



# **MODSafe**

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Seventh Framework Programme  
MODSafe Modular Urban Transport Safety and Security  
Analysis**

**Work package 7: Acceptance, Approval, Certification**

**Review of current AAC-procedures**

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## Table of Content

<b>1</b>	<b>Introduction.....</b>	<b>5</b>
1.1	References .....	6
1.2	Terms and Abbreviations.....	7
<b>2</b>	<b>Overview of acceptance, approval and certification.....</b>	<b>9</b>
2.1	Best practice of other domains .....	11
<b>3</b>	<b>Method of the work package .....</b>	<b>12</b>
3.1	Synergy with work package 6 .....	13
<b>4</b>	<b>Current European Practices .....</b>	<b>14</b>
4.1	Tram/light rail and metro systems.....	15
4.2	Q1: Are there Safety Regulatory Authorities appointed for Metros/Trams? .....	18
4.3	Q2: Is there any legal basis for the Safety Regulatory Authorities' activities? .....	20
4.4	Q3: Are there any national rules or regulations by the Safety Regulatory Authorities for obtaining system approval? .....	23
4.5	Q4: Are there any national functional, technical or operational requirements to be fulfilled for obtaining system approval?.....	25
4.6	Q5: Is the involvement of Independent Safety Assessors regulated? .....	27
4.7	Q7: Are Trams and Metros treated differently in terms of methods or requirements for obtaining system approval? .....	29
4.8	Q11: If the Safety Regulatory Authorities are active, do they delve down into the subsystems?.....	31
4.9	Q16: Are verification and validation of installed equipment or delivered rolling stock prior to operation regulated; who is in charge for these activities and which kinds of documentation is necessary (e.g. safety case)?.....	33
4.10	Q18: Is modification and retrofit of installed equipment or delivered rolling stock after start of operation regulated? If yes, explain who is in charge asking for acceptance for modification / retrofit and who is in charge to supervise these activities. ....	35
<b>5</b>	<b>Case studies .....</b>	<b>37</b>
5.1	London Underground Case Study .....	37
5.2	RATP Case Study .....	38
5.3	The case study for Hungary .....	39
5.4	Danish Case Study.....	40
5.5	Case study for Germany.....	41
<b>6</b>	<b>Lessons learned from current practices and case studies .....</b>	<b>42</b>
6.1	Definition of acceptance, approval and certification .....	42
6.1.1	Acceptance .....	42
6.1.2	Approval.....	42
6.1.3	Certification.....	42
6.2	Main participants of the approval, acceptance and certification processes.....	43
<b>7</b>	<b>Description of approval processes.....</b>	<b>45</b>
<b>8</b>	<b>Conclusion and further work.....</b>	<b>47</b>

## Table of Figures

Figure 1 – Participants of the safety process .....	9
Figure 2 – Work process of WP7 .....	12
Figure 3 – Approval process in France .....	38
Figure 4 – Schema of the Approval Process for the Metro Copenhagen [MODSAFE D1.1] ..	41
Figure 5 – Example of a cross functional flow chart.....	45
Figure 6 – Example of a UML activity diagram.....	46

## 1 Introduction

The Acceptance, Approval and Certification (AAC-) procedures are characterized by high diversity in different European countries. Diverse actors are involved and different procedures and different roles are applied along the AAC-course in the field of urban guided rail systems, which are non-interoperable with other rail systems and are rarely needed for interconnectivity with another rail system (e.g. tram-train). The diversity relates also to functional and safety requirements, safety models. The diversity also includes certain situations, in which there is no need for certification at all. However according to [MODURBAN D93] some synergies can be observed in this field.

The main objective of the work package 7 within this EU-funded MODSafe project is to make the diversity transparent for participants of these processes (suppliers, operators etc.) by developing and proposing a typical optimised framework for the AAC procedures, which is based on elementary activity modules and on an analysis of current AAC procedures over Europe.

This deliverable is the first step within this work, by surveying the current AAC-procedures in different European countries, focusing on Metros, Light Rail Systems, and Trams.

Remark: the abbreviation AAC for Acceptance, Approval and Certification activities is a new term, introduced within the MODSafe project.

## 1.1 References

Reference-ID	Document title, identifier and version
MODURBAN D93	ModUrban Deliverable Report – WP23 – D93
CENELEC	CENELEC EN 50126/50128/50129
Storey 1996	Storey, Neil: Safety-Critical Computer Systems. Addison-Wesley Longman Ltd. 1996.
MODSAFE D1.1	First Draft – State of the Art on Safety Responsibilities and Certification. MODSAFE Deliverable D1.1.DL-D1.1_INRETS_WP1
MODSAFE D6.1	MODSafe WP6: Del. 6.1. Survey of current safety life cycle approaches DEL_6.1_TRIT_WP6_V1.0_31-05-2010
Case study UK	MODSafe WP6/7: Case Study UK (London Underground) Document ID: LU Case Study_WP67_V0_070709
Case study RATP	MODSafe WP6/7: Case Study RATP French case Document ID: REP_FR_RATP_WP6/7_V2_100210
Case study BME	MODSafe WP6/7: Case Study Hungary Document ID: REP_CS_H_BME_WP6/7_V0_150609
GLOSSARY.en	MODSafe Glossary - Deliverable No. D10.5, Document ID: DEL_D10.5_RATP_WP10_091209_V1
Ince 1992	Ince, D. C.: An Introduction to Discrete Mathematics, Formal System Specification and Z. Clarendon Press. Oxford. 1992.
EN 17000	EN ISO/IEC 17000:2004 Conformity assessment -- Vocabulary and general principles
EN 45020	EN45020:1998 Standardization and related activities. General vocabulary

## 1.2 Terms and Abbreviations

The terms used in this project are explained in the document [GLOSSARY.en]. In addition, the following abbreviations are used in this document:

Abbreviation	Explanation
AAC	Acceptance, Approval, Certification
BIRMTG	Bureau Interdépartemental des Remontées Mécaniques et des Transports Guidés
BME	Budapest University of Technology and Economics
BOStrab	Verordnung über den Bau und Betrieb der Straßenbahnen (BOStrab) the German Federal Regulation on Light Rail Systems and Metros.
BSPP	Brigade des Sapeurs Pompiers de Paris
CAA	Civil Aviation Authorities
CCDSA	Commission Consultative Départementale de Sécurité et d'Accessibilité
CENELEC	Comité Européen de Normalisation Electrotechnique (European Committee for Electrotechnical Standardisation)
CNESTG	Commission Nationale d'Évaluation de la Sécurité des Transports Guidés
DDS	Dossier de Définition de Sécurité (Safety Definition Case)
DPS	Dossier Préliminaire de Sécurité (Preliminary Safety Case)
DREIF	Direction Régionale de l'Équipement Ile de France (Regional Department of Equipment for Ile de France area)
DS	Dossier de Sécurité (Safety Case)
DVIS	Dienst Veiligheid en Interoperabiliteit der Spoorwegen (also abbrev SSICF in French)
EN	European Standard
EOQA	Expert ou Organisme Qualifié Agréé (Independent Assessor Body accredited by the National Safety Authority)
ERA	European Rail Agency
ERTMS	European Rail Traffic Management System
EU	European Union
FAA	Federal Aviation Authority
GAME	Globalement Au Moins Equivalent (Globally at least equivalent)
GOA	Grade of Automation
ICP	Independent Competent Person
IMTT	Instituto da Mobilidade e dos Transportes Terrestres
ISA	Independent Safety Assessor
IVW	Inspectie Verkeer en Waterstaat
KHVM	Közlekedési, Hírközlési és Vízügyi Minisztérium (Hungarian Ministry for Water, Telecommunication and Transportation Affairs)
LU	London Underground
NKH	Nemzeti Közlekedési Hatóság
ORR	Office of the Rail Regulator
RA	Railway Authority
RAMS	Reliability, availability, Maintainability and Safety

<b>Abbreviation</b>	<b>Explanation</b>
RATP	Régie Autonome des Transports Parisiens (Autonomous Paris Transport Authority)
ROGS	Railway and Other Guided Transport Systems (Safety) Regulation 2006
SMS	Safety Management System
SSICF	see DVIS
STIF	Syndicat des Transports d'Ile de France
STPG	Safety of Public Guided Transit
STRMG	Service technique des Remontées Mécaniques et des Transports Guidés
TAB	Technische Aufsichtsbehörde (Technical Supervisory Authority)
TSI	Technical Specification for Interoperability
UK	United Kingdom
UML	Unified Modelling Language
US	United States
UTK	Urząd Transportu Kolejowego

The definitions of rail systems, related to this document are specified in [MODSAFE D6.1]:



## 2 Overview of acceptance, approval and certification

The process of putting-into-service of safety-critical systems and especially transportation and railway systems is a complex, multiplayer process, where different actors have different roles and tasks. From a wider point of view, the diversity of these processes in different countries also increases the complexity of AAC process. The aim of these processes (no matter how clearly the processes are specified) is to guarantee that the system installed fulfils certain requirements. Requirements can be classified generally into the following requirement classes [Ince 1992]:

- functional requirements which detail what the system is to do;
- non-functional requirements which constrain the developer in subsequent activities in the life cycle;
- goals which guide the developer where choice exists;
- references to data used by the proposed system;
- design or implementation advices.

