

ProM@in

Task I2 Harmonisation of Safety Assessment Final Report

CONTRACT N° : 1999

PROJECT N° : TN.10991

ACRONYM : ProMain

TITLE : *Progress in Maintenance and Management of Railway
Infrastructure – Final Report of Task I2*

Task Manager: TÜV InterTraffic GmbH, Köln

REPORTING PERIOD: FROM 1 January 2000 TO 31 March 2002

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Date of issue of this report : 31 March 2002



**Project funded by the European Community
under the 'Competitive and Sustainable
Growth' Programme (1998-2002)**

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2. Introduction

The process of giving safety approval for all railway activities is becoming more formalised. Simultaneously, there is pressure to move towards internationalisation of supply processes, so as to secure the benefits of competitive sourcing. This is equally true of rolling stock, as of infrastructure equipment and components, and also services such as maintenance work.

Safety assessment is carried out by competent bodies based on directives of the European Commission and European standards. Still there are different areas with different means of regulation

- European wide regulated area
Activities in this area are based on European wide specifications, as the interoperability directives for high speed lines together with the TSIs (Technical Specifications Interoperability). This part is evolving, since the directive for the Transeuropean network and is undergoing approval and the safety directive is present as a draft version.
- Nationally regulated area
This area is based on national regulations. Approval of competent bodies and rules for carrying out safety assessment are different for different countries.
- Voluntary area
In this area neither national nor international regulations need to be applied.

In all of these areas there are different players in safety assessment regarding manufacturers, operators, other competent bodies and responsible governmental institutions. In addition, there are also areas that overlap with urban mass transport systems and the parties involved there.

This situation gives rise to various difficulties regarding safety assessment.

Based on the main aspects, at the Convention of Decision Makers on September 22, 2000 it has been decided to establish a task I2 "Harmonisation of Safety Assessment". This task, as well as the other tasks was planned for two phases. In the first phase, problems and possible solutions had to be identified. The second phase has been dedicated to further, spin-off projects.

The current report describes the work done in the first phase. Meanwhile, within the 5th framework programme, a specific Thematic Network on Safety, together with accompanying measures are being established. It is a great step forward and a great success for the process of harmonisation on safety assessment that extensive attention and resources are dedicated to safety problems. Therefore, it is not necessary to continue safety as a specific task within the Thematic Network ProM@in.

Section three presents the work done in phase one. The fourth section is dedicated to continue the work, however on a much narrower basis within ProM@in and a strong restriction on track maintenance.

3. Description of Work Carried out

3.1 Workshop

A workshop had been held in Brussels, on March 29, 2001. Here, an overview has been gathered on the situation and main problems have been identified.

Participants were:

- D. Behrends / EBC
- R. van der Burg / Rijkswaterstaat
- H.-P. Cabos / ERC
- P. Firpo / SCIRO
- P. Grillo / European Commission
- H. Jansen / TÜV
- P. Mihm / DB AG
- F. Molinier / SNCF
- H. Schäbe / TÜV
- M. Sturbois / Certifer
- M. Thomas / Railtrack

The following presentations have been given.

- Mr. Schäbe presented the Thematic Network Prom@in and the intentions of task I2 “Knowledge Network for competent bodies - A Practical step to enhance harmonisation of safety assessment”. Goal of task I2 is to contribute to technical issues on harmonisation of safety assessment with the means of a network.
- Mr. Grillo informed about the second railway package.
- Mr. Cabos presented ERC (European Rules for Conformity) and the work that is done by this organisation.
- ERC focuses in its current work especially on harmonisation for conformity assessment procedures and criteria for competence of bodies.
- Currently, many competent bodies are not independent, but the number of independent bodies that could act as a third party is growing.
- Mr. van der Burg presented the Dutch Safety Directive on Light Rail. Safety targets for the system are derived from a database with railway safety data.

