way and using which evidence it intends to prepare the necessary safety case (cf. 5.8), which stages it has planned in this process and when it will submit the various evidence documents. The applicant also explains whether the project complies with current regulations or whether it deviates from them.

The applicant submits the approval concept together with the safety report as an independent document in accordance with 5.8.5. Once the approval procedure has been initiated, the FOT and the applicant together agree on the applicant's approval concept.

Therefore, the approval concept is a framework and process document which can be modified and added to during the approval procedure and which acts as an interface document between the FOT and the applicant.

The approval concept must contain at least the following structural elements:

1. Introduction
2. Abbreviations and definitions

[13] Available only in German, French or Italian

3. Evidence that the design conforms to regulations
4. Special features
5. Stages in the approval procedure
6. Organisation, responsibilities and independent inspection bodies[14]
7. Declaration of completeness and compliance with the requirements

Annex A: Schedule
Annex B: List of documents that have been or are to be submitted
Annex C: Technical data for the object being approved
Annex D: Safety report
Annex E: Safety assessment report (on a case-by-case basis, cf. 5.8.6)

The content of the approval concept is not intended to consist of individual items of evidence. Instead it shows the structure and the concept for the safety case. With the agreement on the approval concept, the fundamental ability of an admission is determined. Therefore, a certain planning certainty can be achieved for the applicant as well as the authority.

For the approval concept as well as the annexes B “List of documents that have been or are to be submitted”, C “Technical data for the object being approved” and D “Safety report” the FOT provides corresponding templates[15].

5.7 Operational testing / transfers

Test drives are used to carry out tests and take the measurements needed for the evidence documents as part of the approval of the vehicle.

The applicant must apply for an interim operating licence[16] in good time. The test drives must be agreed in advance with the infrastructure manager concerned (cf. 5.5.2 and Annex 5). The infrastructure manager shall perform the duties specified in Art. 6*b* para. 2 RailO.

Commercial test operation is also possible, if required, and this also requires an interim operating licence.

For transfers, a temporary operating licence must be applied for, unless they are carried out under the conditions of an existing operating licence for operational testing.

5.8 Safety case

5.8.1 General information

The safety case for rolling stock consists of evidence that its design conforms to the regulations, including the appropriate certificates of conformity, the safety report and, if necessary, the safety assessment report and inspection reports from independent experts. The safety case must be submitted to the FOT as part of the operating licence or type approval procedures.

[14] In accordance with the FOT Directive “Unabhängige Prüfstellen Eisenbahnen” (Independent Railway Inspection Bodies), available on www.bav.admin.ch > Rechtliches > Richtlinien (in German);
Interested parties and their roles: cf. template “Approval concept” (in German)

[15] Available on www.bav.admin.ch > Rechtliches > Richtlinien > Bahn > Zulassung Eisenbahnfahrzeuge (in German)

[16] Interim operating licence in accordance with Art. 6*b* RailO

Safety case		
Evidence that the design conforms to regulations[17]	Safety report	Safety assessment report[18]

Figure 2: Structure of the safety case

The structure of the safety case and, in particular, the evidence that the design conforms to the regulations depend on the design and use of a rail vehicle. A distinction is made between interoperable vehicles, non-interoperable vehicles and service vehicles. The evidence which must be submitted for the individual technical fields is defined in Annexes 2 to 4 of this Directive, specified in the approval concept for the specific approval project and agreed jointly with the FOT.

5.8.2 Safety case for interoperable vehicles under the TSI

The applicant (App) is responsible for providing the safety case.

A safety case must be provided on the basis of the Technical Specifications for Interoperability (TSI) and the Notified National Technical Rules (NNTR) for vehicles operating on interoperable normal gauge routes in Switzerland and, where appropriate, in other European countries.

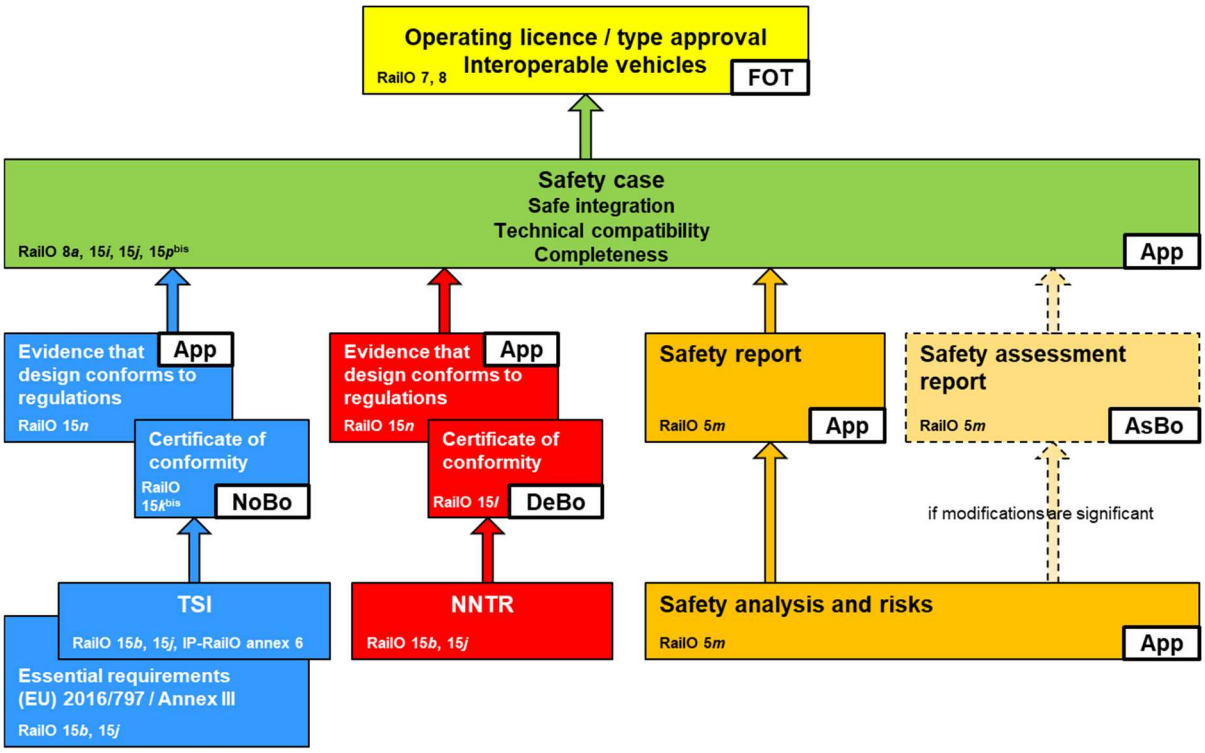

Figure 3: Structure of safety case and responsibilities for interoperable vehicles

Conformity with the TSI is certified by accredited Notified Bodies (NoBo). It must be ensured that Switzerland's Specific cases are also taken into account. These are not listed in the TSI

[17] Cf. Annexes 2 to 4

[18] In case of projects with high complexity or innovation with high safety relevance (significant modifications) in accordance with Art. 5*m* RailO

themselves but in Annex 1 to the Agreement between the Swiss Confederation and the European Community on the Transport of Goods and Passengers by Rail and Road[19].

Conformity with the Notified National Technical Rules (NNTR, cf. the FOT website www.bav.admin.ch > Rechtliches > Notifizierte Nationale Technische Vorschriften [NNTV]; in German) is certified by Designated Bodies (DeBo). The applicant must provide evidence that the design conforms to the regulations, on the basis of the certificates of conformity from the NoBo and DeBo. For structural subsystems and interoperability components in accordance with Annexes II and IV of Directive (EU) 2016/797, the EC declaration of verification provides this evidence. Annex 2 of this current Directive describes the structure and evidence documents of the safety case for interoperable vehicles.

In any case, the compatibility of the vehicle and the infrastructure as well as their fault-free interaction must be demonstrated. The network access conditions of the infrastructure managers concerned must be complied with. The FOT recommends that the technical requirements for the vehicles resulting from the network access conditions are agreed in good time with the infrastructure managers concerned.

The FOT checks whether the complete documentation required for the safety case has been submitted. The FOT makes spot checks of the safety case to identify risks relating to technical compatibility with the infrastructure on which the vehicle will operate and safe integration into the complete system. To do this, the FOT can request the involvement of independent experts and corresponding inspection reports (cf. 5.9).

An interoperable vehicle type can be included in the European Register of Authorised Types of Vehicles (ERATV) during or after the approval procedure. For this purpose, a corresponding (informal) application must be submitted to the FOT via the e-mail address ERATV@bav.admin.ch. The FOT will then enter the vehicle type in the ERATV database and give the applicant access to it. The applicant must then enter the vehicle data itself.

5.8.3 Safety case for non-interoperable vehicles

The applicant is responsible for providing the safety case.

A safety case must be provided in accordance with the Swiss National Technical Rules (NTR) for vehicles operating on non-interoperable routes in Switzerland.

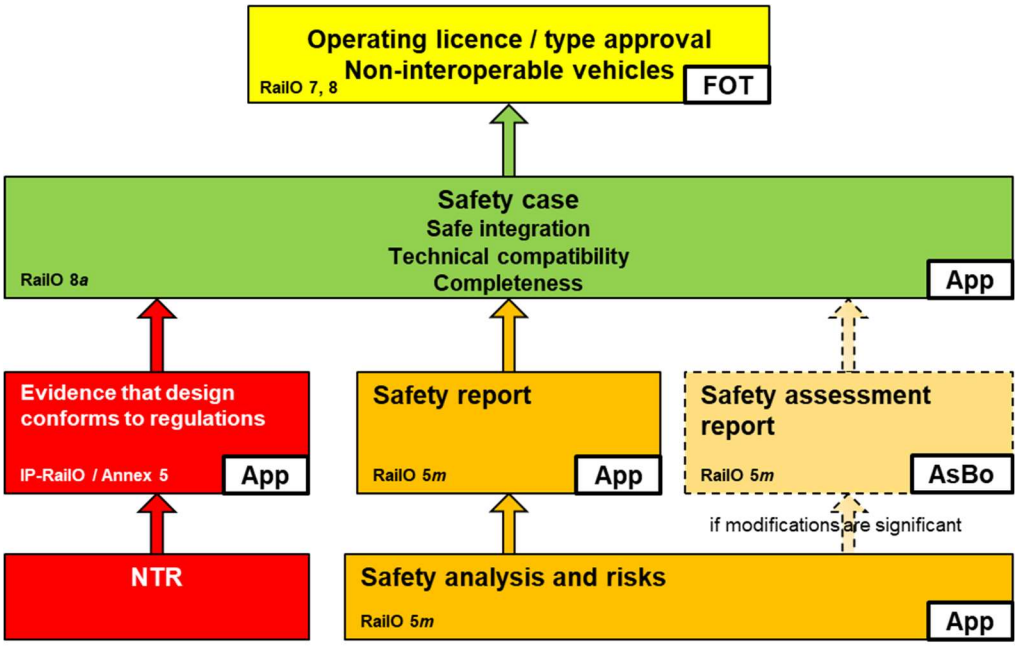

Figure 4: Structure of safety case and responsibilities for non-interoperable vehicles

[19] SR **0.740.72**

The applicant must provide evidence that the safety requirements laid down in the NTR and, in particular, all the provisions of the RailO and the IP-RailO have been fulfilled. The documents to be submitted are listed in Annex 3 of this Directive. If there are deviations from the regulations and figures in the RailO and the IP-RailO, or if there are no regulations or figures in the RailO and the IP-RailO, the applicant must apply for a deviation from the regulations under Art. 5 RailO and provide proof of equivalent safety (for example, by means of the corresponding application of EN 50126) or of a proportionate reduction of risk.