Safety requirements (if there are any) may appear as an individual requirement class or as a part of the functional and non-functional requirements.

The fulfilment of different requirements can be checked by different parties during the life cycle of the system. The different parties have of course in this process different interest, different expertise and knowledge on the system. This is a pre-requisite of the guarantee of independence, which is required by the CENELEC EN 50126 and accompanying standards [CENELEC].

Generally the main participants of this process are

- the supervisory authority, which licenses the operation of the system,
- the customer and operator of the system (for example a transportation company),
- the contractor; the developer and manufacturer industry and
- the safety assessor, independent expert, if required.

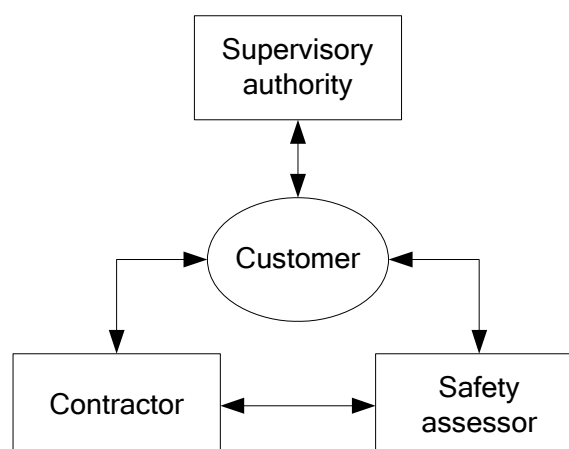


Figure 1 – Participants of the safety process

The transportation company, for example, fixes its requirements on a new system or equipment in a *customer statement of requirements*. In many cases this document has to be

approved by the supervisory authority, and this is the basis for the developer to elaborate the company-specific *system specification*. This system specification is the starting point of the system development. According to the regulation of several European countries, before the installation, the documentation of system and the equipment itself must be examined by an expert. His positive report is a precondition to receive the operation license from the supervisory authority.

The management of the transportation companies, in particular the safety management is supported in many cases by a safety organisation, which coordinates and carries out the tasks of the safety process from the viewpoint of the transportation company. Similarly, the developer also has their own (internal or external) safety organisation, which is responsible for the safety of the supplied system and for the proof, that the specification of safety requirements is fulfilled.

Keeping the level of risk in the transportation processes as low as possible is primarily the responsibility of the transportation companies particularly in case of mass transit. Therefore it is desirable, that the management of the transportation system can prove that the required level of safety for the transportation process is achieved. The setting and agreement of the safety target is often the task of some authority, which is competent in safety issues.

Certification is the process of issuing a certificate to indicate conformance with a standard, a set of guidelines or some similar document [Storey 1996]. According to [MODSAFE D1.1] certification is an activity whereby a designated body, independent of the involved entities, gives a written assurance that a product, process or service conforms to specified requirements.

In fact, any organization or individual may issue a certificate, and its importance will clearly vary with its nature and its issuing body. In some cases a certificate may be required for legal reasons: for example, an airworthiness certificate is required before an aircraft is allowed to fly. In such circumstances the certificate takes on the role of a licence from a statutory authority. The need for such licences for safety-critical systems varies greatly between countries. For the field of urban rail systems the variability is very characteristic as certification is not necessarily required in many cases and the organisations which allow the operation also vary from country to country.

In order to achieve certification, the developer of a safety-related product must convince the appropriate regulator of its safety. Given the abstract nature of safety, this is invariably a difficult task. The developer must be able to show that all important hazards have been identified and dealt with, and that the integrity of the system is appropriate for the application. Certification may also require evidence of compliance with some particular standard, although such compliance is not in itself sufficient proof of the appropriateness of the design. The developer will need to provide extensive evidence of the development methods used, and the testing performed to investigate the system's behaviour. In addition, it will be necessary to produce a rigorous argument to support the claim that the system is sufficiently safe, and that it will remain so throughout its life. The work involved in achieving certification is considerable and requires careful planning.

Note, that definitions for acceptance, approval and certification to be used within the work package 7 will be described in this document in sub-clause 6.1.

## 2.1 Best practice of other domains

In the field of railway transportation (not urban rail systems) the acceptance and certification process for ERTMS systems is also remarkable. These systems have to be assessed with respect to safety and have to be certified for their conformity to European specifications in order to prove the interoperability of these systems. The technical specifications for interoperability (TSI) are published by the European Railway Agency.

The conformity of a system to the specification is examined and certified by so-called notified bodies. A notified body is a certification organisation which the national authority (the competent authority) of a member state designates to carry out one or more of the conformity assessment procedures. A notified body must be qualified to perform its activities. A competent authority may designate as a notified body only organisations that come under its own jurisdiction. The competent Authority notifies those bodies it selects as being suitable to the European commission. The selection criteria are designed to ensure impartiality and expertise of prospective Notified Bodies. After a notified body is appointed the Competent Authority periodically audits it to ensure the expected criteria are still being met. Notified Body status may be withdrawn if these criteria are no longer met [MODURBAN D93]. There is a cross acceptance process between all the Notified Bodies in Europe under the authority or ERA (European Railways Agency).

In other fields certification is often carried out by government bodies, or organisations with a national standing, to indicate 'acceptability' with respect to specific criteria. Examples of non-government bodies that undertake certification include Lloyd's Register in the UK and Underwriters' Laboratories in the US. Certification may also be performed by companies in relation to their suppliers or subcontractors [Storey 1996].

Many industries have a regulatory authority that governs all projects within that sector. For example, all civil aircraft systems must be approved by the Civil Aviation Authority (CAA) in the UK and by the Federal Aviation Authority (FAA) in the US. Other countries have equivalent bodies. Similar regulatory authorities exist in many sectors, including the nuclear, gas supply, rail and mining industries. Military projects are controlled by the appropriate government department, such as the Ministry of Defence in the UK and the Department of Defense in the US [Storey 1996].

### 3 Method of the work package

In this chapter we introduce briefly the method how this work package 7 can reach its desired aim.

As mentioned in the introduction, the Acceptance, Approval and Certification (AAC-) procedures are characterised by high diversity in different European countries. The main objective of this work package is to develop a typical optimised framework for the AAC procedure based on elementary activity modules and on an analysis of current AAC procedures over Europe.

Such typical optimised framework could offer relevant authorities a common reference over Europe and therefore facilitate the creation of new urban rail systems.

A typical optimised framework AAC-procedure can only be proposed based on an adequate analysis and synthesis process (Figure 2). The analysis phase of this WP consists of two steps: first the current AAC-procedures in different countries and cities of Europe will be reviewed. This is done in this deliverable. Secondly, in this survey the elementary activity steps will be identified. As a result a list of elementary activity modules will be provided. In the synthesis phase first a typical model of an AAC-procedure will be drafted based on the elementary activity modules. In a second step, based on the typical model, a typical optimised framework AAC-procedure will be proposed.

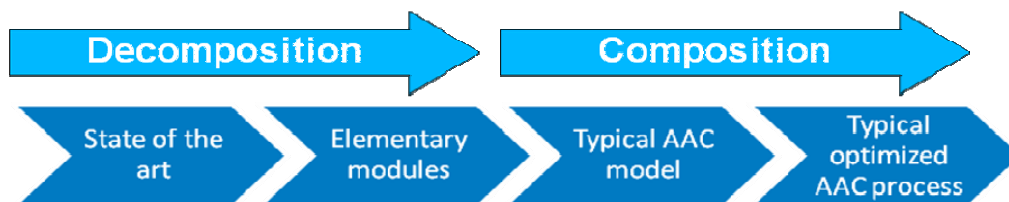


Figure 2 – Work process of WP7

The work process is organized into different tasks:

#### **Task 7.1: Survey of current AAC-procedures**

Any future proposal can reach its aim only if the current situation is clear, functions and motivations in the current processes are understood. Thus, in this task a compilation of current AAC-procedures in different European countries is carried out.

#### **Task 7.2: Identifying elementary activity modules**

A convergence of the different national and regional framework AAC-procedures may only be successful, if a generic AAC-model consists of *elementary activity modules*. Though carried out by different authorised bodies or at different phases of the safety life cycle the formal activities carried out in the different AAC-procedures are to a wide extent similar. A main task is to identify the major *activity modules* on which the AAC-processes are in principle based.

#### **Task 7.3: Typical AAC-model**

Under this task a typical AAC-procedure, based on the elementary activity modules is modelled and proposed.