- Mr. Thomas informed about the situation with notified bodies in U.K.. It will take some time until notified bodies will become really active. For a notified body the workload regarding safety assessment is expected to be peaky. Information exchange is needed to support the construction of a notified body.
- Mr. Sturbois pointed out which problems can currently be found in safety assessment:
e.g.
 - conditions to apply the EN 50126 standard (for safety critical products, for complex products);
 - Methodology to combine the EN 50126 standard with specific standards for the product (national standards used in a country). Examples for additional standards: EMC, fire and smoke emission, specific climatic conditions, mechanical conditions, specific required performance of the product;
 - Impact of the assessment type (audit, evaluation, test, etc.) for the same product on the costs;
 - Methods to take the quality assurance system into account during an assessment (type of documents to be evaluated);
 - Reasons when to apply evaluation or an audit in the design / manufacturing phases.
- Mr. Firpo gave information about notified bodies in Italy and presented information on the companies applying.
Partially, consortia are founded. Then, the companies have to harmonise their assessment guidelines and their quality management systems (for assessment purposes).
- Mr. Mihm explained the German proposal for cross certification.
- Mr. Behrends presented the organisation of the German notified body EBC.

The material is annexed in Annex 1.

As a conclusion, a list of problems has been elaborated that were judged to be the most important. The list is given in annex 2.

3.2 Status Paper

A status paper was elaborated describing the actual status of safety assessment and showing the players in the area. The paper is based on the results of the workshop and personal discussion with experts, in particular from the European Commission.

The paper is annexed in annex 3.

3.3 Work on Human Factors

Within a membership agreement with Railway Safety, a state of the art report has been elaborated. The report gives a good overview on current problems and activities. The report is included as annex 4.

3.4 Dissemination Activities

The following dissemination activities have been carried out. The material is attached in separate annexes. Partially the material presented refers directly to the status of safety assessment as elaborated within ProM@in. Partially other results have been disseminated that have been obtained outside the network, but that are of interest within safety assessment. The table below presents the conference or workshop attended and the title of the paper given. The full text is supplied in the annexes

Conference / workshop	Title of paper	Annex
Seminar June 11 / 12, at Bombardier Transportation premises for Product Unit Safety Managers from Europe and U.S.A.	<ul style="list-style-type: none"> • Safety Approval • Experience with SIL Allocation in Railway Applications 	5
European Safety and Reliability 2001, Torino, 16.-20.09.2001	Different Approaches for Determination of Tolerable Hazard Rates	6
World Congress on Railway, Research, Cologne, November 2001	Different Principles Used for Determination of Tolerable Hazard Rates	7

European Safety and Reliability 2002, Lyon, 19.-21.03.2002	The Safety Philosophy behind the CENELEC Railway Standards	8
VDI conference "Rail Traffic" Aachen, 13.6.2002 – 14.6.2002	Safety Assessment and Approval Process of Rolling Stock in Europe	11

4. Future Activities

4.1 Safety problems in track maintenance

The following safety problems connected with track maintenance have been identified so far. However, during participation in the work within the other clusters of ProM@in, additional problems are expected to be identified.

- Workshop on maintenance activities

A workshop on the new maintenance directive is planned to be prepared together with AEIF. A status paper on stake holders on RAMS and accident databases is to be elaborated.

- Support for RAMS databases activities

Support regarding modelling and statistical inference with incomplete data will be given

4.2 Contact with Projects and Thematic Networks within the SMARTRAIL Programme of the European Commission

A close contact will be established with the new upcoming thematic network on safety, SAMNET, and the supporting measures on track, SAMRAIL, and other projects and thematic networks on railway safety.

In particular, the results of ProM@in, especially in the form of the present report will be made available to the projects. Help and support will be given to establish further contacts and to use effectively the results achieved so far.

Annexes

Annex 1 Material of Workshop in Brussels, March 29, 2001.

provided in separate file

Annex 2 Questions, Answers, Ideas concerning Technical Issues of Harmonisation of Safety Assessment

1. Scope

The following short paper is dedicated to collect questions, answers and ideas regarding harmonisation of safety assessment. The paper is thought as a starting point from which experience shall be gathered. In coincidence with the role of a thematic network, solutions to open questions first will be searched from experts. For those questions, where this will not be possible, separate research and/or development projects will be proposed.