In any case, the compatibility of the vehicle and the infrastructure as well as their fault-free interaction must be demonstrated. The network access conditions of the infrastructure managers concerned must be complied with. The FOT recommends that the technical requirements for the vehicles resulting from the network access conditions are agreed in good time with the infrastructure managers concerned.

The FOT checks whether the documentation required for the safety case has been submitted in full. The FOT makes spot checks of the safety case to identify risks relating to technical compatibility with the infrastructure on which the vehicle will operate and safe integration into the complete system.

In the case of projects with high safety relevance, the FOT generally requires inspections by independent experts[20]. Annex 3 of this Directive specifies which technical areas must be inspected by independent experts. As part of the process of agreeing on the approval concept, the FOT will specify in which technical areas an inspection by independent experts is needed for a specific approval project.

5.8.4 Safety case for special vehicles

5.8.4.1 Service vehicles

Service vehicles are:

- Railbound vehicles with adhesion operation, self-propelled or hauled, for the construction, maintenance and inspection of the track, structures, substructure and contact line systems (overhead line or third rail)[21], for operation on tracks with train detection systems;
- Road-rail vehicles/machines[22], self-propelled, for operation on or off track, including those for operation with signalling and control systems;
- Demountable machines[23], self-propelled, not intended for operation with signalling and control systems;
- Trailers[24], hauled, no transport on their rail wheels between work areas, not for operation with signalling and control systems.

Service vehicles require an operating licence from the FOT for use on the Swiss rail network, including for hauling.

Simplifications under Art. 57.2 point 1 RailO are possible for service vehicles. Service vehicles can be approved as interoperable vehicles under the TSI (cf. 5.8.2) or as non-interoperable vehicles (cf. 5.8.3). If service vehicles are to be approved as non-interoperable vehicles, the safety case must include, in addition to general details (cf. 5.5.2), the specific documents listed in Annex 4.

[20] RailO Art. 5/ para. 3

[21] EN 14033-1, -2, -3

[22] EN 15746-1, -2

[23] EN 15955-1, -2

[24] EN 15954-1, -2

In any case, the compatibility of the vehicle and the infrastructure as well as their fault-free interaction must be demonstrated. The network access conditions of the infrastructure managers concerned must be complied with. The FOT recommends that the technical requirements for the vehicles resulting from the network access conditions are agreed in good time with the infrastructure managers concerned.

For operational testing, the documents listed in Annex 5 must be submitted.

Operational testing an examination with road-rail vehicles/machines, demountable machines and trailers for the purpose of the safety case shall in principle not be carried out on the licensed rail infrastructure. However, if operational testing an examination on the licensed rail infrastructure is necessary, a request for authorisation must be addressed to the FOT.

In the case of projects with high safety relevance, the FOT generally requires inspections by independent experts. Annex 4 of this Directive specifies which technical areas must be inspected by independent experts. As part of the process of agreeing on the approval concept, the FOT will specify in which technical areas an inspection by independent experts is needed for a specific approval project.

Occupational health and safety on service vehicles (insofar as it goes beyond safe workplace design) is not covered by this Directive. Suva[25] is the competent body in questions of occupational health and safety.

5.8.4.2 Heritage rolling stock

The term “heritage rolling stock” means older vehicles that are primarily used to keep obsolete technologies operational for the general public. They include vehicles that have been withdrawn from regular service. They may be original or rebuilt vehicles that were typically placed in service in Switzerland in this condition 30 or more years ago.

The options for authorising historic vehicles must be agreed with the FOT on a case-by-case basis.

5.8.5 Safety report

For all projects that require an operating licence, the applicant must submit a safety report as part of the preparation of the approval concept. The safety report[26] must contain the following elements:

- Evaluation of whether the design conforms to the regulations on the basis of the evidence to be submitted as part of the approval concept.
- If there are deviations from the regulations, a safety analysis must be provided which highlights the resulting risks and the measures taken to counteract these risks[27].
- Supplementary safety analysis concerning other risks involved in operational use, such as risks in connection with ICT security[28], including the measures taken to counteract these risks.
- In case of modifications: classification of the modifications (cf. 5.13 and/or Annex 6).

[25] Swiss National Accident Insurance Fund

[26] Template “Safety report", available on www.bav.admin.ch > Rechtliches > Richtlinien > Bahn > Zulassung Eisenbahnfahrzeuge (in German)

[27] For example on the basis of EN 50126 and of the Implementing Regulation (EU) No 402/2013 of 30 April 2013 on the common safety method for risk evaluation and assessment (CSM)

IP-RailO 2.1[bis]. For further information, see the FOT’s Directive “Cybersecurity Railway (CySec-Rail)”, available at www.bav.admin.ch > Rechtliches > Richtlinien (in German).

5.8.6 Safety assessment report

Under Art. 5*m* RailO, railway undertakings must carry out the risk management procedure in accordance with the CSM regulation[29] if there are significant modifications. If the risk management procedure has been carried out during a project, this should be reviewed by a Risk Assessment Body (AsBo). This body will assess the risk management procedure to check that the safety requirements have been met and will issue the safety assessment report.

Significant modifications[30] are understood to be projects with

a) high safety relevance associated with innovation or

b) high safety relevance associated with complexity.

High safety relevance is defined in Art. 5l.3 point 1 IP-RailO. An innovation or a complex project is defined as a project that contains innovative elements which are unique or unfamiliar and, therefore, lie outside the standards or the current state of technology.

5.9 Inspections carried out by the FOT

The FOT must verify at least the following aspects on the basis of the RailO and IP-RailO:

- The completeness of the safety case and spot checks of technical compatibility with the infrastructure on which the vehicle will operate and safe integration into the complete system;
- Compliance with the interoperability requirements for vehicles and components that can be used for network access or in cooperation on the infrastructure of another railway undertaking;
- Spot checks on the structure and function of vehicles and their components and on maintenance planning.

The FOT checks whether the complete documentation required for the safety case has been submitted. The FOT makes spot checks of the safety case to test for risks relating to technical compatibility with the infrastructure on which the vehicle will operate and safe integration into the complete system. To do this, the FOT can request the involvement of independent experts and corresponding inspection reports. The requirements for independent experts are specified in the Directive “Unabhängige Prüfstellen Eisenbahnen” (Independent Railway Inspection Bodies)[31].

The FOT and/or an independent expert carries out a technical operational safety assessment to check that the essential regulations have been complied with, by means of spot checks of the vehicle. Using the documents and evidence submitted, the FOT decides how this inspection is to be carried out and by whom, or whether it can be waived altogether. If the inspection is carried out by an independent expert, the FOT will base its decisions on his or her reports.

For a series of identical vehicles, the technical operational safety assessment will generally be carried out on one or more prototype vehicle. If a declaration of conformity confirms that the vehicles are identical, the FOT can waive a technical operational safety assessment of the production vehicles.

5.10 Type approval

Type approval is intended for vehicles and their components (see Annex 1) that are used in exactly the same way and perform the same function in multiple applications (series). Type

[29] Implementing Regulation (EU) No 402/2013 of 30 April 2013 on the common safety method for risk evaluation and assessment (CSM)

[30] Art. 8*c* RailO

[31] Available in German at: www.bav.admin.ch > Rechtliches > Richtlinien

approval is intended to simplify and speed up the inspections by the FOT that form part of the operating licence procedure (Art. 7 RailO).

5.11 Operating licence

Every vehicle operating in Switzerland requires a valid operating licence (Art. 8 RailO). Exceptions are vehicles that run exclusively on private sidings (in other words, not beyond the connection point). Other exceptions are described in chapter 6.3.

For a series of identical vehicles, a declaration of conformity can be used to confirm that the vehicles are identical. This applies accordingly to the safety report required under Art. 5*m* for each operating licence, in which case the conformity of the safety report must be explicitly stated. In this case, to simplify the procedure, the FOT will issue the operating licence on the basis of the declarations of conformity alone, provided that there is a type approval and/or an operating licence for a prototype of the vehicle type in question.

Operational testing and the delivery of vehicles also require an operating licence in the form of an interim order with a time restriction[32] (cf. 5.7).

5.12 Options and duplicates

Vehicles ordered as options of a series of vehicles that have been approved or are undergoing the approval process will be regarded as new vehicles requiring approval. The decisive factor is the status of the regulations at the time of the application for approval of the option in accordance with chapter 2. The same applies to duplicate vehicles without a contractual option.

If the regulations have changed between the approval of the series of vehicles and the order for the option or the duplicate without an option, the current regulations must be applied. In certain justified cases, older regulations can be applied following a corresponding application. The application must contain an analysis of the deviations relating to the current regulations and an assessment of these deviations. The FOT will make the final decision in these cases.

5.13 Subsequent modifications

In accordance with Art. 8 para. 1bis RailO, an operating licence is required for the commissioning of substantially modified vehicles. Substantial modifications are safety-related modifications to systems, components or functions. The applicant must decide whether a modification is substantial or not. In the case of interoperable vehicles for which the safety case has been provided according to chapter 5.8.2, the allocation shall be made according to Art. 15*d* RailO. For the purposes of the safety case, substantial modifications are classified into different categories of modification. Depending on the category of modification (see Figure 5) corresponding reports from independent inspection bodies can be necessary.