#### **Task 7.4: Proposal for a typical optimised AAC process**

Based on the survey and based on the generic description of an AAC-process a typical (i.e. clear, logical and both in time and cost minimal resources) process framework will be developed and proposed.

#### **3.1 Synergy with work package 6**

The work package WP6 and WP7 have in MODSafe a common outgoing base, namely the current state of the art of European Practices on Life Cycle issues (WP6) and Acceptance, Approval and Certification (WP7). Therefore at the beginning of the common work it was decided to merge the survey of this two work packages in order to avoid unnecessary duplication.

## 4 Current European Practices

In [MODSAFE D6.1] a questionnaire was introduced in order to get a high level overview on current European practices on Safety Life Cycle approaches (WP6) and Acceptance, Approval and Certification processes (WP7). The questionnaire consists of 19 questions, from which the following questions are relevant for AAC-procedures:

1. Are there Safety Regulatory Authorities appointed for Metros/Trams?
2. Is there any legal basis for the Safety Regulatory Authorities' activities?
3. Are there any national rules or regulations by the Safety Regulatory Authorities for obtaining system approval?
4. Are there any national functional, technical or operational requirements to be fulfilled for obtaining system approval?
5. Is the involvement of Independent Safety Assessors regulated?
7. Are Trams and Metros treated differently in terms of methods or requirements for obtaining system approval?
11. If the Safety Regulatory Authorities is active, do they delve down into the subsystems? If yes, explain who is in charge for these activities.
16. Are verification and validation of installed equipment or delivered rolling stock prior to operation regulated; who is in charge for these activities and which kinds of documentation is necessary (e.g. safety case)?
18. Is modification and retrofit of installed equipment or delivered rolling stock after start of operation regulated? If yes, explain who is in charge asking for acceptance for modification / retrofit and who is in charge to supervise these activities.

The questionnaire was intended to fill for all countries in the EU, however some countries, which have not got actually metro or tram systems have been ignored. These countries are:

- Cyprus,
- Lithuania,
- Luxembourg,
- Malta,
- Slovenia.

For some of the countries which do have metro and/or tram/light rail systems, the approval and certification process is not elaborated or used and in some cases the relevant information was not available for this deliverable, therefore the following countries will be ignored furthermore in the following examinations.

- Bulgaria,
- Finland,
- Ireland,
- Latvia,
- Romania.

If later on more information can be gained from these countries, they can be involved in the examinations.

The source of information is the MODSafe deliverable D6.1 [MODSAFE D6.1].

In the following the examined European countries will be summarised with respect of having tram/light rail and/or metro systems. Then the responses will be demonstrated and analysed.

#### 4.1 Tram/light rail and metro systems

In the following compilation the European countries are summarised with respect of their tram and metro systems, which shall be taken into account in further investigations.

Country	Tram/Light rail	Metro
Austria	Yes, e.g. Vienna, Linz, Graz, Innsbruck and Gmunden	Yes, Vienna
Belgium	Yes, e.g. Antwerp*, Ghent and Brussels, the Kusttram, and the Charleroi Pre-metro*. * Metro metro-style underground sections (Light rail)	Yes, Brussels
Czech Republic	Yes, e.g. Prague, Brno, Ostrava, Plzeň, Olomouc, Most and Litvínov, Liberec / Jablonec	Yes, Prague
Denmark	No	Yes, Copenhagen
Estonia	Yes, e.g. Tallin	No
France	Yes, e.g. Paris, Lyon, Marseille, Nantes, Grenoble, Montpellier, St Etienne , Strasbourg, Bordeaux, Nice, Valenciennes, Clermont Ferrand, Le Mans, Mulhouse, Orléans, Rouen	Yes, Paris, Rennes, Toulouse, Lyon, Lille, Marseille
Germany	Yes, Tram: Berlin, Brandenburg, Leipzig, Erfurt, Nürnberg, München etc. Light rail: Hannover, Dortmund, Essen, Köln etc.	Yes, Berlin, Hamburg, München, Nürnberg (3 <sup>rd</sup> rail systems)
Greece	Yes, e.g. Athens	Yes, Athens, Thessaloniki (under construction)

Country	Tram/Light rail	Metro
Hungary	Yes, Budapest, Szeged, Debrecen, Miskolc	Yes Budapest
Italy	Yes, e.g. Milan, Rome, Naples, Bergamo, Sassari, Trieste, Cagliari, Genoa, Padova, Perugia	Yes, e.g. Rome, Milan, Brescia, Turin
The Netherlands	Yes, e.g. Amsterdam and area, Rotterdam and area, The Hague and area, Utrecht.	Yes, Rotterdam, Amsterdam
Poland	Yes, e.g. Bydgoszcz, Częstochowa, Elbląg, Gdańsk, Gorzów Wielkopolski, Śląski region przemysłowy, Grudziądz, Kraków, Łódź, Poznań, Szczecin, Toruń, Warszawa and Wrocław.	Yes, Warszawa
Portugal	Yes, e.g. Lisboa, Porto* * Metro metro-style underground sections (Light rail)	Yes, Lisboa
Slovakia	Yes Bratislava, Košice	No
Spain	Yes e.g. Barcelona, Valencia, Bilbao, Alicante*, Madrid, Velez Malaga, Parla, Sóller, Vitoria-Gasteiz * Metro metro-style underground sections (Light rail)	Yes Barcelona, Madrid, Bilbao, Valencia, Palma. Seville
Sweden	Yes e.g. Gothenburg, Stockholm, and Norrköping.	Yes Stockholm
UK	Yes e.g. Nottingham, Sheffield, Blackpool, Croydon, West Midlands, Docklands Light Rail	Yes London Underground, Newcastle, Glasgow



Note, that there are special kinds of light rail / metro / tramway operation, whereas at specified parts of the track the term “tram” can be applied to the same mode of transportation, while on other parts of the track the same vehicle operates as light rail (like tram-train systems or trams in the border areas (eg. Strasbourg and Lille)).

Also note that metro systems may operate at different grades of automation (GOA). This however does not have any effect on the *process* of the approval, acceptance and certification. Therefore no distinction was made in this sense in the table.

#### 4.2 Q1: Are there Safety Regulatory Authorities appointed for Metros/Trams?

<b>Question:</b>	Are there Safety Regulatory Authorities appointed for Metros/Trams?	
<b>Country</b>	<b>Answer</b>	<b>Explanation</b>
Austria	Yes	One authority for every Bundesland
Belgium	No	For tramways / trams / (pre-) metros and Light Rail the Region (e.g. for Flanders the Flemish government) is sole responsible (this is a regionalised subject with exclusive competences for the Region). Exception: for the brake systems DVIS / SSICF is responsible.
Czech Republic	Yes	A "Safety Regulatory Authority" on an approach defined in this questionnaire does not exist in the Czech Republic. In most of the cases the function of a safety regulation is performed by "Drážní úřad" (Rail Authority)
Denmark	Yes	Trafikstyrelsen for Jernbane og Færger (Traffic Authority for Railway and Ferries)
Estonia	No	The city of Tallinn is responsible and the operator is the Tallinna Trammi – ja Trollibussikoondise.
France	Yes	For BIRMTG (cf. sub-clause 8.1.3 of [MODSAFE D1.1])
Germany	Yes	One authority ("Technische Aufsichtsbehörde", TAB) for every state (Bundesland). These authorities are different from those of railways.
Greece	Yes	Ministry of Transport / Attiko Metro & expert opinion from accredited Inspection Body
Hungary	Yes	NKH, National Transport Authority
Italy	No	Ad hoc "commissione di sicurezza" and expert opinion from accredited Inspection Body. Relations between safety entities and applicant (manufacturers or operators) are not well known, the legislation about safety of transportation systems being in Italy a priori in process of development.
The Netherlands	Yes	Inspectie Verkeer en Waterstaat (IVW) - Inspection Traffic and Water
Poland	Yes	For metros UTK (for metro only). Local authorities (Województwa) for trams.

Question:	Are there Safety Regulatory Authorities appointed for Metros/Trams?	
Country	Answer	Explanation
Portugal	Yes	The Safety Regulatory Authority is part of the central government and is called IMTT - mobility and terrestrial transports authority and covers all railroads, including metro, light rail and tram systems.
Slovakia	Yes	The Railway Regulatory Authority (Úrad pre reguláciu železničnej dopravy)
Spain	No	Every autonomous region has its own legislation. In Valencia, e.g., autonomous region there is no Safety Regulatory authority appointed for metro, light rail and tram.
Sweden	Yes	The Swedish Rail Agency (Järnvägsstyrelsen). Swedish Transport Agency (Transportstyrelsen) was established in 2009 where the former "The Swedish Rail Agency (Järnvägsstyrelsen)" is a part together with road, aviation and shipping.
UK	Yes	The Office of Rail Regulation (ORR).