2. Safety Case

The structure of a safety case is prescribed for signalling and control systems in EN 50129. Which shall be the structure of the Safety Case for other technical systems (not signalling and control). Can the structure from EN 50129 be applied? This structure can be recommended, is logical, but cannot be required. Therefore, different authors may deviate from this structure.

Can EN 50129 also be used for other electric / electronic sub-systems? From a pragmatic point of view this can be done, however it is not mandatory.

3. Design measures

A safety integrity level consists of two main requirements. The first one is that the function of the object in regard shall not exceed a target value for dangerous failures. Second, certain design requirements have to be fulfilled. EN 50129 presents design requirements for signalling and control. Can these requirements be adopted for other electrical and electronic subsystems? Where shall design requirements be taken from for other (non-electrical) sub-systems?

Especially, which standards can be used for mechanical and civil engineering when design methods for SIL1...SIL4 are to be used or checked ?

4. Safety Targets

How shall safety targets be set up: for the entire system or by apportionment to sub-systems? The question is especially interesting, when already existing systems are changed

and a new subsystem is installed. If only an overall system target is present, the entire system would have to be evaluated in order to find out the target for the new sub-system. Harmonised risk acceptance criteria are needed in this regard.

5. National Safety Standards

Often additional, national safety related standards have to be used (EMC, fire protection, etc.).

Are there countries that do not require the use of additional safety standards (EN 50126 / 50129 is sufficient)?

Example: The German EBA allows the use of EN 50129 , or alternatively Mü8004 (national standards) for signalling and control.

In France, additional requirements exist concerning fire protection.

Are there overview lists of such standards for several countries or persons / institutions that can give information?

6. Quality assurance system

EN 50126 / EN 50129 require the existence and application of a quality management system. By which criteria has a quality assurance system to be judged to be sufficient for a safety relevant (sub-)system? Is an ISO 9001 certificate sufficient? Which additional requirements have to be made? Are there requirements for the qualification of the personnel?

7. Assessment methods

In which phase of the development / manufacturing process are the methods “evaluation” and “audit” appropriate? Can the evaluation of an object be replaced by an audit of the underlying process?

8. Rail Competence criteria for Notified Bodies / Competent bodies

The new approach framework requirements for certification (Notified) bodies have no Rail specific competence requirements for Notified Bodies. How can we have confidence in their certification if there is no requirement for specific knowledge of Railway technical systems or operations.

The TSIs deal with Interoperable Trains interfacing to Interoperable Infrastructure. How will notified bodies deal with Interoperable trains that need to operate with national

infrastructure? Also how will they deal with infrastructure systems that need to interface with existing infrastructure? On operational issues: how can NBs have knowledge of all countries operating rules?. The ideal way to overcome these issues is through an all encompassing safety case (see above).

Analogous problems are expected for other competent bodies.

9. Practical problems regarding Notified bodies

In some countries, notified bodies will not exist within the next 1-3 years. Then, assessment has to be carried out abroad. This implies a need for harmonisation of assessment rules.

In the harmonised area, an assessment from a notified body from another country must be accepted from a legal point of view. However, how much confidence is in such an assessment? How much can harmonised assessment rules enhance confidence?

10. Responsibility

What responsibilities remain with the contracting company to ensure all the assessed systems work with existing systems and what remains with the competent body?

Also, what responsibility lies within the state (governmental institution)?

11. Cross-certification

Which schemes for cross certification are currently proposed? Is there already practical experience with these different conceptions? Which obstacles have been identified?

12. European Projects

Is the Generalised Assessment Method (GAM) (CASCADE) known and used?

Are the results of AcruDa known and used?

Annex 3: Players in Safety Assessment in Rail Technology, Accreditation, Approval, Manufacturing and Operation of Safety Relevant Systems

The following short paper is intended to show different players and their roles in safety assessment in rail technology and the areas connected with it. A graphical representation is given on the last page.

Safety assessment in rail technology is an activity that has to be carried out prior to application for safety approval. It is an analysis and judgement on the activities of a manufacturer or operator especially dealing with the safety case, regarding activities that are dedicated to a safe railway system and a safe exploitation of the railway system, regarding product and process inspections rather as pre-supposition than as a main subject of work.