[32] Art. 6*a* RailO

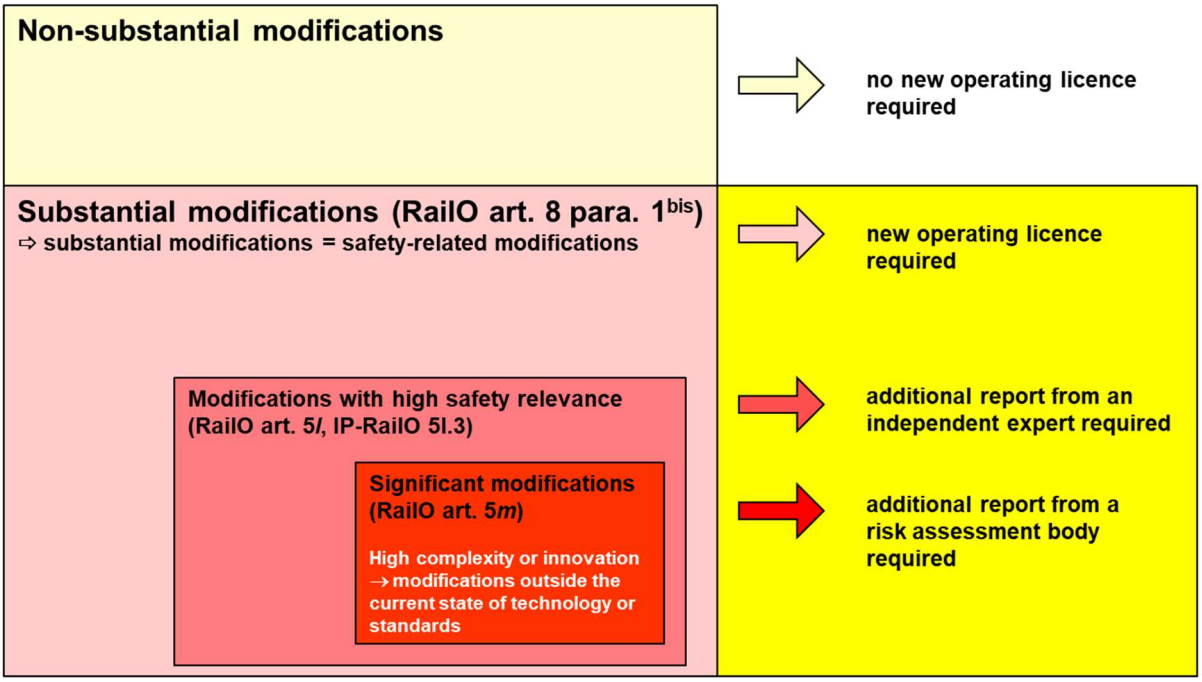

Figure 5: Modification categories

The applicant must provide the following documents in the safety case submitted for the purpose of obtaining an operating licence after modifications:

- Description of the modification;
- Evidence that the design conforms to regulations;
- Evidence of correct functioning;
- Evidence of the lack of retroactive effects;
- Report from independent experts (if the modifications have a high safety relevance);
- Safety report;
- Report from risk assessment body (if there are significant modifications).

The FOT's inspection is based on the procedure in 5.9 and is limited to the modifications, if it can be demonstrated that these have no retroactive effects.

Annex 6 describes the processes and decision-making aids for preparing the safety case in the event of subsequent modifications to rolling stock.

If the regulations have changed between the approval of a vehicle and a subsequent modification, the current version of the regulations applies to the safety case for these modifications. In the case of vehicles not approved under the TSI which require subsequent substantial modifications on the basis of the TSI, appropriate evidence of compliance with current standards and, in the case of modifications with high safety relevance, reports from independent experts can be submitted as part of the safety case, instead of certificates of conformity from notified bodies. The FOT will decide on the specific procedure.

6 Acceptance of existing approvals

6.1 Transitional provisions

In accordance with Art. 83*g* RailO, vehicles or components that were in operation in Switzerland on 1 January 1999 are regarded as having been approved.

In accordance with Art. 83*h* RailO, vehicles or components that were put into operation during the interim period from 1 January 1999 to 31 December 1999 with the consent of SBB on the basis of previous legal provisions are regarded as having been approved.

The transitional provisions of Art. 83*a-j* RailO also apply.

6.2 Approvals by other countries

6.2.1 Compatibility with the infrastructure

As part of an ongoing approval procedure, the FOT can recognise approvals issued by other countries[33]. Vehicles with foreign approval must be shown to be compatible with the technical network access conditions of the Swiss infrastructure.

6.2.2 German routes on Swiss territory

The following sections of line:

- Basel Bad Bf – border (– Weil am Rhein)
- Basel Bad Bf – border (– Basel Bad Rbf)
- Basel Bad Bf – infrastructure border BEV/HBS (– Basel Kleinhüningen Hafen)
- Basel Bad Bf – infrastructure border BEV/SBB (– Basel SBB PB/RB)
- Basel Bad Bf – border (– Grenzach)
- Basel Bad Bf – border (– Lörrach)
- (Kreuzlingen –) infrastructure border SBB/BEV – border (– Konstanz)
- (Kreuzlingen Hafen –) infrastructure border SBB/BEV – border (– Konstanz)
- Schaffhausen – border (– Gottmadingen)
- Schaffhausen – border (– Erzingen [Baden])

are German routes on Swiss territory which are operated by the infrastructure manager Bundeseisenbahnvermögen (BEV) and comply with the infrastructure standards of DB InfraGO.

On the basis of the compatibility of the vehicle and the infrastructure, on these routes and on tracks compatible with the vehicles in the community station of Schaffhausen the FOT recognises authorisations for placing rolling stock into service of the EBA or the ERA and will not issue its own operating licences. This applies accordingly to vehicles which were approved by the relevant authority before 31 December 1993 in accordance with Section 32 of the German Ordinance on the Construction and Operation of Railways for unrestricted use in public rail transport within the Federal Republic of Germany and for which in the interim the inspection intervals specified in Section 32 of the above ordinance can be shown to have been complied with. However, an operating licence from the FOT is required to operate vehicles on routes belonging to SBB Infrastruktur or Hafenbahn Schweiz AG (HBS) which are adjacent to the routes referred to above.

For service vehicles in accordance with 5.8.4.1 which are used on the infrastructure of BEV for the purpose of construction or maintenance and which have to access sections of the infrastructure between Basel Bad Bf and Basel SBB/RB in this context, the FOT recognises authorisations for placing rolling stock into service of the EBA or the ERA and will not issue its own operating licenses, provided the approval of SBB Infrastructure.

The relevant provisions of RailO and its implementing provisions (IP-RailO) that go beyond the compatibility between the vehicle and the infrastructure, and the provisions of other Swiss acts and ordinances must be complied with, regardless of the fundamental acceptance of the German vehicle approval.

[33] Mandatory acceptance where there are corresponding international agreements

6.2.3 Austrian routes on Swiss territory

The following sections of line:

- St. Margrethen – border (Austria)
- Buchs SG – border (Principality of Liechtenstein)

are Austrian routes on Swiss territory which are operated by the infrastructure manager ÖBB-Infrastruktur and comply with its infrastructure standards.

On the basis of the compatibility of the vehicle and the infrastructure, on these routes and on tracks compatible with the vehicles in the border stations of Buchs SG and St. Margrethen the FOT recognises authorisations for placing rolling stock into service issued by the BMK or the ERA as well as permits to operate on the ÖBB-Infrastruktur network issued by the operational management of ÖBB-Infrastruktur and will not issue its own operating licences. However, an operating licence from the FOT is required to operate vehicles on routes belonging to SBB Infrastruktur which are adjacent to the routes referred to above.

For service vehicles in accordance with 5.8.4.1 which are used on the infrastructure of BEV for the purpose of construction or maintenance and which have to access sections of the infrastructure between Basel Bad Bf and Basel SBB/RB in this context, the FOT recognises the German Federal Railway Authority's authorisations for placing rolling stock into service and will not issue its own operating licenses, provided the approval of SBB Infrastructure.

The relevant provisions of RailO and its implementing provisions (IP-RailO) that go beyond the compatibility between the vehicle and the infrastructure, and the provisions of other Swiss acts and ordinances must be complied with, regardless of the fundamental acceptance of the Austrian vehicle approval.

6.3 Vehicles bearing RIV/RIC/TEN markings

Vehicles that have been approved in other countries before 1 July 2013 and bear the RIV/RIC marking are considered to be approved in Switzerland.

Freight wagons that have been approved for use on the basis of the Wagons TSI (WAG TSI) and the Noise TSI (NOI TSI) and that meet the requirements of the G1 loading gauge are considered to be approved in Switzerland. To operate in Switzerland they must have one of the following markings for interoperable use: RIV, TEN G1 or TEN GE.

Passenger rolling stock that has been approved for use on the basis of the Locomotives and Passenger Rolling Stock TSI (LOC & PAS TSI) and that meet the requirements of the G1 loading gauge are considered to be approved in Switzerland. To operate in Switzerland they must have "CH" among the country codes or have the RIC marking for interoperable use.

As part of its supervisory activities, the FOT can impose certain restrictions or conditions.

6.4 Approval on cross-border routes

6.4.1 Agreements with neighbouring countries

On the basis of Art. 21 (8) of Directive (EU) 2016/797 in conjunction with Art. 12 of Implementing Regulation (EU) 2018/545, neighbouring safety authorities may draw up agreements regulating the mutual recognition of authorisations on cross-border routes.

Until such agreements are concluded, the FOT may issue route-related authorisations in accordance with a simplified procedure (section 6.4.2).

6.4.2 Simplified approval on cross-border routes

On specific stretches of line, approvals for foreign rolling stock can be issued using a simplified procedure, which involves making the preceding inspections simpler. In the case of series of identical vehicles, a declaration of conformity can be used to confirm that the vehicles are identical.

Agreements on approval for cross-border railway lines do not give rise to rights and duties, in particular, those of railway undertakings, infrastructure managers, owners, keepers or manufacturers.

The applicant must submit the following documents to the FOT together with the application:

- A valid operating licence of the neigbouring country or the ERA;
- Evidence of compatibility with the infrastructure of the stretch of line in question.

In addition to the requirements of the RailO and the IP-RailO, it should be shown that the relevant infrastructure manager's conditions of access to the network have been complied with.

In providing evidence of compatibility with the infrastructure, the following points should be taken into account:

- Train control system. When using ETCS, proof of safety for cross-border routes must be provided in accordance with the safety proof concept for obtaining an ETCS authorisation in Switzerland ("Sicherheitsnachweiskonzept für die Erlangung einer ETCS-Zulassung in der Schweiz")[34]. The NNTRs relevant to ETCS specify whether they are to be taken into account for authorisation on cross-border routes;
- Evidence of operation that is free of faults and external influences (electromagnetic compatibility, grid compatibility);
- Evidence of appropriate operation by staff;
- Evidence of appropriate boarding conditions for passengers;
- Designation of any operational restrictions;
- Compatibility of categories of line;
- Compatibility of clearance gauge or reference line;
- Compatibility of wheel profile with regard to running factors;
- Compatibility of pantograph/contact line;
- Communication systems.