Analysing the answer, we can conclude that the existence of an authority may have different levels (explained bellow) in different countries. The levels may vary according to metro or tram systems, and there may be other differentiations, e.g. some of the authorities only regulate for transport systems that operate above certain speed limits. The levels which can be identified are the following:

1. No authority or supervisory body: in this case the safe operation is not supervised by an independent body, the operator of the transportation system is responsible for the correct operation. This may be the case often for tram systems, or tram systems with a limited speed (e.g. 20 km/h), but in some cases (e.g. Belgium) it applies also for metro systems.
2. Local supervisory body: in other cases the operator is supervised by a local authority or in other terms by the city in which the transportation operation is carried out. This may be the case for both trams and metros, e.g. in Estonia.
3. State authorities: countries, which have a federation governmental structure (like Austria or Germany) have usually individual regulatory authorities in different federal states.
4. National level authority: in other cases the country has a central, national regulatory authority, which is usually a governmental organisation.

#### 4.3 Q2: Is there any legal basis for the Safety Regulatory Authorities' activities?

Question:	Is there any legal basis for the Safety Regulatory Authorities' activities?	
Country	Answer	Explanation
Austria	Yes	"Strassenbahnverordnung, (Strab VO)" [Regulation on Building and Operating Tramways (including light rail and metro)], 1999. A regulation which is very similar to German BOStrab
Belgium	Yes	Reference legislations are a "Royal Decision" of 15 September 1976 and the "Loi-Programme"/"Programma-wet" of 19 December 2006 modified by the "Loi-Programme"/"Programma-wet" of 22 December 2008 updated on 30 December 2009.
Czech Republic	Yes	The legal basis for the activity of Rail Authority is the Act No. 266/1994 Coll. on railways, as amended. The same Act also establishes the Railway Authority.
Denmark	Yes	"Bekendtgørelse om opgaver og beføjelser i Trafikstyrelsen for Jernbane og Færger" (Decree on the tasks and authorities of Safety Regulatory Authority).
Estonia	No	
France	Yes	By Prefect (specific decree for each authorizations)
Germany	Yes	Personenbeförderungsgesetz (Passenger Transport Act) with BOStrab (Verordnung über den Bau und Betrieb der Straßenbahnen / Regulations on the construction and operation of light rail transit systems) is the federal legal base.
Greece	No	
Hungary	Yes	Ministry decree 18/1998. (VII. 3.) KHVM

<b>Question:</b>	Is there any legal basis for the Safety Regulatory Authorities' activities?	
<b>Country</b>	<b>Answer</b>	<b>Explanation</b>
Italy	Yes	When a manufacturer needs to define a new guided transport system, it must provide a document called "Customer Technical Specs. International standards". It can either carry out the safety study by itself or delegate to an external consultant chosen by their RAMS department. This safety study must include both qualitative and quantitative evaluations by preliminary hazard identification list, subsystem and system hazard analysis, interface hazard analysis, operating and support hazard analysis, Failures Modes Effects and Criticality Analysis, fault tree analysis. The responsibility of this study is incumbent on the manufacturer itself, the consultant activity being constantly monitored by the manufacturer's RAMS department. After having checked the safety abilities of the system, the manufacturer must provide the safety study to the operator or to other entities when requested. To have the approval for the start-up of the project, the operator must have the authorisation of the local safety authorities. Relations between safety entities and applicant (manufacturers or operators) are not well known, the legislation about safety of transportation systems being in Italy a priori in process of development.
The Netherlands	Yes	No information
Poland	Yes	No information
Portugal	Yes	During the design phase, the operator provides a safety and environmental study concerning specifications and operational documents in order to establish the safety/environmental case, which is then transmitted to the safety/environmental authority within the central government. After this, the central government can, according with the documents provided by the operator, allow the construction of the new or renewed system. During the commissioning phase, the operator must validate in collaboration with the manufacturer's factories assessment reports, acceptance tests and functional tests on site. Then, they deliver the following documents to the central government to the Safety Regulatory Authority in order to obtain the license of exploitation: Systems and equipments descriptions, Procedure documents, Test results documents, Maintenance documents, Safety cases, assessment reports, Revised operational documents

<b>Question:</b>	Is there any legal basis for the Safety Regulatory Authorities' activities?	
<b>Country</b>	<b>Answer</b>	<b>Explanation</b>
Slovakia	Yes	Act no. 164/1996 Law on railways
Spain	No	There are different state rail transport laws but no one for a Safety Regulatory Authority for metros and trams.
Sweden	Yes	1990:1157 – Law about safety in Metros/Trams 1990:1165 – Constitution about safety in Metros/Trams JvSFS2007:4 – Safety regulation for Metros/Trams JvSFS 2007:5 – Internal control for Metros/Trams JvSFS 2007:6 – Application of approval for Metros/Trams JvSFS 2006:1 –Regulations of the Swedish Transport Agency on the approval of subsystems in railways, etc (incl Metros and Trams) TS JV 2009:002 - Guide to the approval procedure
UK	Yes	ROGS (Railway and Other Guided Transport Systems (Safety) Regulations 2006).

It is not surprising, that in countries, that haven't got safety authorities there isn't any legal basis for their activities. In every case, where an authority (at local, state or national level) is active, its activity is based on some legislation. However the type of legislation may differ: it can be a law, an act or a decree. We remark, that it is not easy to compare these types, as the system of law and order in different countries may be rather different.

#### 4.4 Q3: Are there any national rules or regulations by the Safety Regulatory Authorities for obtaining system approval?

<b>Question:</b>	Are there any national rules or regulations by the Safety Regulatory Authorities for obtaining system approval?	
<b>Country</b>	<b>Answer</b>	<b>Explanation</b>
Austria	Yes	Regulated by Strab VO
Belgium	Yes	Relevant safety documentation has to be provided to DVIS/SSICF (for brake system). See also answers to Q1 and Q2.
Czech Republic	Yes	As the basis serves the Act No. 266/1994 Coll. on railways as amended and further more relevant national (ČSN) and European standards (EN) which step by step are taken over and gradually introduced to the Czech legislation.
Denmark	Yes	“lov om jernbane” (Railway Law) For the Copenhagen Metro the Danish Safety Regulatory Authority has adopted the German BOStrab and keeps to it as far as applicable.
Estonia	No	
France	Yes	3 files : DDS, DPS, DS (see in more details in sub-clause 8.1.3 of [MODSAFE D1.1])
Germany	Yes	Regulated in BOStrab, supported by other regulations and subordinated guidelines and technical rules.
Greece	No	CENELEC approach is applied for Thessaloniki Metro
Hungary	Yes	Regulated in ministry decree 18/1998. (VII. 3.) KHVM
Italy	Yes	No further information
The Netherlands	Yes	Trams and metros underlie the old railway law from 1875. IVW has to make a “survey” which is not further specified. However, IVW uses the norm document veiligheid Lightrail (Normative document safety Lightrail).
Poland	No	
Portugal	No	The scope of the Safety Regulatory Authority is stated by law.

<b>Question:</b>	Are there any national rules or regulations by the Safety Regulatory Authorities for obtaining system approval?	
<b>Country</b>	<b>Answer</b>	<b>Explanation</b>
Slovakia	Yes	There is the Slovak National Accreditation Service (SLOVENSKÁ NÁRODNÁ AKREDITAČNÁ SLUŽBA). It is a sole accreditation body to execute accreditation in Slovakia.
Spain	No	The regulation of urban transport is entirely controlled by the autonomous region.
Sweden	Yes	According to JvSFS 2006:1 the systems for Metros and Trams shall follow the 'national approval process'.
UK	Yes	ROGS

The answers that could be collected to this answer show a great variability. Some of the answers show, that the *procedure* of obtaining of a system approval is regulated, while others show the *documents* which are necessary to hand-over in order to obtain the system approval, and in some cases the answers combine these two aspects.

To make these differences more transparent, in the later phases of this work package the national rules and regulations for obtaining system approval have to be investigated in more detail in order to have the possibility to compare them.



#### 4.5 Q4: Are there any national functional, technical or operational requirements to be fulfilled for obtaining system approval?

<b>Question:</b>	Are there any national functional, technical or operational requirements to be fulfilled for obtaining system approval?	
<b>Country</b>	<b>Answer</b>	<b>Explanation</b>
Austria	Yes	Regulated in Strab VO, supported by subordinated rules and regulations.
Belgium	No	
Czech Republic	Yes	Selected equipments (known as "specified technical equipments" - in Czech "určená technická zařízení, UTZ") are liable to an approval procedure. STE have to comply with functional and technical requirements and this pays for the whole life cycle.
Denmark	No	The German BOStrab is applied for the Copenhagen Metro.
Estonia	No	
France	Yes	No further information
Germany	Yes	Regulated in BOStrab, supported by other regulations and subordinated guidelines and technical rules.
Greece	No	Attiko Metro has defined the requirements for the Thessaloniki Metro
Hungary	Yes	Only for metros and local (light) railways: 18/1998. (VII. 3.) KHVM rendelet (Ministry decree)
Italy	Yes	It is requested to conform either to European norms, or to Italian norms where the European ones are absent, and to comply with the Ministry of Transport procedures.
The Netherlands	Yes	No further information
Poland	No	
Portugal	Yes	There is a protocol between the Safety Regulatory Authority and the operator.
Slovakia	Yes	Technical conditions (specifications) for road systems and rolling stock.
Spain	No	

<b>Question:</b>	Are there any national functional, technical or operational requirements to be fulfilled for obtaining system approval?	
<b>Country</b>	<b>Answer</b>	<b>Explanation</b>
Sweden	Yes	According to JvSFS 2006:1.
UK	No	Euronorms are applied where appropriate

It can be observed, that only countries which have national or state level regulatory authorities fix some functional, technical or operational requirements at a high level. In some cases these requirements are contained by the decree, act or law, which regulates the approval process and the activity of the regulatory authority.