Safety assessment is closely connected with other processes and activities. In many cases, safety assessment is carried out by a competent body that is acknowledged / approved by an authority. Therefore, the authorities acknowledging / approving competent bodies play a role in safety assessment. Based on safety assessment, safety approval is given by authorities for technical systems and parts of them. The authorities pose certain requirements on the process of safety assessment.

Manufacturers and operators of safety relevant systems and their organisation also play an important role, since safety is achieved via design and operation.

The following main areas of different kinds of technology can be considered regarding safety assessment. First of all, three areas are identified for railways:

- European wide regulated area
Activities in this area are based on European wide specifications. Here, the interoperability directive for high speed lines together with the TSIs (Technical Specifications Interoperability) have to be mentioned as well as the safety directive and the directive on Transeuropean Networks. This part is evolving. The interoperability directive for high speed lines, together with the Technical Specifications for Interoperability have been approved and an interoperability directive for the

Transeuropean network (conventional rail) is undergoing approval. A directive on safety is elaborated.

On the basis of the high speed interoperability directive, notified bodies are currently nominated by national, governmental organisations. National organisations as well as the European Commission are in the course of preparing means of co-ordination of notified bodies. A secretariat has been set up by the European Commission. Assessment is carried out by notified bodies that are accredited by national authorities. Some countries have already accredited notified bodies, others are in the course of doing so.

- Nationally regulated area

This area is based on national regulations. Approval of competent bodies is carried out according to national law by national authorities that are not necessarily the same as for the European wide regulated area. Currently, part of the nationally regulated area is taken over by European wide regulations.

- Voluntary area

In this area neither national nor international regulations need to be applied. However, assessment is done on a voluntary basis, mostly because regulations are expected to become mandatory or to have an advantage on the market. In some countries accreditation based on the EN 45000 series is offered.

The European standards EN 50126, EN 50128, EN 50129 play an important role in safety assessment and approval in all three areas. They are intended to enhance harmonisation in safety assessment.

- Other transport systems

In addition, a close connection exists with other transport systems, especially with urban mass transport systems. This connection arises due to several reasons. First, manufacturers are the same for many systems used in urban mass transport and railway systems. Second, interoperable systems are becoming active, e.g. trams using railway line as well as their own lines. In this area, other national authorities are acting as accrediting bodies or giving approval for safety. However, the European standards EN 50126, EN 50128 and EN 50129 are partially also applied here.

The authorities in the different areas are different national authorities. That means, for safety approval, different authorities have to agree for different areas. Within the nationally

regulated area, there are different authorities for different countries. Regarding "other transport systems" there might even be different authorities in the same country, as e.g. in Germany.

In Europe, national accreditation bodies co-operate in EA (European Accreditation). That means, that accreditation of inspection bodies, testing laboratories and certification bodies is carried out nationally, but on a basis of a European series of standards, EN 45000. Accreditation delivers confidence in certificates and reports by implementing widely accepted criteria set by the European (CEN) or international (ISO) standardisation bodies. The standards address issues such as impartiality, competence and reliability; leading to confidence in the comparability of certificates and reports across national borders. Governments have confidence in testing and certification in support of regulatory functions.

Assessment bodies are acknowledged / approved within the different areas: European wide regulated, nationally regulated, voluntary area and area of urban and mass transport. Within the European wide regulated area, acknowledged assessment bodies are the notified bodies. In the other areas, the acknowledged /approved bodies are called authorised bodies. Partially, the organisations that act in different areas in the role of a notified body or authorised body are the same. That means, an organisation works in several areas as a competent body, holding acknowledgements / approval /accreditations in some of these areas.

Besides notified bodies and authorised bodies, there exist other competent bodies which are also involved into the work of safety assessment. These can be organisations acting as testing laboratories, bodies carrying out verification activities and others. The competent bodies (not being formally acknowledged or approved within a certain area) are involved in the work of the authorised bodies, in some cases as sub-contractors.