7 Loads

7.1 Standard ISO containers

Standardised ISO containers are subject to the provisions of the Container Safety Convention (1985) and are approved in Switzerland.

7.2 Swap bodies and freight containers

Swap bodies and freight containers are cargo and not rolling stock. The FOT is therefore not involved in their approval process. The safe operation of the vehicle and the cargo is the responsibility of the railway undertakings (RUs).

[34] Available at www.bav.admin.ch > Verkehrsmittel > Eisenbahn > Fachinformationen > Zugbeeinflussung > ETCS > Weitere Informationen für Fachleute (in German)

7.3 Coding of wagons

Swap bodies, freight containers and semi-trailers are cargo and not rolling stock. The FOT is therefore not involved in their approval process. The safe operation of the vehicle and the cargo is the responsibility of the railway undertakings (RUs).

SBB Infrastructure has an information and testing centre:

SBB Infrastruktur
Anlagen und Technologie – Technischer Netzzugang
Hilfikerstrasse 3
CH-3000 Bern 65
Tel: +41 51 285 03 78 / +41 51 285 03 79

E-mail: info.tnz@sbb.ch

Website: www.sbb.ch/technischer-netzzugang

8 Equal access for people with disabilities

The Disability Discrimination Act (DDA)[35] gives rise to particular provisions in the Public Transport Adaptation Ordinance (PTAO)[36], the DETEC Ordinance on the Technical Requirements for the Adaptation of Public Transport to the Needs of People with Disabilities (PTRDO)[37], the IP-RailO and the Persons with Reduced Mobility TSI, which must be taken into account in the approval procedure.

The umbrella association for organisations for disabled people, Inclusion Handicap[38] in Bern, represents the organisations for disabled people that have a right of appeal in accordance with Art. 9 DDA in conjunction with Annex 1 of the Ordinance on the Elimination of Discrimination against People with Disabilities (EPDO)[39]. The FOT recommends that companies planning to construct or operate rolling stock should contact and involve Inclsuion Handicap at an early stage, so that any measures can be implemented as cost-effectively as possible.

However, Inclusion Handicap is not a certification body, and there is therefore no obligation to obtain its signature. The approval and the final evaluation of DDA conformity is the responsibility of the FOT.

The FOT has issued a Directive which regulates the minimum percentage of long distance trains that can be used independently. This can be found on the FOT website at www.bav.admin.ch > Rechtliches > Richtlinien.

9 Reporting obligation

On the basis of Art. 15 RailO, any findings and/or occurrences of relevance to safety concerning approved vehicles or components must be reported immediately to the FOT. This reporting obligation applies throughout the entire life cycle of the vehicle or component concerned and its repeated use (development, trials, manufacture, storage, transport, operation, maintenance, disposal).

[35] Act on the Elimination of Discrimination Against People with Disabilities (DDA), SR **151.3**

[36] Ordinance on the Adaptation of Public Transport to the Needs of People with Disabilities (PTAO), SR **151.34**

[37] DETEC Ordinance on the Technical Requirements for the Adaptation of Public Transport to the Needs of People with Disabilities (PTRDO), SR **151.342**

[38] www.inclusionhandicap.ch

[39] Ordinance on the Elimination of Discrimination against People with Disabilities (EPDO), SR **151.31**

10 Revocation of approvals

The FOT can revoke an approval if:

- operational safety can no longer be guaranteed;
- the present conditions of use do not correspond to those specified in the approval.

11 Processing the documents submitted

FOT employees who process documents submitted by an applicant in association with the approval procedure are obliged to observe professional, business and official secrecy in accordance with the provisions of the Federal Personnel Act[40].

The documents submitted are subject to the Federal Act on Freedom of Information in the Administration (FoIA)[41].

12 Fees

Fees are charged in accordance with the provisions of the FOT Fees Ordinance[42]. The FOT will charge fees according to its actual costs.

[40] SR **172.220.1**

[41] SR **152.3**

[42] SR **742.102**

Annex 1: Vehicles and components requiring approval

Rolling stock includes (the list is not comprehensive):

- Locomotives
- Engine coaches
- Multiple unit trainsets (EMU and DMU)
- Passenger carriages
- Freight wagons[43]
- Tramway vehicles and light rail vehicles (LRV)
- Service vehicles

Components[44] include (the list is not comprehensive):

- Bogies
- Wheels and wheelset axles
- Coupling devices
- Brake equipment
- Train control system equipment
- Radio equipment
- Pantographs
- Radio remote control units
- Tilting equipment
- Computer-based control and communication systems for safety-related functions
- Combustion engines

[43] The contact point for questions concerning the transport of dangerous goods is the Federal Office of Transport, Environment Section, CH-3003 Bern. Information by telephone: 058 463 21 54

[44] Interoperability components according with Directive (EU) 2016/797 are not objects for approval for the purposes of this Directive.

Annex 2: Structure and evidence documents for the safety case for interoperable vehicles

1. EVIDENCE THAT THE DESIGN CONFORMS TO REGULATIONS	
1.A.1	**General information**
	– Approval concept (FOT template) – List of all evidence documents (list of documents: FOT template) – Drawing of the type with the most important layouts and the main dimensions – Technical vehicle data (FOT template) – Technical description of the complete vehicle – Description of the use and conditions of use of the vehicle
1.B.1	**Certificate of conformity for the subsystem TSI Freight Wagons**
1.B.2	**EC declaration of verification for the subsystem TSI Freight Wagons**
1.C.1	**Certificate of conformity for the subsystem TSI Control, Command and Signalling**
1.C.2	**EC declaration of verification for the subsystem TSI Control, Command and Signalling**
1.D.1	**Certificate of conformity for the subsystem TSI Locomotive and Passenger Rolling Stock**
1.D.2	**EC declaration of verification for the subsystem TSI Locomotive and Passenger Rolling Stock**
1.E.1	**Certificate of conformity for the subsystem TSI Energy**
1.E.2	**EC declaration of verification for the subsystem TSI Energy**
1.F.1	**Certificate of conformity for the subsystem TSI Noise**
1.F.2	**EC declaration of verification for the subsystem TSI Noise**
1.G.1	**Certificate of conformity for the TSI Persons with Reduced Mobility**
1.G.2	**EC declaration of verification for the TSI Persons with Reduced Mobility**
1.H.1	**Certificate of conformity for the TSI Safety in Railway Tunnels**
1.H.2	**EC declaration of verification for the TSI Safety in Railway Tunnels**

1.I.1	**Certificates of conformity for the notified national technical rules NNTR[45]**
1.I.2	**Declaration of verification for the notified national technical rules NNTR**
2. SAFETY REPORT (FOT template)	
3. SAFETY ASSESSMENT REPORT	
4. INSPECTION REPORTS FROM INDEPENDENT EXPERTS[46] (COMPLETE SYSTEM)	

[45] Art. 48 para. 3 RailO

[46] Art. 15*i^bis^* RailO

Annex 3: Structure and evidence documents for the safety case for non-interoperable vehicles

1. EVIDENCE THAT THE DESIGN CONFORMS TO REGULATIONS	
1.0	**General information**
	– Approval concept (FOT template) – List of all evidence documents (document list: FOT template) – Drawing of the type with the most important layouts and the main dimensions – Technical vehicle data (FOT template – Technical description of the complete vehicle – Description of the use and conditions of use of the vehicle
1.1	**Running behaviour**
1.1.a	Drive systems – Report on calculations, simulation and the assumptions made – Test plan – Report on the tests with assessment of the results – Expert report according to FOT Guideline «Nachweis sicheres Fahrverhalten Meterspur-, Spezialspur- und Zahnradbahnen» (in German)
1.1.b	Protection against derailment – Mathematical evidence of adhesion and/or cog-wheel operation – Drawings and technical description of the wheel flange lubrication – Expert report according to FOT Guideline «Nachweis sicheres Fahrverhalten Meterspur-, Spezialspur- und Zahnradbahnen» (in German)
1.2	**Vehicle superstructure**
1.2.a	Vehicle body – Drawings of the vehicle body with add-on parts – Drawings of the layout of the devices – Drawings of the boarding area and interior fittings – Evidence of the load-bearing capacity of the vehicle body – Evidence of resistance to longitudinal compressive forces – Evidence of crashworthiness – Evidence of load calculation for passenger vehicles – Expert report on load-bearing capacity, resistance to longitudinal compressive forces and crashworthiness of the vehicle body
1.2.b	Devices under the vehicle floor or on the roof – Drawings of add-on parts including rail guards – Evidence of the strength of the add-on parts
1.3	**Draw and buffer gear**
	– Drawing of the draw and buffer gear and its installation – Declaration of conformity on draw and buffer gear – Evidence that overriding will not occur
1.4	**Bogie and running gear**
1.4.a	Documentation on running gear, drive and brakes – Drawings of the rail guards

	– Drawings of the running gear and its connection to the case – Drawings of the integrated running gear and the transfer of the traction/braking forces – Drawings of the axle boxes in the case of special designs – Drawings of the layout of the earthing brushes and axle sensors on the axles – Drawings of the suspension springs, with characteristic curves – Installation drawing of all brakes for adhesion vehicles – Drawings of the drive and coupling for cog-wheel/adhesion operation for combined vehicles – Installation drawing of the torque limiter of the drive train for cog-wheel vehicles – Drawings of the mechanical stopping brakes for cog-wheel vehicles – Drawings of the holding brakes for cog-wheel vehicles – Drawings of the ratchet brake for cog-wheel vehicles
1.4.b	Evidence on running gear, drive and brakes – Evidence of the fatigue strength of the frame and the add-on parts – Evidence of the static strength of the frame – Evidence of the strength of the axle guides – Evidence of the strength of the stabilisers – Evidence of the strength of the cross-beams – Evidence of the FMEA (failure mode and effects analysis) – Expert report on strength evidence and FMEA – Evidence of the meshing for cog-wheel vehicles – Expert report on the meshing of the drive and braking cogs
1.4.c	Weight of the vehicle – Report on wheel load weighing – Evidence of wheel load distribution (IP-RailO)
1.5	**Wheelset/wheelset bearing**
1.5.a	Drawings of the wheelsets, axle shafts and wheels
1.5.b	Evidence of wheelsets and wheels – Evidence of strength of wheelset shafts – Evidence of strength of wheels – Evidence of the thermal capacity of the wheels – Expert report
1.6	**Brake system**
1.6.a	Brakes – Brake concept and technical description of the brake equipment – Braking calculation for the brake system design – Wiring diagrams for the pneumatic, hydraulic and vacuum systems – Equipment lists for the pneumatic, hydraulic and vacuum systems – Test plan and results for the static commissioning of the brakes – Report on the dynamic brake tests – Assessment of the brakes including documentation of the brake markings – Expert report