In case of such high level requirements usually some deeper level, subordinated guidelines, rules and regulation are additionally used for regulation purposes.

In other cases, where there are safety authorities, the functional, technical or operational requirements are not defined at a high level, but it is agreed from project to project between the operator and the authority.

#### 4.6 Q5: Is the involvement of Independent Safety Assessors regulated?

<b>Question:</b>	Is the involvement of Independent Safety Assessors regulated?	
<b>Country</b>	<b>Answer</b>	<b>Explanation</b>
Austria	Yes	Individual persons recognised.
Belgium	No	
Czech Republic	Yes	Safety cases are checked by an external technical approver.
Denmark	No	For the involvement of Independent Safety Assessors the CENELEC standards were / are applied.
Estonia	No	
France	Yes	The decree defines the mission and agreement process of EOQA (Independent Assessor).
Germany	No	Dependent from the Bundesland / Authority. Independent Safety Assessors (officially recognised experts) can be involved on individual request by a Safety Regulatory Authority or by an operator or by a supplier.
Greece	No	
Hungary	No	
Italy	Yes	No further information.
The Netherlands	No	Not formally. In practice, it is mostly required that the Independent Safety Assessor is a Notified Body. In several projects, IVW has the right of rejecting an Independent Safety Assessor.
Poland	No	
Portugal	No	But if present, they must be approved by the Safety Regulatory Authority.
Slovakia	No	
Spain	No	
Sweden	Yes	According to JvSFS 2006:1 (5kap. 3§). The Swedish Transport Agency will require the applicant to have an independent safety assessor to carry out checks of functions that affect traffic safety. The independent safety assessor must be approved by the Swedish Transport Agency.

<b>Question:</b>	Is the involvement of Independent Safety Assessors regulated?	
<b>Country</b>	<b>Answer</b>	<b>Explanation</b>
UK	No	ROGS regulations give guidance on competence. Network Rail maintains a list of Independent Safety Assessors.

The most interesting conclusion which can be drawn from the responses above is that there is a relative strong interest in involving an Independent Safety Assessor in the approval and certification processes. This can be observed by responses, where the short answer is “No”, i.e. that the involvement of a Safety Assessor is not regulated, but there is an explanation, why is the Assessor still involved somehow.

#### 4.7 Q7: Are Trams and Metros treated differently in terms of methods or requirements for obtaining system approval?

<b>Question:</b>	Are Trams and Metros treated differently in terms of methods or requirements for obtaining system approval?	
<b>Country</b>	<b>Answer</b>	<b>Explanation</b>
Austria	No	
Belgium	Yes	There is only one real metro: Brussels, which has a somewhat apart status.
Czech Republic	Yes	The different character of operation and safety requirements connected with each system are taken into consideration in sectoral decrees of the Transport Ministry.
Denmark	n/a	There are no trams in Denmark
Estonia	n/a	There are no metros in Estonia.
France	No	
Germany	Yes	Concerning methods: no; concerning requirements: yes.
Greece	Yes	Different operators, even for Athens Metro
Hungary	Yes	Trams are treated as street vehicles, while metros are railway systems.
Italy	No	
The Netherlands	Yes	The same law, but there are different underlying rules: tramreglement / metroreglement.
Poland	Yes	
Portugal	Yes	This is due to the main activity of the Safety Regulatory Authority being affected to main railways.
Slovakia	n/a	Slovakia has no metros
Spain	No	
Sweden	No	According to JvSFS 2006:1 Metro and Trams are handled in the same way as Railway (1kap, 2§).
UK	Yes	ROGS only partially applies to tramways (except that there is no requirement for Safety Certification / Authorisation and Annual Safety Report)

As it is obvious from the form, about half of the examined countries treat trams and metros

separately and about half of them together (with ignoring the countries which have no trams or metros). The latter case however does not necessarily mean that the same requirements must be fulfilled for metros and trams, but that their approval process is regulated in the same way.

#### 4.8 Q11: If the Safety Regulatory Authorities are active, do they delve down into the subsystems?

<b>Question:</b>	If the Safety Regulatory Authorities are active, do they delve down into the subsystems?	
<b>Country</b>	<b>Answer</b>	<b>Explanation</b>
Austria	Yes	Depends on authority how much depth is gone into.
Belgium	Yes	In case of subsystem “brake” DVIS / SICF is responsible. (see also answer for question 1).
Czech Republic	No	The chosen manufacturer must provide to the operator a complete safety case that may be designed or checked by an external technical approver. The supervision of safety is ensured by independent inspections (technical, operational and even legislative) of the RA, the Rail Inspection (Dražní inspekce) and competent departments of transport.
Denmark	No	The authority relies on recommendations of the Independent Safety Assessors.
Estonia	No	
France	No	
Germany	Yes	Safety Regulatory Authority is active for any kind of system / subsystem and even for any modification of an installed system.
Greece	Yes	For the Thessaloniki Metro Attiko Metro acts as a Safety Authority, but also as the operator. In so far they partly delve down into details in order to check the fulfilment of contractual and so for the safety requirements. On the other hand they rely on Independent Safety Assessors for some aspects.
Hungary	Yes	For signalling systems: The National Transport Authority requires for systems and subsystems an “Applicability Certification”. This must be obtained from an independent expert (currently two universities are notified as such experts) by the supplier of the system or subsystem.  For rolling stock: yes (the authority itself).
Italy	Yes	For main components the Ministry of Transport is in charge for such activities.

<b>Question:</b>	If the Safety Regulatory Authorities are active, do they delve down into the subsystems?	
<b>Country</b>	<b>Answer</b>	<b>Explanation</b>
The Netherlands	Yes	Depending on the person they do it with different depth.
Poland	No	
Portugal	No	
Slovakia	No	
Spain	No	Not usually
Sweden	Yes	Refer to “The regulations of the Swedish Transport Agency on the approval of subsystems in railways, etc.” JvSFS 2006:1. This also covers subsystems of metros and trams.
UK	No	This is the responsibility of the Transport Undertaking / Infrastructure Manager as they have been licensed by the ORR.

If a Safety Regulatory Authority is active in a country, this usually requires information down to subsystem level. It then varies from country to country, whether the examinations are carried out by the Authority itself (like in many cases in Germany) or (e.g. in Denmark or Hungary) it is dedicated to another organisation. If the examinations (or a part of them) are not carried out directly by the authority, then the authority requires some kind of independent assessment report either directly from an assessor (as the supporter of the Authority) or the supplier of the system has to employ this assessor, and the supplier delivers the report of the assessor along with the other documentation of the system.



**4.9 Q16: Are verification and validation of installed equipment or delivered rolling stock prior to operation regulated; who is in charge for these activities and which kinds of documentation is necessary (e.g. safety case)?**

Question:	Are verification and validation of installed equipment or delivered rolling stock prior to operation regulated; who is in charge for these activities and which kinds of documentation is necessary (e.g. safety case)?	
Country	Answer	Explanation
Austria	Yes	No further information
Belgium	No	For tram / metro / light rail such a regulation is planned. Currently these activities are under the responsibility of the operating company. However, they are looking for solutions from abroad.
Czech Republic	Yes	The manufacturer must provide to the operator a complete safety case that may be designed or checked by an external technical approver. For selected equipments checking report is demanded as a basis for an award of a certificate of qualification STE. The certificate of qualification allows asking for equipment use.
Denmark	No	The authority relies on recommendations of the Independent Safety Assessors.
Estonia	No	
France	Yes	No further information
Germany	Yes	Regulated in §§60, 61, 62 BOStrab. Can be done by the “railway authority (responsibility of the “Betriebsleiter”). The supplier is supervised by the “Betriebsleiter” or Safety Assessor, the result has to be provided in an “examination report”.  E.g. for signalling, train control and protection systems the process is regulated by TR SIG ZA.
Greece	Yes	For the new Thessaloniki Metro
Hungary	Yes	The authority requires usually a safety case.
Italy	Yes	For safety issues the Ministry of Transport is in charge for such activities.
The Netherlands	Yes	Safety case is necessary
Poland	Yes	For metros only