The difference between authorised and competent bodies is not clear, since a competent body might be authorised in one area, but might work in another area solely as a competent body, without being authorised therefore. E.g. a competent body is authorised within the nationally regulated area, but has no authorisation in the European wide regulated area (is not a notified body). However, in the European wide regulated area, the competent body works together as a partner or subcontractor with another competent body which is a notified body. So, each competent body holds a set of authorisations, acknowledgements and

accreditations in different areas, sub-areas and countries. Generally this set is different for different competent bodies.

Assessment bodies can have different backgrounds. Railway or transport system operators are acting as competent bodies. Also, manufacturers or genuine technical expert organisations which neither operate nor manufacture railway systems act as competent bodies. Whereas a manufacturer in its function as an assessment body mostly works on assessment and expertise of his own products and of his sub-suppliers, operators and technical expert organisations can also assess systems and constituents of competing manufacturers. Transport system operators usually assess only those systems they use themselves.

A main role is played by manufacturers. The manufacturers supply systems and constituents for all four said areas. In many cases, the same piece of equipment might be intended to be used in different areas. The manufacturers have their organisation UNIFE, which supports the development of the railway supply industries and promotes rail transport initiatives. It monitors and influences EU policies and supports members with products and services.

Another main group are the railway operators. In the area of safety, they are responsible for safe railway operation and must ensure that only safe technology is used. They work closely together with their national authorities, manufacturers and other competent bodies. UIC is the worldwide organisation of the railway operators for co-operation among railway companies. Its activities encompass all fields related to the development of rail transport.

The situation is analogous regarding operators within the area of mass transport systems. However, usually they act in an area or a region, rather than in a whole country. In several cases there is also a close co-operation with railway operators. UITP is a world wide association of urban and regional passenger transport operators, their authorities and suppliers. It seeks to promote a better understanding of the potential of Public Transport. It provides information, research and analysis on all aspects of Public Transport including infrastructure, rolling stock, organisation and management.

AEIF is a joint organisation of UIC, UNIFE and UITP to put forward activities that are in the interest of all partners and to co-ordinate work in this area.

European Rules for Certification (ERC) is part of AEIF. ERC is working towards harmonisation of conformity assessment, certification and assessment procedures. ERC, is elaborating guidelines for certification to be applied in Europe, thus promoting uniform testing and certification in the railway area, taking the EN 45000 series as a base. The guidelines are intended to promote multilateral acceptance of railway product certificates and regard competence of certification, inspection and testing bodies. The work already done by ERC can be very useful to enhance certification especially in the nationally regulated area and the voluntary field.

Further information:

Co-ordination group of notified bodies

Technical secretariat

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Scetauroute

eurlpourcin@wanadoo.fr

Administrative secretariate

C. Correia

EOTC

carlos.correia@eotc.be

Selected Web-Adresses

UIC: <http://www.uic.asso.fr>

UTIP: <http://www.uitp.com>

UNIFE: <http://www.unife.org>

European Accreditation: <http://www.european-accreditation.org/>

ProM@in: <http://promain.server.de>

Interoperability directive on high speed:

http://www.europa.eu.int/eur-lex/en/lif/dat/1996/en_396L0048.html

Interoperability Directive on Transeuropean networks:

http://europe.eu.int/eur-lex/en/com/dat/1999/en_599PC0617.html

Notified bodies

PRE-NOTIFICATIONS AND NOTIFICATIONS under article 20 of directive 96/48

no	Date of reference letter	MS	Authority	P/N	name of (Pre-) Notified Body Contact person	Product range
1	29.01.98	F	Ministère de l'Equipeement, des Transports et du Logement, Direction des Transports Terrestres, Sous-Direction des Transports Ferroviares, PARIS	P	CERTIFER VALENCIENNES Mr jean-Yves Taillé Tel. +33 3 272 83 500 Fax +33 3 272 83 509	Subsystems, Consituents
2	25.06.99	DK	Permanent Representation BRUSSELS	P	DET NORSKE VERITAS, DANMARK A/S (DNV) Mr Sven Johansen Tel +45 3945 4841 fax +45 3945 4801	Subsystems, Consituents
3	25.06.99	UK	RIG5 (International Railways) Department of the Environment, Transport and the Regions, LONDON	P	RAILTRACK SAFETY AND STANDARDS DIRECTORATE RAILTRACK PLC LONDON Mr MH Waletel Tel +44 171 557 8746 Fax +44 171 557 9070	Subsystems, Consituents
4	25.06.99	UK	RIG5 (International Railways) Department of the Environment, Transport and the Regions, LONDON	P	AEA TECHNOLOGY RAIL DERBY Mr Richard Gostling Tel +44 1 332 2646 88 Fax +44 1 332 2649 83	Subsystems, Consituents
5	21.10.99	A	Bundesministerium für Wissenschaft und Verkehr	N	Österreichische Forschung und Prüfzentrum Arsenal (arsenal research) WIEN Mr gerhard List Tel +43 1 79747/288 Fax +43 1 79747/593	Subsystems, Consituents
6	10.12.99	UK	RIG5 (International Railways) Department of the Environment, Transport and the Regions, LONDON	P	LLOYD'S REGISTER CROYDON Tel +44 181 681 4826 Fax +44 181 681 4923	not specified

ISEB

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7	22.12.99	UK	RIG5 (International Railways) Department of the Environment, Transport and the Regions, LONDON	P	THE ENGINEERING LINK DERBY Tel +44 1332 263 448 Fax +44 1332 264 960	Rolling stock subsystem and relevant constituents
8	06.01.00	DK	Bundesministerium für Verkehr	N	BENNAANTE STELLE INTEROPERABILITÄT BEIM EISENBAHN-BUNDESAMT BONN Mr A. Thomasch Tel +49 228 9826 701 Fax +49 228 9826 711	Subsystems, Constituents
9	19.01.00	NL	Department van Verkeer en Waterstaat	P	LUXCONTROL NEDERLAND BV BRIELLE Mr Ulrich Haspel Tel +31 181 417 088 Fax +31 181 415 247	Subsystems, Constituents
10	19.01.00	NL	Department van Verkeer en Waterstaat	P	NEADTRAIN CONSULTING UTRECHT Mr Lex Frunt Tel +31 30 300 4714 Fax +31 30 300 4800	Rolling stock and relevant constituents, incl. Energy
11	19.01.00	NL	Department van Verkeer en Waterstaat	P	LLOYD'S REGISTER QUALITY ASSURANCE ROTTERDAM Mr H. Holthuis Tel +31 10 414 5088 Fax +31 10 411 5105	Subsystems, Constituents
12	19.01.00	NL	Department van Verkeer en Waterstaat	N	STICHTING KEMA RTC UTRECHT Mr F.T.M. Walenberg Tel +31 30 235 8173 Fax +31 30 235 7329	Subsystems, Constituents
13	19.01.00	NL	Department van Verkeer en Waterstaat	N	RAILCERT UTRECHT Mr W.J. Coenraad Tel +31 30 265 4778 Fax +31 30 265 4761	Control_command and relevant Constituents