1.6.b	Wheel slip and slide protection – Type approval and safety certificates, declarations of conformity – Technical and functional description of the equipment – Commissioning report on the dynamic driving and braking tests with assessment of the results – Expert report for non-type-approved and active slip protection system
1.6.c	Sander – Installation drawing and technical-functional description of the sander – Evidence for the sander system
1.7	**Pressurised systems**
1.7.a	Certificates and evidence – Certificates SVTI (Swiss Association for Technical Inspections) for boilers – Certificates SVTI (Swiss Association for Technical Inspections) for compressed air tanks
1.8	**Pantograph**
	– Drawing of the pantograph with the main dimensions – Declarations of conformity – Evidence of compliance with the interaction conditions between the pantograph and the overhead line for v > 120 km/h
1.9	**Windows**
	– Overview drawings / Sketch of all glazings – Certificates of windscreens – Certificates of side windows (TSG/LSG) – Certificates of internal windows, compartment walls and doors (TSG/LSG)
1.10	**Doors**
	– Layout drawings of entry doors with main dimensions – Technical description and documentation of the safety functions – Test plan and test report for commissioning – Declaration of conformity to SN EN 14752 – Expert report in compliance with SN EN 14752
1.11	**Connection between carriages**
	– Drawings of door with locking device – Drawing of floor connecting section – Drawing of grab handles
1.12	**Energy supply**
1.12.a	Auxiliaries – Technical description and functions – Layout drawings for installation – Evidence of electric shock protection of the electrical system – Documentation of symbols and warning signs
1.12.b	High- and low-voltage components – Technical description and functions – Layout drawings for installation – Documentation of the access, closure concept, locking mechanisms

	– Evidence of electric shock protection, symbols, warning signs
1.12.c	EMC and circuit feedback
	– Evidence of EMC with the signalling and communication system
	– Evidence of compatibility with the energy supply
	– Test plan and test reports with assessment of the results
1.12.d	Earthing concept
	– Earthing diagram
	– Definition of cable cross-sections
	– FMEA report on the safety concept and component earthing
	– Evidence of impedance measurement between the highest vehicle point and the rail
	– Evidence of electrical resistance between the wheel treads
1.13	**Control systems**
1.13.a	Wiring diagrams
	– Main and control power circuits
	– Equipment list for the wiring diagrams
1.13.b	Evidence on vehicle control system
	– Technical description and specification of the functions
	– Compliance with the manufacturer’s safety requirements
	– Evidence on safe integration into the vehicle
	– Test plan and test report for commissioning
	– Safety certificates, type approvals, declarations of conformity
1.13.c	Evidence on remote control, multiple units under remote control
	– Technical descriptions and specifications of the functions
	– Compliance with the manufacturer’s safety requirements
	– Evidence on safe integration into the vehicle
	– Test plan and test report for commissioning
	– Safety certificates, type approvals, declarations of conformity
1.13.d	Evidence on radio remote control and licence (OFCOM)
	– Technical descriptions and specifications of the functions
	– Compliance with the manufacturer’s safety requirements
	– Evidence on safe integration into the vehicle
	– Test plan and test report for commissioning
	– Safety certificates, type approvals, declarations of conformity
1.13.e	Evidence on automatic train control system
	– Technical descriptions and specifications of the functions
	– Compliance with the manufacturer’s safety requirements
	– Evidence on safe integration into the vehicle
	– Test plan and test report for commissioning
	– Safety certificates, type approvals, declarations of conformity
1.13.f	Evidence on tilt control, roll compensation and other elements
	– Technical descriptions and specifications of the functions
	– Compliance with the manufacturer’s safety requirements
	– Evidence on safe integration into the vehicle

	– Test plan and test report for commissioning
	– Safety certificates, type approvals, declarations of conformity
1.13.g	Implemented software
	– Software versions on devices with functions subject to verification
1.13.h	Expert report on functional safety (items b to f)
1.14	**Drinking water and wastewater systems**
	– Description of the type of treatment system for released water
	– Declaration of conformity to the Waters Protection Ordinance (WPO)[47]
1.15	**Environmental protection**
1.15.a	Diesel engines
	– Declaration of conformity to the exhaust emission thresholds
	– Test certificate for fuel tank tightness
1.15.b	Noise emissions
	– Test report and declaration of conformity to IP-RailO
1.16	**Fire prevention**
	– Report on risk assessment and rating
	– Evidence of materials
	– Drawings or sketch showing the position of fire extinguishers, fire alarms, fire fighting equipment
	– Description of fire alarms, fire fighting equipment
	– Expert report
1.17	**Occupational health and safety and compliant workplace design**
1.17.a	Compliant workplace design (safety, ergonomics)
	– Depiction of the driver's cab, including fittings and controls
	– Depiction of visibility conditions, including assessment
	– Glare protection measures
1.18	**Vehicle gauge**
	– Evidence of restriction calculation, including space for pantograph
	– Expert report
1.19	**Safety systems**
1.19.a	Audible signals
	– Layout drawings / sketches for installation
	– Main technical data (e.g. sound, volume)
1.19.b	Visual signals
	– Layout drawing / sketch for installation and control system
	– Main technical data (e.g. luminosity, illumination)
1.19.c	Evidence of speed recording and driving data recording
	– Technical descriptions and specification of the functions
	– Test report for commissioning
	– Safety certificates, type approvals, declarations of conformity
1.19.d	Evidence of safety control/vigilance system
	– Technical descriptions and specification of the functions

[47] SR **814.201**

	– Test report for commissioning – Safety certificates, type approvals, declarations of conformity
1.19.e	Evidence of monitoring of operating modes for cog-wheel vehicles – Technical descriptions and specification of the functions – Test report for commissioning – Safety certificates, type approvals, declarations of conformity
1.19.f	Evidence of overspeed monitoring including deceleration monitoring for cog-wheel vehicles – Technical descriptions and specification of the functions – Test report for commissioning – Safety certificates, type approvals, declarations of conformity
1.19.g	Evidence of monitoring of roll-back protection system for cog-wheel vehicles – Technical descriptions and specification of the functions – Test report for commissioning – Safety certificates, type approvals, declarations of conformity
1.19.h	Train radio equipment – Technical description – Safety certificates, type approvals, licence (OFCOM)
1.19.i	Emergency brake request & emergency brake override – Technical description – Test report for commissioning and functional test – Evidence of finctional and technical safety
1.19.j	Train control system ETCS – Safety case according to «Sicherheitsnachweiskonzept für die Erlangung einer ETCS-Zulassung in der Schweiz» (in German)
1.19.k	Train control system ZBMS – Safety case according to «Zulassungsprozess und Nachweisführung von Meter- und Spezialspurfahrzeugen nach der Nachrüstung mit einem Zugbeeinflussungssystem gemäss ZBMS-Standard» (in German)
1.19.l	Train control system different type – Evidence of compliance with the manufacturer’s safety requirements – Evidence of safe integration into the vehicle – Evidence of correct interaction with the route – Safety certificates, type approvals, declarations of conformity
1.19.m	Transition (system handover) – Evidence of safe handover to other systems – Technical description and specification of the functions – Test report for commissioning – Safety certificates, type approvals, declarations of conformity
1.19.n	Expert report on items c to g and i to m
1.20	**Signs and symbols**
	– External signs: Signs and layout drawings/photographs – Driver’s cab: Signs and layout drawings/photographs – Passenger area: Signs and layout drawings/photographs

1.21	**Joining systems**
	– Welding certificates – Bonding certificates – Evidence of bolted joints
1.22	**Maintenance manual**
	– Manufacturers' maintenance requirements – Evidence of modifying the maintenance routine in the event of deviations from the regulations
1.23	**Operating manual**
	– Vehicle operating instructions/operating regulations
1.24	**Equipment**
1.24.a	Drawings of internal fittings in the passenger area – Layout drawing and design of luggage holders – Layout drawing of the use of the multifunctional area – Position overview of vehicle electrical system and communication equipment
1.24.b	Evidence of internal fittings in the passenger area – Evidence of slip resistance of floor coverings
1.24.c	Evidence of compliance with the requirements of the DDA according to «Leitfaden für BehiG-Sachverständige» (in German) – Concept and layout drawing for grab rails – Documentation of the Customer information system (CIS) – Entry doors, control elements and sensors – Emergency telephones – Dimensions and position of wheelchair areas – Dimensions of toilets – Lighting, contrasts and colour scheme – Independent access for people with reduced mobility – Reports on vehicle inspections – Expert report
1.25	**Faults and accidents**
	– Evidence of vehicle securing – Concept for passenger evacuation/rescue, links between systems (CIS, multimedia etc.) – Vehicle recovery concept – Expert report
2. SAFETY REPORT (FOT template)	
3. SAFETY ASSESSMENT REPORT	
4. INSPECTION REPORTS FROM INDEPENDENT EXPERTS (COMPLETE SYSTEM)	

Annex 4: Structure and evidence documents for the safety case for service vehicles

1. EVIDENCE THAT THE DESIGN CONFORMS TO REGULATIONS	
1.0	**General information**
	– Approval concept (FOT template) – List of all evidence documents (list of documents: FOT template) – EC declaration(s) of confirmity – Description of the use and conditions of use of the vehicle
1.1	**Overview drawing and technical data**
1.1.a	Overview drawing – Drawing of the type with the most important layouts and the main dimensions – Position of the centres of mass – Position of the signal lights – Position of the warning systems – Weights – Smallest negotiable horizontal and vertical radius – Lifting and jacking points – Position of the exhaust pipes – Position of the draw and buffer gear
1.1.b	Technical data (FOT template)
1.2	**Vehicle gauge**
	– Evidence of calculation of restriction, including space for pantograph – Expert report
1.3	**Weight of the vehicle**
	– Report on wheel load weighing – Evidence of wheel load distribution (IP-RailO)
1.4	**Suspensions**
	– Drawings of the suspension springs with characteristic curves
1.5	**Bogie movements**
	– Evidence of rotational and displacement movements
1.6	**Running behaviour**
1.6.a	Drive systems – Report on calculations, simulation and the assumptions made – Test plan – Report on the tests with assessment of the results – Expert report according to «SN EN 14033-x» resp. FOT Guideline «Nachweis sicheres Fahrverhalten Meterspur-, Spezialspur- und Zahnradbahnen» (in German)
1.6.b	Protection against derailment – Evidence of the driving on twisted tracks – Evidence of longitudinal force influence in S-bends