<b>Question:</b>	Are verification and validation of installed equipment or delivered rolling stock prior to operation regulated; who is in charge for these activities and which kinds of documentation is necessary (e.g. safety case)?	
<b>Country</b>	<b>Answer</b>	<b>Explanation</b>
Portugal	Yes	Regulated by the protocol between the Safety Regulatory Authority and the operator: Systems and equipments descriptions, Procedure documents, Test results documents, Maintenance documents, Safety and security cases, Assessment reports, Revised operational documents.
Slovakia	Yes	It is contained in Technical conditions for road systems and rolling stock (TP 09/2008; TP 10/2008, ...)
Spain	Yes	<p>The safety case of the manufacturer is written either by themselves or with a safety entity. All technical documents and other documents inherent to the safety like the safety case are transmitted by the operator to the safety authority (“Direccio General de Transport Terrestre, Generalitat de Catalunya” in the case of Barcelona Metropolitan and “Consortio de Transportes de Madrid” in the case of Madrid Metropolitan). The operator/safety authority will accept the new material taking into account the safety case, the test acceptance and, if they require it, an Independent Safety Assessment (ISA).</p> <p>The installed equipment or delivered rolling stock are verified and validated by the project promoters.</p>
Sweden	Yes	Regulated in JvSFS 2006:1. The CENELEC railway application standards are referenced therein and respective activities and documentation are required accordingly.
UK	Yes	On a high level the ORR issues licences. The licenses are issued to the Transport Undertaking / Infrastructure Manager and they are charged with validation, verification and acceptance of safety case documentation.

From the analysis of the answers it seems, that in most of the examined countries (13 out of 16) some kind of safety case is required. In this documentation the supplier of the system or in some cases the operator has to demonstrate that safety of the system.

**4.10 Q18: Is modification and retrofit of installed equipment or delivered rolling stock after start of operation regulated? If yes, explain who is in charge asking for acceptance for modification / retrofit and who is in charge to supervise these activities.**

<b>Question:</b>	Is modification and retrofit of installed equipment or delivered rolling stock after start of operation regulated? If yes, explain who is in charge asking for acceptance for modification / retrofit and who is in charge to supervise these activities.	
<b>Country</b>	<b>Answer</b>	<b>Explanation</b>
Austria	Yes	Strab VO,requires approval. The respective company is in charge for application. Supervision depends from the authority.
Belgium	No	
Czech Republic	Yes	The modification and retrofit activities are exercised by technical units of an operator in cooperation with the manufacturer and the Railway Authority, which establishes relevant conditions for innovations /modifications necessary to be fulfilled. The inspections are exercised by technical units of the operator, but the supreme supervision is exercised by the Railway Authority, which realizes an inspection of the prescribed conditions fulfilment.
Denmark	No	For safety related modifications the authority relies on recommendations of the Independent Safety Assessors.
Estonia	No	
France	Yes	Every significant modification has to submit to safety authorities
Germany	Yes	Same responsibilities and procedures as for new installations or new rolling stock.
Greece	No	It is assumed that the responsibility is assigned to the operator.
Hungary	Yes	Major modifications of installations have to be let approved repeatedly by the Authority.
Italy	Yes	Known, the legislation about safety of transportation systems being in Italy a priori in process of development.
The Netherlands	Yes	Same as for systems
Poland	No	

<b>Question:</b>	Is modification and retrofit of installed equipment or delivered rolling stock after start of operation regulated? If yes, explain who is in charge asking for acceptance for modification / retrofit and who is in charge to supervise these activities.	
<b>Country</b>	<b>Answer</b>	<b>Explanation</b>
Portugal	No	Regulation is made inside operators. In the case of Metro Lisboa, the standard EN 50126 is applied by internal departments of the operator. Different departments and directorates are involved in acceptance.
Slovakia	No	
Spain	Yes	Depending of the operator's criteria.
Sweden	Yes	Regulated in JvSFS 2006:1. The Contractor (normally Banverket or rolling stock owners) initiate the project and The Swedish Transport Agency are involved for approval of the procedure to get the project approved.
UK	Yes	Safety verification scheme required as part of SMS (from ROGS) and therefore the Railway Undertaking / Infrastructure Manager is responsible for acceptance of changes to equipment.

## 5 Case studies

To evaluate the different approval, acceptance and certification processes some case studies have been developed, also together with work package 6. The case studies included the following countries or cities:

- London Underground Case Study [Case Study UK],
- RATP for Paris [Case Study RATP],
- Case Study for the Hungarian Approval Process [Case Study BME].

Furthermore in [MODSAFE D6.1] the

- Danish and the
- German

approval processes were presented as case studies in more detail.

In the following sections we will evaluate these case studies for the scope of work package 7, with respect to approval, acceptance and certification processes. Therefore the main participants in these processes will be analysed with their task in the process.

### 5.1 London Underground Case Study

The approval process of railways and other guided transport systems are regulated in the UK by ROGS (Railways and Other Guided Transport (Safety) Systems Regulations 2006).

From the case study of London Underground [Case Study UK] it can be understood that the main participants of the approval process of railway and other guided transport systems are the followings:

- ORR: Office of the Rail Regulator,
- ICP: Independent Competent Person,
- Transport Undertaking or Infrastructure Manager.

The main task of ORR is to assess the Safety Management System of Transport Operating companies (such as London Underground) and grant them a Safety Certificate. ORR may be regarded as the main Regulatory Authority in the UK. The Safety Certificate has a time limit of 5 years, and allows the Transport Operator to carry out the specified operations within this time limit. To obtain the Safety Certificate two key factors are necessary:

- Written Safety Verification Scheme and
- the use of Independent Competent Persons (ICP).

The Transport Operator should devise the scheme taking into consideration the advice of the ICP. The ICP should be also involved in the establishment of the verification criteria. The ICP is expected to have appropriate levels of impartiality and independence.

## 5.2 RATP Case Study

The case study for RATP [Case Study RATP] describes the process of approval, based on the following diagram.

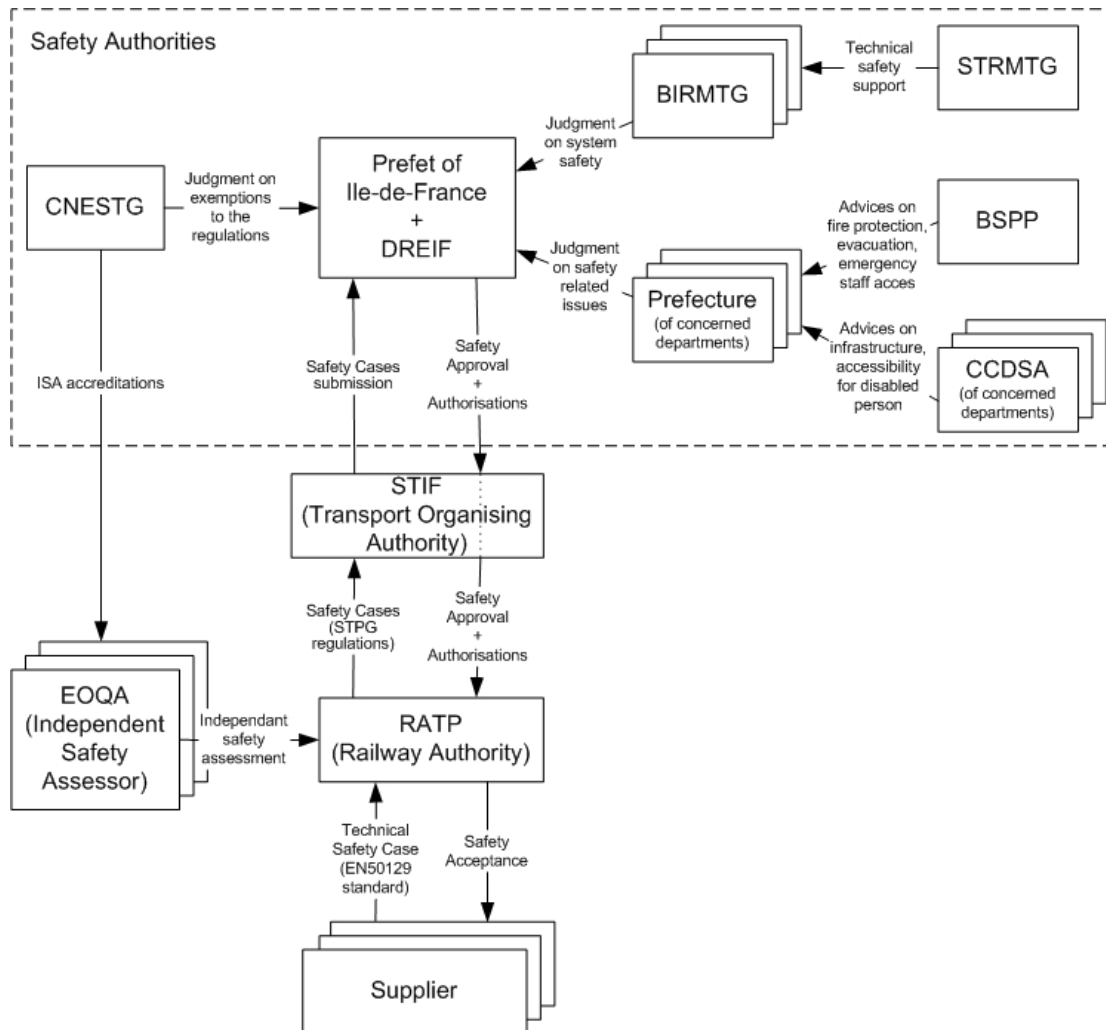


Figure 3 – Approval process in France

The various actors in this process and their jobs are described below :