For information

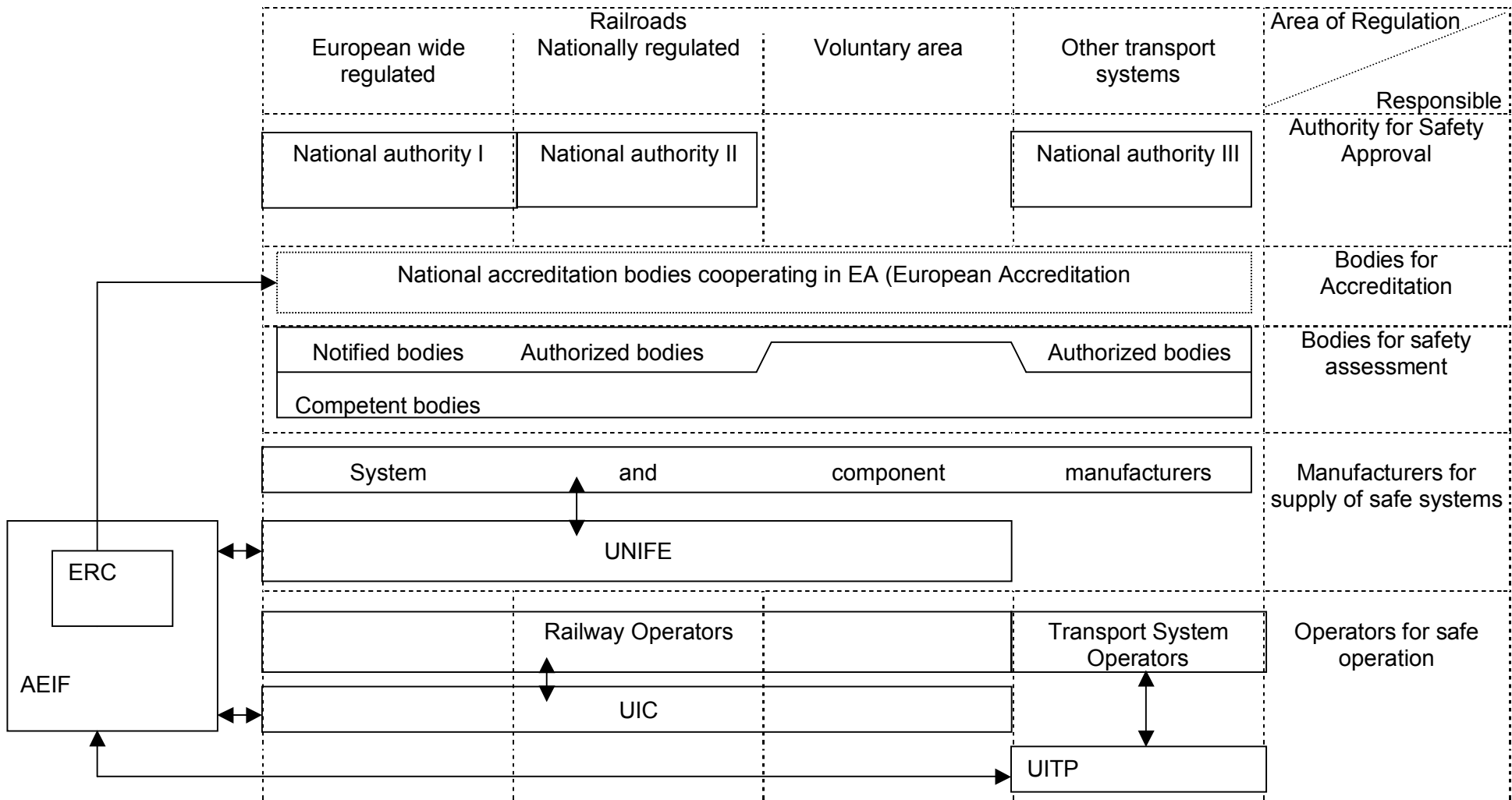
14	10.12.98	L	No official note from L to the Commission
15	PV12	E	
16	PV12	I	