	– Expert report according to «SN EN 14033-x» resp. FOT Guideline «Nachweis sicheres Fahrverhalten Meterspur-, Spezialspur- und Zahnradbahnen» (in German)
1.7	**Vehicle superstructure**
1.7.a	Vehicle frame resp. rail runnig gear fastening – Drawings of the vehicle frame resp. rail runnig gear fastening – Drawings of the rail guard – Evidence of the strength of the vehicle frame – Evidence of resistance to longitudinal compressive forces – Expert report
1.7.b	Add-on parts – Drawings of the add-on parts – Drawing of the pantograph with the main dimensions – Evidence of the strength of the add-on parts – Evidence of compliance with the interaction conditions between the panto-graph and the overhead line for v > 120 km/h
1.7.c	Joining systems – Welding certificates, including SN EN 15085-2 – Bonding certificates – Evidence of bolted joints
1.8	**Environmental protection**
1.8.a	Evidence of compliance with exhaust emission thresholds for explosion engines – Declaration of conformity for compliance with exhaust emission thresholds – Evidence of the exhaust aftertreatment system and the particle number limit value
1.8.b	Electric, hybrid and similar drives and power supplies – Report on compliance with railway standards
1.9	**Power**
	– Tractive force/speed diagram – Gradient/speed diagram – Evidence of towing loads
1.10	**Brake system**
	– Brake concept and technical description of the brake equipment – Braking calculation for the brake system design – Test reports on static and dynamic brake tests – Drawings and technical description of the brake pads/discs – Evidence of the compressed air volume of the compressor – Expert report
1.11	**Bogie and running gear**
1.11.a	Bogies – Drawings of the bogie frames – Drawings of the rail guards – Evidence of the strength of the bogie frames
1.11.b	Wheelsets/wheels

	– Drawings of the wheelsets – Drawings of the wheelset shafts – Drawings of the wheels – Drawings of the wheel profiles – Drawings of the wheelset bearings – Report on compatibility with hot box detectors – Evidence of strength of wheelset shafts – Evidence on the wheels – Expert report
1.11.c	Cog-wheel vehicles – Drawings of the drive and coupling for cog-wheel/adhesion operation for combined vehicles – Expert report on the meshing of the drive and braking cogs
1.12	**Locking and safety devices**
	– Evidence of the locking devices of the working tools – Evidence of the limiting devices of the working tools – Evidence of fall arresters for moving machine parts that may fall on the track
1.13	**Draw and buffer gear**
	– Drawing of the draw and buffer gear and its installation – Declaration of conformity – Evidence that overriding will not occur – Evidence of buffer plate size – Bracing diagram
1.14	**Signs and symbols**
	– Signs and symbols on the outside of the vehicle and in the driving and working cabins – Board of inscriptions / technical inscriptions (FOT template)
1.15	**Cabin**
	– Visualisation and assessment of visibility conditions for drivers and attendants – Certificates of windscreens and side windows
1.16	**Pressurised systems**
	– Scheme of pneumatic system, including equipment list – Scheme of vacuum system, including equipment list – Scheme of fuel system, including equipment list – Scheme of hydraulic system, including equipment list – Scheme of water system for working tools, including equipment list – Certificates and declarations of conformity for pressure vessels and tanks – Description of the hydraulic/pneumatic system for rail wheel suspension and locking on two-way vehicles
1.17	**Occupational safety and fire prevention**
1.17.a	Fire prevention – Report on risk assessment and rating – Description of fire alarms, fire fighting equipment – Expert report

1.17.b	Occupational safety – Compliant workplace design (safety, ergonomics)
1.18	**Safety systems**
1.18.a	Audible signals – Layout drawings / sketches for installation – Main technical data (e.g. sound, volume)
1.18.b	Visual signals – Layout drawing / sketch for installation and control system – Main technical data (e.g. luminosity, illumination)
1.18.c	Evidence of speed recording and driving data recording – Technical descriptions and specification of the functions – Test report for commissioning – Safety certificates, type approvals, declarations of conformity
1.18.d	Evidence of safety control/vigilance system/dead-man – Technical descriptions and specification of the functions – Test report for commissioning – Safety certificates, type approvals, declarations of conformity
1.18.e	Evidence of overspeed monitoring including deceleration monitoring for cog-wheel vehicles – Technical descriptions and specification of the functions – Test report for commissioning – Safety certificates, type approvals, declarations of conformity
1.18.f	Train radio equipment – Technical description – Safety certificates, type approvals, licence (OFCOM)
1.18.g	Train control system ETCS – Safety case according to «Sicherheitsnachweiskonzept für die Erlangung einer ETCS-Zulassung in der Schweiz» (in German)
1.18.h	Train control system ZBMS – Safety case according to «Zulassungsprozess und Nachweisführung von Meter- und Spezialspurfahrzeugen nach der Nachrüstung mit einem Zugbeeinflussungssystem gemäss ZBMS-Standard» (in German)
1.18.i	Train control system different type – Evidence of compliance with the manufacturer’s safety requirements – Evidence of safe integration into the vehicle – Evidence of correct interaction with the route – Safety certificate, type approval, declaration of conformity
1.18.j	Expert report on items c to e and g to i
1.19	**Operating and maintenance manuals**
	– Manufacturers' maintenance requirements – Vehicle operating instructions/operating regulations
1.20	**Energy supply**
1.20.a	EMC and circuit feedback – Evidence of EMC with the signalling and communication system – Evidence of compatibility with the energy supply

	– Test plan and test reports with assessment of the results
1.20.b	Earthing concept
	– Earthing diagram
	– Evidence of impedance measurement between the highest vehicle point and the rail
	– Evidence of electrical resistance between the wheel treads
1.21	**Control systems**
1.21.a	Wiring diagrams
	– Main and control power circuits
1.21.b	Evidence on vehicle control system
	– Technical description and specification of the functions
	– Compliance with the manufacturer's safety requirements
	– Evidence on safe integration into the vehicle
	– Test plan and test report for commissioning
	– Safety certificates, type approvals, declarations of conformity
1.21.c	Evidence on remote control, multiple units under remote control
	– Technical descriptions and specifications of the functions
	– Compliance with the manufacturer's safety requirements
	– Evidence on safe integration into the vehicle
	– Test plan and test report for commissioning
	– Safety certificates, type approvals, declarations of conformity
1.21.d	Evidence on radio remote control and licence (OFCOM)
	– Technical description and specification of the functions
	– Compliance with the manufacturer's safety requirements
	– Evidence on safe integration into the vehicle
	– Test plan and test report for commissioning
	– Safety certificates, type approvals, declarations of conformity
1.21.e	Implemented software
	– Software versions on devices with functions subject to verification
1.21.f	Expert report on functional safety (items b to d)
2. SAFETY REPORT (FOT template)	
3. SAFETY ASSESSMENT REPORT	
4. INSPECTION REPORTS FROM INDEPENDENT EXPERTS (COMPLETE SYSTEM)	

Annex 5: Documents/details needed for an interim operating licence[48] for operational testing

The following documents and evidence must accompany an application (cf. 5.7) for an interim operating licence for operational testing in accordance with Art. 6*b* RailO:

- Details of a plausible time limit for the operating licence, coordinated with the testing programme;
- The 12-digit vehicle number[49] (incl. NID_ENGINE for operational testing for vehicles with ETCS equipment) of each vehicle to be authorised or the technical identification of components;
- The country code and the vehicle keeper marking (VKM) of the vehicles;
- The name and the address of the applicant and the vehicle keeper;
- A testing programme including maintenance that is coordinated with the infrastructure manager and the railway undertaking that performs it;
- Where applicable, declaration of compatibility with vehicles that are already approved;
- A scale image of the type with main dimensions, distance between axles;
- Weights as evidence of compliance with permissible axle loads, minimum axle loads and metre loads;
- Normal gauge: brake calculation in accordance with UIC 544-1, including static testing protocols, if braking performance is to be considered;
- Meter and special gauge: brake calculation in accordance with IP-RailO (adhesion and/or cog braking systems), including static testing protocols, if the braking performance is to be considered;
- Depending on the planned vehicle, evaluations of the interaction between the vehicle and the infrastructure relating to the following elements may need to be submitted:
    - Pantograph
    - Clearance gauge or reference line
    - Train control systems (e.g. SIGNUM, ZUB, ETCS), including manufacturer's commissioning protocol
    - Radio (analogue, GSM-R)
    - Wheel-rail compatibility
    - Tilting technology
    - Grid compatibility
    - Aerodynamics
- Operational conditions for test drives:
    - Smallest curve radius (depot, on track)
    - Ban on hump tests, if applicable
    - Prevention of rolling stock runaway
    - Service lighting/signalling devices
    - For automatic coupling: coupling junction with UIC screw coupling, auxiliary coupling
    - Planned exceeding of limits
    - Planned monitoring (technical, operational)
    - Recovery and re-railing
    - …

[48] Interim operating licence for operational testing in accordance with Art. 6*b* RailO

[49] Excluding road-rail vehicles, demountable vehicles and similar vehicles

The scope of the documents and evidence depends on each project and should therefore be coordinated with the FOT, which reserves the right to request further documentation.

If functions are missing or available only in part as well as in the case of innovative projects, a risk assessment and corresponding measures must demonstrate how the required level of safety can be ensured, taking into account the technical and operational aspects. The risk assessment must be accompanied by a statement from the relevant infrastructure manager.

If there is no train control system, the vehicle must not be used to pull a train. However, if this is necessary for the verification as part of operational testing, the RU responsible must apply to the FOT for exceptional authorisation.[50]

The FOT directive “Fahrten ohne ausreichende Zugbeeinflussungseinrichtung” (Journeys without an adequate train control system) describes the procedure. It is available in German on the FOT website at www.bav.admin.ch > Rechtliches > Richtlinien.

[50] Art. 5 RailO

Annex 6: Preparing safety cases for modifications to rolling stock

1 Objective

This annex is intended as an aid for the applicant and other interested parties in preparing a safety case for modifications to rolling stock which already has a valid operating licence or a valid type approval. It provides more detailed information relating to chapter 5.13 “Subsequent modification”.

Deviations are permitted, provided that the objective of the acts, ordinances, implementing provisions and directives can be achieved in another way. Applicants who follow this annex closely can be certain that the authorities will accept the information they have prepared for consideration. Failure to do so could result in the rejection of their safety case.

2 Legal foundations

The legal foundations for the approval of rolling stock in Switzerland are the Railways Act (RailA), the Railways Ordinance (RailO), in particular Art. 6*a*, 6*b*, 7, 8 and 15*a*-*z*, and the implementing provisions to the Railways Ordinance (IP-RailO). The preparation of a safety case for the purpose of obtaining an operating licence is based on Art. 8*a*, 8*b* and 15*i* RailO.