- Prefet of Ile-de-France  
The Prefet of Ile-de-France delegates the treatment of the safety cases to the DREIF.
- DREIF (Direction Régionale de l'Équipement d'Ile-de-France)  
The DREIF receives the safety cases and forwards them to the several concerned bodies (BIRMTG and prefectures of concerned departments). Ultimately, it pronounces the Safety Approval and signs the needed authorisations.
- STIF (Syndicat des Transports d'Ile de France)  
In Ile-de-France, the STIF is the Transport Organising Authority which delegates the safety cases production to the Operators (RATP) and is responsible for the safety cases submission to the Prefet of Ile-de-France.

- BIRMTG (Bureau Interdépartemental des Remontées Mécaniques et des Transports Guidés)  
The BIRMTG are the local inspection services in charge of the safety cases treatment. There are 5 BIRMTG on the national territory. The north-west BIRMTG, linked with the DREIF is in charge of the projects in Ile-de-France. The BIRMTG give a judgment on the system safety to the DREIF.
- STRMTG (Service technique des Remontées Mécaniques et des Transports Guidés)  
The STRMTG is the national inspection service linked with the Ministry of Transport which gives technical supports to the BIRMTG. It checks compliance with the initial safety requirements, the GAME requirements, the safety standards and the safety regulations.
- Prefectures of the departments  
The Prefects of departments (concerned by the project) give a judgment on safety related issues. Each Prefect could ask for advices to the BSPP and to the CCDSA of his department.
- BSPP (Brigade des Sapeurs Pompiers de Paris)  
The BSPP gives advices on fire protection, on passenger evacuation arrangements and on access arrangements for emergency staff.
- CCDSA (Commission Consultative Départementale de Sécurité et d'Accessibilité)  
Each department has a CCDSA which is consulted each time a project includes a tunnel longer than 300m (or between 100 and 300m if trains are transporting more than 500 passengers). The CCDSA gives advices on infrastructure safety issues and on accessibility to disabled persons.
- CNESTG (Commission Nationale d'Évaluation de la Sécurité des Transports Guidés)  
The CNESTG gives advices on special dispensation or exemption to the regulations (in case of technologic innovation for example). It gives also accreditation to ISA in accordance with STPG regulations.
- EOQA (Expert ou Organisme Qualifié Agréé)  
The EOQA (ISA) performs an independent safety assessment on the system safety based on the Supplier's safety analysis (plus the RATP analysis if needed) to check the compliance with the initial safety requirements, the GAME requirements, the safety standards and the safety regulations.
- RATP  
The RATP (Railway Authority) performs its own assessment on the system safety and gives the Safety Acceptance to the Supplier(s). It produces the various safety cases for the Safety Authorities in accordance with the regulations annexing the EOQA (ISA) assessment report and submits them to the STIF (Transport Organising Authority) to obtain the needed authorisations:
  - authorisation to start civil engineering works and public road works,
  - authorisation to perform specific tests during operation (if needed),
  - authorisation to put the system into service and begin commercial operation.
- Suppliers  
The Suppliers design the system and its safety, perform the safety analysis, produce the technical Safety Case in accordance with the EN50129 standard and submit it to the RATP to obtain a Safety Acceptance.

### 5.3 The case study for Hungary

The case study for Hungary [Case Study BME] gives a concise overview on the approval process in Hungary.

The main participants in this process are:

- developer/supplier of the system,
- transport operator,
- independent certifier,
- National Transportation Authority.

The procedure applied is not very difficult and differs not significantly from that of other countries with respect to the participants and their role.

The National Transportation Authority may give operation license to the transport operator. In case of rolling stock this means a type licensing, in case of infrastructure (including signalling systems) each installation needs a separate license. In case if signalling systems an independent certifier is also used in the process. In fact this certifier takes over some conformance assessment activities from the authority, however it carries out its activities in charge of the supplier of the system.

The approval process has more phases:

- only in case of infrastructure a building license is given out, before the installation starts;
- the next phase is a preliminary operating license (for infrastructure) or a prototype license (for rolling stock); with this licences a test operation may begin, after which the results are evaluated by the authority or the independent certifier.
- if the test operation is closed positively, then the authority may issue the definitive operating license.

#### 5.4 Danish Case Study

In Denmark there is one single light rail system, which is the Copenhagen Metro [MODSAFE D1.1]. Its approval process was influenced mainly by the CENELEC EN 50126 / 50129 / 50128 standards and by the German approval process, regulated in BOStrab.

According to this the participants of the process are:

- supplier of the system,
- the operator (railway authority, Metroselskabet),
- safety authority (Trafikstyrelsen) and the
- independent assessor.

This arrangement is in line with the mentioned CENELEC standards. The project was divided into several phases. At the end of each phase the independent safety assessor produced a report on the relevant activities of the given state and the safety authority issued for each phase an approval, based on its own activity and on the report of the independent safety assessor. With the last approval the system went into service. This procedure is depicted in the following figure.



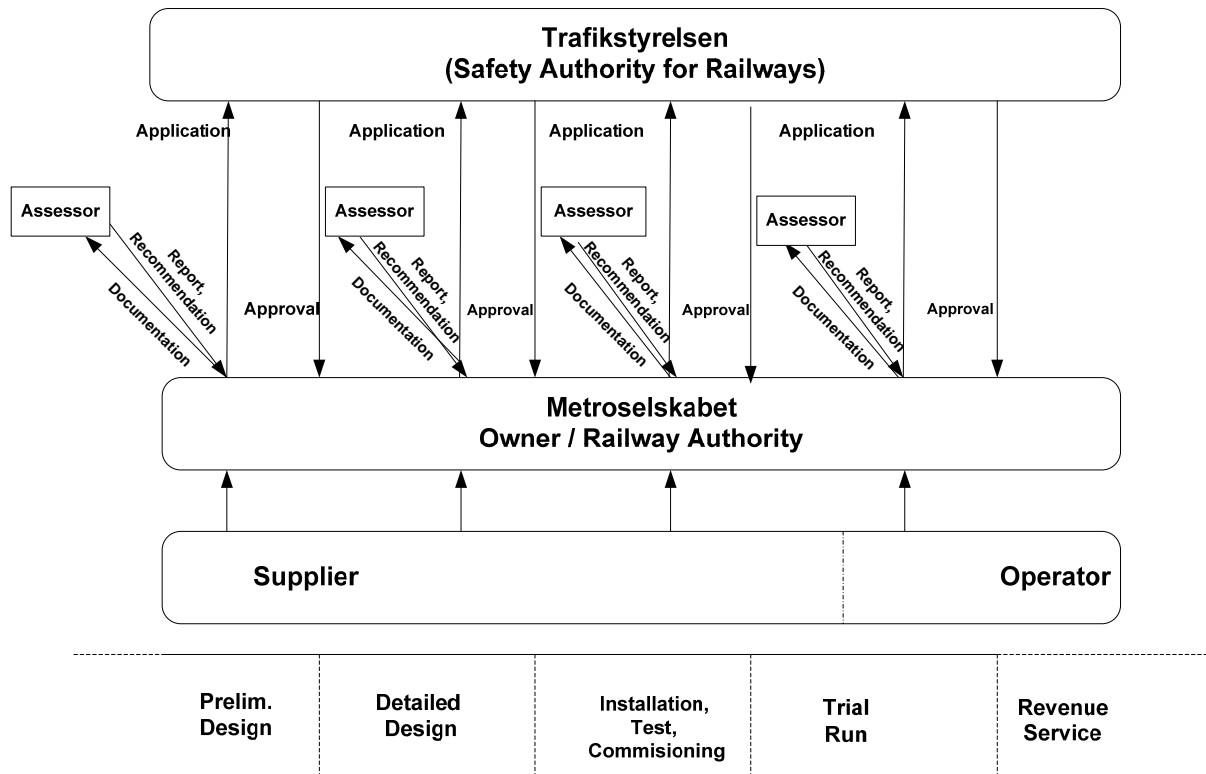


Figure 4 – Schema of the Approval Process for the Metro Copenhagen [MODSAFE D1.1]

## 5.5 Case study for Germany

From the German case study it can be understood that generally there is an authority body in Germany to approve urban guided rail systems: Technical Supervisory Authority (TAB).