The current status of the regulations at the time when the specification is approved, if the approval has been applied for, or at the time when the application for approval is submitted is the definitive status. If new, safety-related findings come to light between the approval of the specification or the submission of the application for approval and the commissioning of the vehicle, the FOT can, in justified cases, apply more recent regulations to the application procedures that are already in progress.

3 Modification process

3.1 Introduction and restrictions

Under Art. 8 para. 1 point b RailO, an operating licence is required for the commissioning of substantially modified vehicles or retrofitted vehicles (under Art. 23*d* RailA), regardless of whether these are interoperable or non-interoperable vehicles. Substantial modifications are safety-related modifications to systems, components or functions (cf. 3.2.3).

The one-to-one replacement or exchange of components as part of the maintenance process is not a modification of the vehicle under Art. 8 para. 1 point b RailO. It must be carried out and documented in accordance with the existing maintenance regulations.

If new interoperability components are to be used in a vehicle, no evidence needs to be supplied that the design of these components conforms to the regulations, provided that EC declarations in accordance with Directive (EU) 2016/797 are available. However, it is important to evaluate, as part of the process of integrating the components into a vehicle, whether this involves a substantial modification to the vehicle and, therefore, whether an operating licence is needed. Particular attention must be paid to the interfaces.

If an operating licence is required, a safety case must be submitted to the FOT. The safety case can be restricted to the modified systems, components or functions, provided that there is evidence of a lack of retroactive effects on the vehicle’s systems or functions that have not been modified (delta approach). The following chapters describe the necessary stages of the process of preparing a safety case from the perspective of the applicant. Because modifications to the software occur relatively frequently, chapter 4 of this annex contains examples of

the classification of software modifications, together with a description of the procedure for the safety case and the documentation expected by the FOT.

3.2 Stages of the process

3.2.1 Overview of the modification process from the applicant's perspective

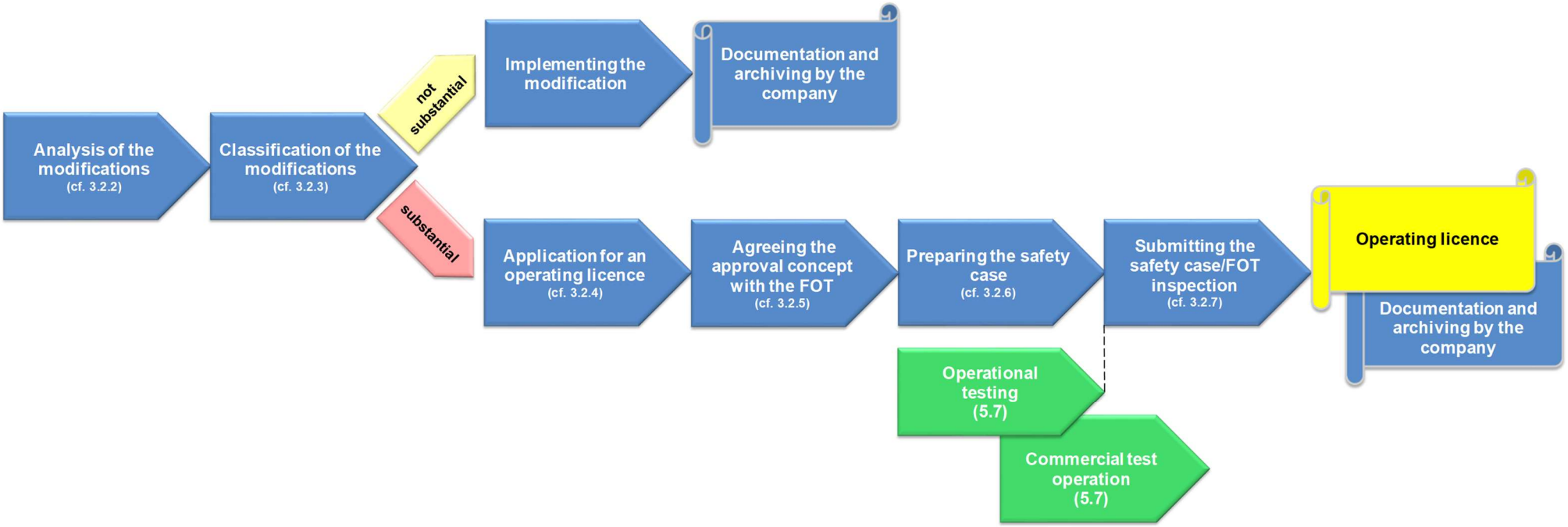

Figure 6: Modification process

3.2.2 Analysis of the modifications

Activities:

- Describing and specifying the planned modifications.
- Impact analysis: Which subsystems and functions of the vehicle are affected?
- Safety analysis: Which risks arise as a result of the modifications to the vehicle and which measures are taken to counteract the risks?

Evidence:

- Description and specification of the modification
- Impact analysis
- Safety analysis

3.2.3 Classification of the modifications

Activities:

- Classification of the modifications on the basis of the analysis in accordance with chapter 3.2.2 and allocation to the corresponding category of modification (see Figure 7). In the case of interoperable vehicles for which the safety case has been provided according to chapter 5.8.2, the allocation shall be made according to Art. 15*d* RailO.

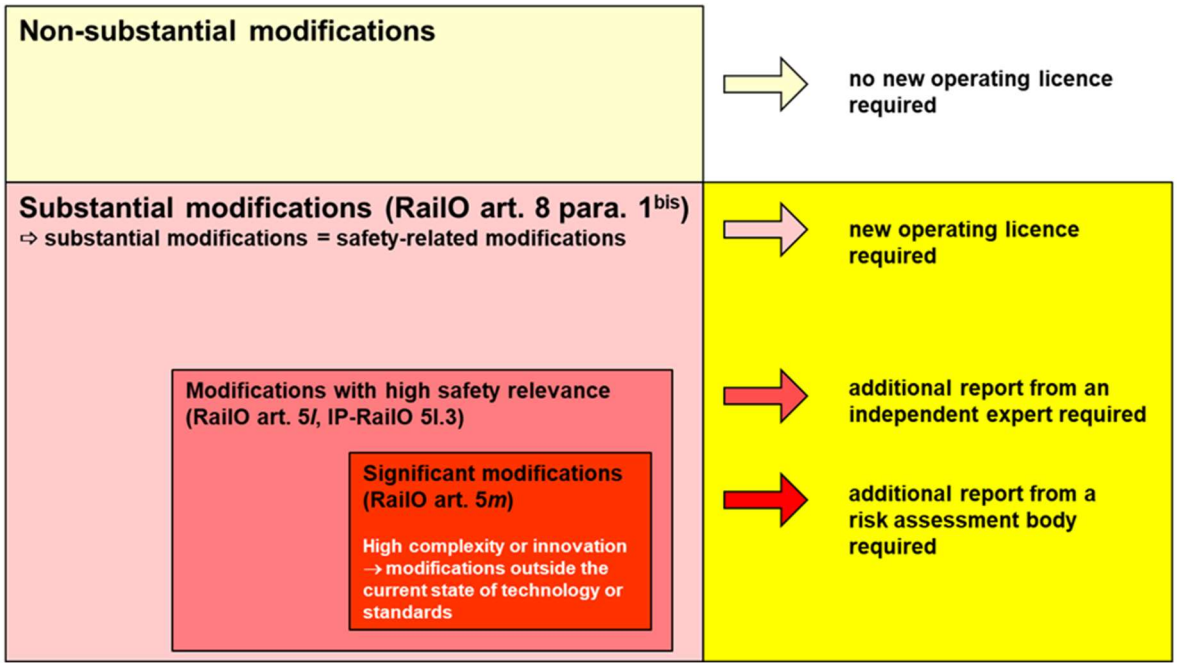

Figure 7: Modification categories

- Preparation of a safety report based on the safety analysis in accordance with chapter 3.2.2 and description of the choice of modification category. If these are **non-substantial modifications**, no operating licence is required. The modifications can be made (without notification to the FOT[51]), but must **always** be **documented** to ensure their traceability. If there is any uncertainty about the classification of the modifications, the FOT can be consulted.

[51] In the case of non-significant modifications to the ETCS equipment (e.g. BugFix), the obligation to inform the TET vehicle in accordance with the "Sicherheitsnachweiskonzept für die Erlangung einer ETCS-Zulassung in der Schweiz" (in German) applies.

Evidence:
- Safety report

3.2.4 Application for an operating licence

In the case of **substantial modifications**, an application for an operating licence must be submitted to the FOT before the modified vehicles are commissioned. The stages of the approval procedure are described in chapter 5.2 of this Directive.

Activities:
- Preparing an approval concept: Which safety case will be prepared for the modification and which independent inspection bodies[52] will be involved?
- Submitting the application to the FOT.

Evidence:
- Application for an operating licence because of a substantial modification
- Description of the modification (cf. 3.2.2)
- Safety report (cf. 3.2.3)
- Approval concept: The approval concept must be agreed with the FOT (cf. 3.2.5). The approval concept must also take into consideration the need for interim orders, which are required for example for an interim operating licence for operational testing.

3.2.5 Agreeing the approval concept with the FOT

The FOT and the applicant will agree jointly on the applicant's approval concept after the approval procedure has started.

The approval concept contains a schedule for submitting the evidence and determines the sequence of the individual stages of the approval procedure. This includes involving independent inspection bodies. The information about the evidence to be submitted takes the form of a list which must include at least the document name, issue date and version of the evidence. This must be clear and easily traceable. The applicant must specify which evidence will be submitted and the submission dates. As certain evidence can only be provided in full when the adaptations and modifications have been completed and successfully tested, the applicant must also state which preliminary versions will be submitted. However, the number of preliminary versions for each item of evidence must be restricted to one or two at a maximum. This is because an inspection can only be carried out when the complete evidence is available. The approval concept must also indicate how the modification will be rolled out to a specific fleet of vehicles and which combinations of modified and unmodified vehicles are permitted or not permitted during the roll-out.

The structure of the entire documentation must correspond with Annex 5 of IP-RailO or with Annexes 2 to 4 of this Directive. If only individual parts are being converted, the sections relating to other parts can be left empty or omitted. However, the numbering must follow Annex 5 of IP-RailO. This means that the documentation can easily be submitted to the FOT and processed by the FOT.

Activities:
- Agreeing and coordinating the approval concept between the applicant and the FOT, in particular with regard to the classification of the modifications and the involvement of independent inspection bodies.

Evidence:
- Agreed approval concept

[52] In accordance with the FOT Directive "Unabhängige Prüfstellen Eisenbahnen" (Independent Railway Inspection Bodies), available at www.bav.admin.ch > Rechtliches > Richtlinien (in German)

3.2.6 Preparing the safety case

After the approval concept has been agreed by the applicant and the FOT and the safety case concept has been prepared, the modifications can be made and the necessary documents for the safety case can be produced.

Activities:

- Carrying out the modifications to the vehicle
- Preparing the safety case

Evidence:

- Safety case

A safety case for a vehicle or a conversion consists of all the individual partial safety cases relating to a system (for example, doors). The applicant is responsible for deciding how the safety cases are structured. The applicant must ensure that all the relevant or modified parts, including the relevant interfaces, are covered in full.

In the case of larger conversions, it makes sense to prepare individual partial safety cases, for example for each converted assembly or system. This is because these include areas that involve substantial changes and other areas with a high safety relevance and, therefore, require an additional report from an independent inspection body.

If individual partial safety cases are prepared, an overall safety case must be provided that references all the partial safety cases and gives an overall assessment.

The safety case of a partial aspect must contain the following elements:

1. Summary

   This must explain in brief what the safety case is about (context) and summarise the result.

2. Description

   The system or the function which is affected and which the safety case refers to must be described. In the case of modifications, these must be described and presented.

3. Assumptions and boundaries with other systems

   The assumptions and the system boundaries must be described. What is included and what is no longer included? Where are the interfaces? What information can be found in another safety case?

4. Relevant regulations and standards

   The relevant regulations and standards and the specifications on which the inspection is based must be listed.

5. Evidence that the design conforms to the regulations
   - In the case of interoperable vehicles[53]: Certificates of conformity affected by the modification from the Notified Bodies or Designated Bodies, if available.
   - In the case of non-interoperable vehicles: Evidence affected by the modification in accordance with Annex 5 of IP-RailO or with Annexes 3 or 4 of this Directive.

6. Evidence of correct functioning

[53] For the structural subsystems and the interoperability components described in Annex II and IV of Directive (EU) 2016/797, the EC declaration of verification corresponds with this evidence.

Evidence must be provided to document the fact that the modified system or modified function meets the requirements. This evidence can take the form of validation reports or test logs, for example.

7. Evidence of a lack of retroactive effects

   Evidence that the modifications have no influence on the systems, components or functions that are not affected. This evidence can be provided in the form of an analysis or of test logs (for example, regression tests).

8. Expert report[54]

   If the modification has high safety relevance, reference must be made to the required report from an independent expert.

9. Safety report

   For all projects that require an operating licence, the applicant must submit a safety report as part of the preparation of the approval concept. The safety report must contain the following elements:

   - Evaluation of whether the design conforms to the regulations on the basis of the evidence to be submitted as part of the approval concept. If there are deviations from the regulations, a safety analysis must be provided which highlights the resulting risks and the measures taken to counteract these risks[55].
   - Supplementary safety analysis concerning other risks involved in operational use, including the measures taken to counteract these risks.
   - In the case of modifications, an evaluation of their significance.

10. Safety assessment report

    If the modification is significant, under Art. 8*c* RailO railway undertakings must implement a risk management procedure in accordance with the CSM Regulation[56]. Reference must be made to the necessary report from the risk assessment body.

11. Results and measures

    The results of the measures must be assessed and any operational measures must be indicated or described.

12. Conclusion

    Here the applicant must state at a minimum that from the applicant's perspective the (modified) vehicle complies with the regulations and can be operated safely, provided that the specified measures are taken.

13. Signatures

    The person or people responsible for the safety case must sign the document.

[54] In accordance with the FOT Directive "Unabhängige Prüfstellen Eisenbahnen" (Independent Railway Inspection Bodies), available at www.bav.admin.ch > Rechtliches > Richtlinien (in German)

[55] For example on the basis of EN 50126 and of Regulation (EC) No 402/2013 of 30 April 2013 on the common safety method for risk evaluation and assessment (CSM)

[56] Regulation (EC) No. 402/2013 of 30 April 2013 on the common safety method for risk evaluation and assessment (CSM)

3.2.7 Submitting the safety case and FOT inspection

Activities:

- Submitting the complete safety case to the FOT

Evidence:

- Safety case (cf. 3.2.6)

The FOT checks whether the complete documentation required for the safety case has been submitted. The FOT makes spot checks of the safety case to test for risks relating to technical compatibility and safe integration. The FOT also ensures that the measures identified in the safety report under Art. 8*a* para. 2 RailO have been implemented.

The FOT and/or an independent expert carries out a technical operational safety assessment to check that the essential regulations have been complied with, by means of spot checks of the vehicle. Using the documents and evidence submitted, the FOT decides how this inspection is to be carried out and by whom, or whether it can be waived altogether. If the inspection is carried out by an independent expert, the FOT will base its decisions on the expert's reports.

4 Software modifications

4.1 Classification of software modifications

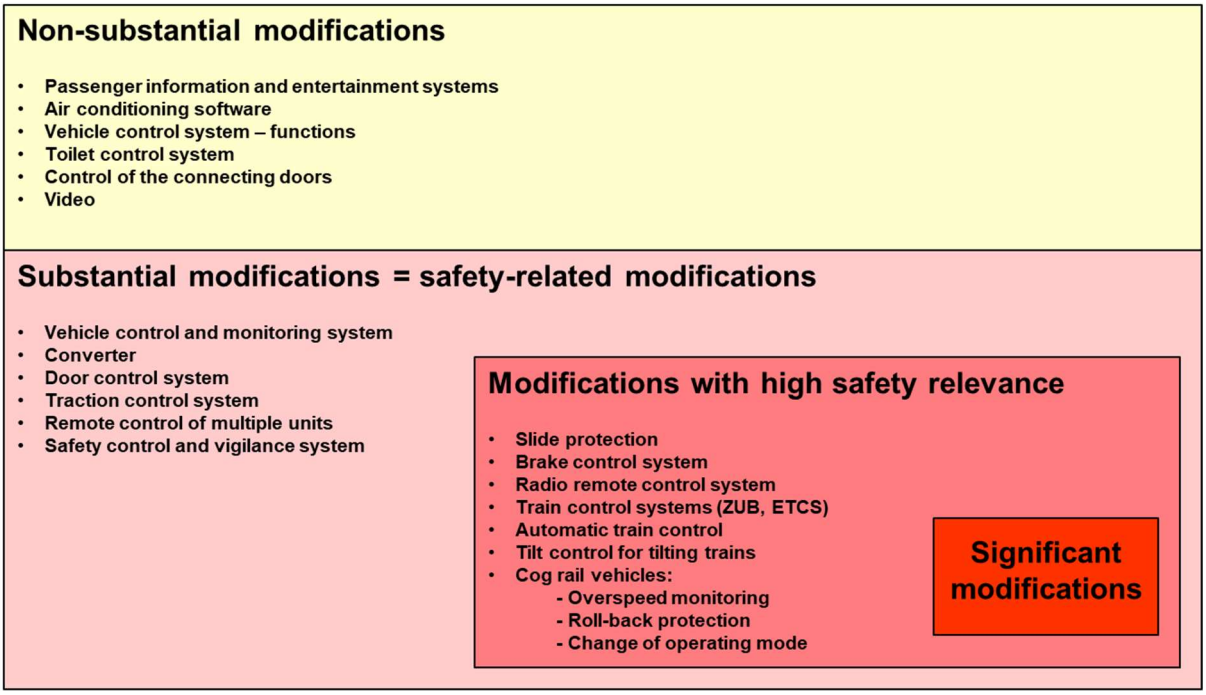

Figure 8: Classification of software modifications (the list of examples is not comprehensive)

4.2 Procedure and documentation for safety cases for non-substantial software modifications

Non-substantial modifications

- ⇨ No application to the FOT required
- ⇨ Validation and testing on the track and in commercial operation at the railway undertaking's own responsibility
- ⇨ Documentation and preparation of evidence
  - Main document with:
    - List of modifications
    - Description of software modifications, software requirements specification
    - Evaluation of the safety relevance of the modifications
    - Explanation of the fitness for service and lack of retroactive effects
    - List of documents containing further evidence
  - Release notes
  - Test and validation reports, including lack of retroactive effects
  - Software configuration list

Figure 9: Non-substantial modifications

4.3 Procedure and documentation for safety cases for substantial software modifications

Substantial modifications = safety relevant modifications

⇨ **Interim operating licence for operational testing**
- Interim order if validation on the track is needed.
- Application to the FOT for operational testing specifying the place and time, describing the modifications and providing the available evidence.

⇨ **Interim operating licence for commercial testing**
- Interim order for 1-2 vehicles.
- Application to the FOT for operational testing specifying the place and time, describing the modifications and providing the available evidence.
  (For example, report from static and dynamic testing, validation, approval by the operator, for example SIOP B).

⇨ **Operating licence after modification for commercial operation**
- Application for operating licence with information as described in the Directive on the Approval of Rolling Stock

⇨ **Submission of documentation (safety case) to the FOT**
- Main document with:
  - List of modifications
  - Evaluation of the safety relevance of the modifications
  - Explanation of the fitness for service and lack of retroactive effects
  - Explanation that the design conforms to the regulations
  - List of documents containing further evidence
- Release notes with description of the software modifications, software modification specifications
- Report on operational testing and commercial testing
- Test and validation reports, including lack of retroactive effects
- Software configuration list
- Safety report
- For interoperable vehicles: Reports from the DeBo and NoBo if the TSI or NNTR are affected.

Figure 10: Substantial modifications

4.4 Procedure and documentation for safety cases for software modifications with high safety relevance

Modifications with high safety relevance

⇨ **Interim operating licence for operational testing**
- Interim order if validation on the track is needed.
- Application to the FOT for operational testing specifying the place and time, describing the modifications and providing the available evidence.

⇨ **Interim operating licence for commercial testing**
- Interim order for 1-2 vehicles.
- Application to the FOT for operational testing specifying the place and time, describing the modifications and providing the available evidence.
  (For example, report from static and dynamic testing, validation, approval by the operator, for example SIOP B).

⇨ **Operating licence after modification for commercial operation**
- Application for operating licence with information as described in the Directive on the Approval of Rolling Stock

⇨ **Submission of documentation (safety case) to the FOT**
- Main document with:
  - List of modifications
  - Evaluation of the safety relevance of the modifications
  - Explanation of the fitness for service and lack of retroactive effects
  - Explanation that the design conforms to the regulations
  - List of documents containing further evidence
- Release notes with description of the software modifications, software modification specifications
- Report on operational testing and commercial testing
- Test and validation reports, including lack of retroactive effects
- Software configuration list
- Safety report
- For interoperable vehicles: Reports from the DeBo and NoBo if the TSI or NNTR are affected.
- Report by an independent expert covering at least the following points:
  - Design that conforms to the regulations
  - Correct functioning
  - Lack of retroactive effects
  - Conclusions, recommendations, conditions

Figure 11: Modifications with high safety relevance