TAB is designated by the government of the federal states. Building projects are running under the supervision of TAB, which may delegate independent, competent individuals to examine the design, the materials used, safety requirements etc. In this meaning the process is similar to the one used in the UK.

## 6 Lessons learned from current practices and case studies

Based on a general introduction to acceptance, approval and certification, and on the survey of the current European AAC-practices and by taking into account the lessons learned from the case studies, in this chapter

- definitions will be given to approval, acceptance and certification and
- the main participants of these processes will be identified and presented.

### 6.1 Definition of acceptance, approval and certification

In this document we would like to specify some terms in order to use in the same meaning in subsequent activities within this work package, therefore the definitions are limited to work package 7.

#### 6.1.1 Acceptance

The term “acceptance” is not defined in EN 50126 nor in EN 50129, only “safety acceptance” is defined, as

*“the safety status given to a product by the final user.”*

In a similar way we could define “acceptance” as “the status given to a product by a final user.” In case of urban rail guided system the final user is the operator, so the acceptance shows the operator’s positive opinion about a specified technical system. This does not necessarily mean a final permission for putting the systems into service, as in many cases further, independent certification is needed (see also 6.1.2 and 6.1.3).

#### 6.1.2 Approval

The term “approval” is not defined in EN 50126 nor in EN 50129, only “safety approval” is defined, as

*“the safety status given to a product by the requisite authority when the product has fulfilled a set of predetermined conditions”.*

However EN 50129 defines the term “authorisation” as

*“the formal permission to use a product within specified application constraints.”*

This latter could be the more appropriate definition for “approval”. ([MODSAFE D1.1] also defines “approval” as a synonym of “authorisation”). In this meaning “approval” could mean the final (formal) decision to permit to use a system, regardless of which body, authority or institution makes this final decision. (In some cases the final decision is made by the operator – in these cases acceptance and approval may cover the same activity).

#### 6.1.3 Certification

The term “certification” is not defined in EN 50126 nor in EN 50129. The standard [EN 17000] defines certification as a

*“third-party attestation related to products, processes, systems or persons”*

whereas attestation is

*“issue of a statement, based on a decision following review, that fulfilment of specified requirements has been demonstrated”*

According to [EN 45020] certification is

*“a procedure by which a third-party confirms in writing that a product, process or service conforms to specified requirements.”*

Both definitions emphasize that the action of certification must be carried out by a third party, i.e. by an independent body. This independence is in line with the philosophy of EN 50126 and EN 50129.

For the scope of MODSafe WP7 certification can be interpreted as a procedure of examination or investigation, fulfilled by an independent body (i.e. independent from the developer, the supplier and the operator of the system), in order to state, whether the examined product or system fulfils some functional and/or safety requirements.

The independent body can be in some cases an authority or another designated, competent person or body.

## 6.2 Main participants of the approval, acceptance and certification processes

If we examine the current practices and especially the case studies on the approval, acceptance and certification procedures of urban rail systems, we can state that there must be at least two key players in these processes:

- the operator and
- the supplier.

There are additional players that can be involved in these processes, like

- an authority or
- an independent body.

The **operator** is a public or private undertaking which runs transport services. The term “operator” in this case designates an entity which is responsible for both the management of the infrastructure and the operation of the trains and rail services. The operator will be the final user of any urban guided rail system, regardless of the type of this system: it can be a vehicle or a trackside equipment.

The second necessary player is the **supplier** of any new system for the operator. It must be noted, that one single supplier usually delivers products to several different operators, whereas functional and safety requirement of different operators may be rather different.

According to the current regulation of many European countries, urban rail systems require operation permission from a designated **authority**. The authority therefore is often playing an important role in acceptance, approval and certification process. Note that not every European country requires authority decisions for urban rail systems.

According to the current regulation of many European countries, a safety-critical

transportation system may only be approved (i.e. put into service) if at least one independent body has examined the system and its application environment, and his report is positive on the system. This **independent body** may be an independent safety assessor, an independent competent person or an independent certifier or a combination of these. Again, these players are not required in all countries in Europe.

In subsequent tasks of this work package 7 the tasks of these elementary players will be examined and described with respect to different European countries. To achieve a comparable description about this procedures a common, formalised way of description shall be selected.

## 7 Description of approval processes

For more detailed comparison of the processes it seems to be advisable to describe the different approval procedures in the same way, i.e. using the same formalization. For this purpose several methods could be applied:

- Simple block diagram (like e.g. in the case study of France): it has the disadvantage that this method does not represent well the timing aspects, but on the other hand the relations between organizations are represented clearly.
- Flow chart: flowcharts represent the successiveness of processes well, but the different actors are not easy to distinguish;
- Cross functional flowchart: it has all the advantages of flowchart, plus the activities can be clearly distributed between the actors; this method was used to describe the Hungarian approval process (see a cut as an example)

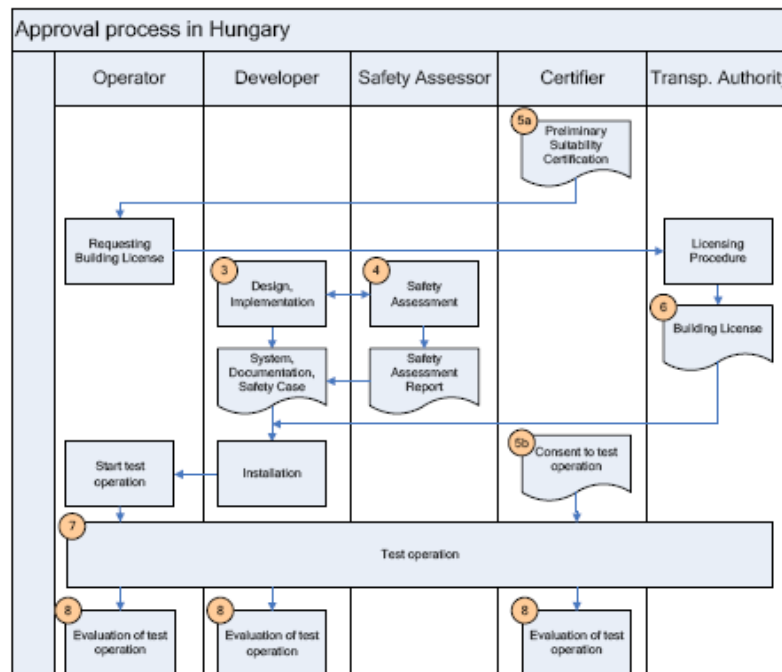


Figure 5 – Example of a cross functional flow chart

- UML activity diagram: it is a well formalised method to describe processes; the information content is similar to cross functional flowcharts (Fig. 6)

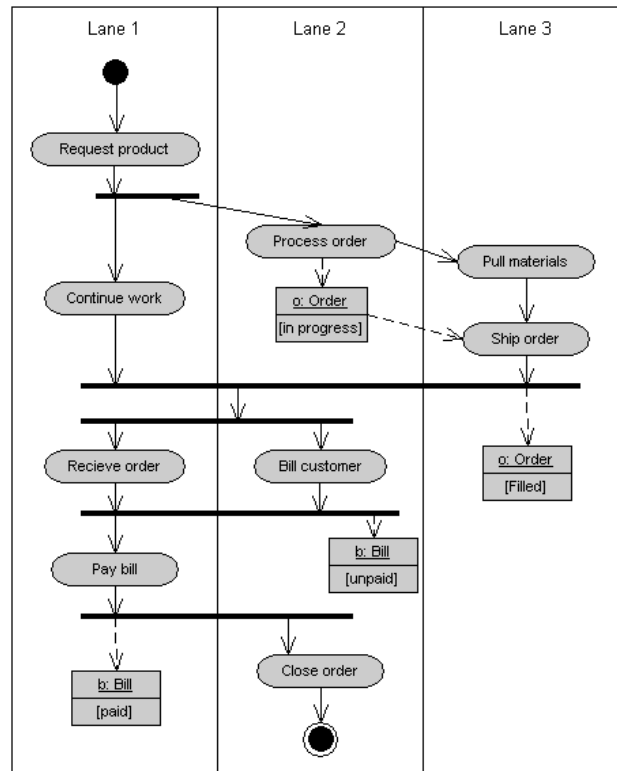


Figure 6 – Example of a UML activity diagram

In later phases of this work package an adequate method for the description can be selected for the description of approval processes.

## 8 Conclusion and further work

The compilation, presented in this deliverable will serve as a basis for further activities in work package 7. The survey of current practices allows us to further investigate the AAC-process of countries with relevant urban rail transport systems, thus allowing us to identify the common practices.

Further investigations will result in the break-down of the AAC-processes into so-called elementary activity modules, which could be the atomic parts of the processes. Later on with help of these “bricks” we can describe any AAC-process which is practised in any EU-country and to propose an ideal framework for these processes.