P: pre-notification

N: notification

SOCIÉTÈ NATIONALE DE CONTRÔLE TECHNIQUE-
HOMOLOGATIONS (SNCT-H) SANDWEILER
ADAF
Italian Body

Organisations involved in Safety Assessment



**Annex 4: Human factors contribution to quantitative methods
survey**

- provided in separate file -

Annex 5: Presentations given at Seminar in Hennigsdorf 2001

- provided in separate file -

Annex 6: Presentation at European Safety and Reliability 2001

- provided in separate file -

**Annex 7: Presentation given at World Congress on Railway
Research**

- provided in separate file -

Annex 8: Presentation at European Safety and Reliability 2001

- provided in separate file -

Annex 9: List of Experts

Theme	Title	Name	Surname	Institution	Street	ZIP code	Town	Phone	Fax	e-mail
Quantitative methods	Dipl. – Ing.	Mihm	Peter Eberhard	Deutsche Bahn AG L FTZ 251	Völckerstraße 5	D - 80939	München	++ 49 89 1308-2540	++49 89 1308-1844	Peter.Mihm@ bku.db.de
	Dr.	Hessami	Ali	Railtrack	Euston Square, Floor 8, Raintrack House	GB	London NW 1 2EE	0044- 7899934762		A.G.Hessami@IEEE.Org HessamiA.Railtrack@EMS.Rail.Co.UK
	Mr.	ElKoursi	Miloudi	inrets INRETS - LILLE-VILLENEUVE D'ASCQ	20, rue Elisée Reclus	LILLE-VILLENEUVE D'ASCQ	LILLE-VILLENEUVE D'ASCQ	+33 320 43 83 24	+33 3 20 43 83 59	el-miloudi.el-koursi@inrets.fr
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National standards	Mr.	Bjerager	Peter	DNV	Tuborg Parkvej 8	DK – 2900	Hellerup	0045 – 39 45 4810	0045 – 39 45 4801	Peter.Bjerager@dnv.com
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	Mr.	Carrillo	Antonio M.	RENFE	Av. Pio XII - 110,	E 28026	Madrid	+34 91 200 83 42	+34 91 315 81 67	carillo@recol.es
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Annex 10 Additional Material Regarding Safety Harmonisation

- provided in separate file –

Annex 11 Paper submitted to VDI-conference Rail Traffic (13.6.-14.6.)

Safety Assessment and Approval Process of Rolling Stock in Europe

Sicherheitsbegutachtung und Zulassung von Schienenfahrzeugen in Europa

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Zusammenfassung

Der Vortrag befasst sich mit der Sicherheitsbegutachtung auf der Basis der Norm EN 50126. Die Komplexität des Prozesses wird gezeigt, insbesondere die Schwierigkeiten, die für alle Beteiligten auf dem Gebiet der Bahntechnik aus ihren neuen Funktionen und Verantwortlichkeiten in Rahmen der neuen Standards erwachsen. Es wird ein Überblick über die an der Sicherheitsbegutachtung beteiligten Parteien in Europa gegeben. Es werden Erfahrungen aus zwei Projekten vorgestellt. In beiden Projekten wurde eine Sicherheitsbegutachtung an Schienenfahrzeugen durchgeführt, die in andere Europäische Länder geliefert wurden. Die neuen Standards erweisen sich als hilfreich bei der Harmonisierung der Sicherheitsbegutachtung in Europa. Trotzdem gibt es neben den Europäischen Normen nationale Regelungen, die zusätzlich anzuwenden sind.

Abstract

The following paper is dedicated to safety assessment on the base of EN 50126. The report shows the complexity of the process, especially the difficulties that arise to all stakeholders in the railway sector to adapt to the new roles and responsibilities under the regime of the new standards. An overview on players in the area of safety assessment in Europe is presented. Experience from two international projects is given. In both projects, safety assessment has been carried out for rail vehicles that were supplied cross border within the European Community. The new standards act as a driver towards harmonisation of safety assessment. Nevertheless, besides the European standards, national regulations still exist and are applied in addition.

1. Introduction

During the recent years a joint working group of CEN and Cenelec has worked out EN 50126 [2] applicable for the rail sector dealing with RAMS Management. On the other hand, Subcommittee A of TC9(X) created European Standards dealing with programmed electronic equipment in Signalling Systems and related safety assessment and demonstration techniques (EN 50128 [3], prEN 50129 [4]). The standards EN 50128 [3] and prEN 50129 [4] are applicable to signalling. Outside the area of signalling, no adequate standard similar to [3,4] exists, discussions are running how to close this gap. The new standards give impulses for harmonisation, although still national regulations exist and gaps within European regulations have to be closed.

The general picture on players that are involved in safety assessment is presented in section two.

Experience is presented from two projects that have been carried out together by Bombardier (supplier) and TÜV (assessor) in the next two sections.

The first project is a tramway supplied by Bombardier to SEMITAN (Nantes / France). Here, assessment has been based on the CENELEC standards, using the German BO Strab (Betriebsordnung Straßenbahn) as a supplement. Of course, the French standards have been used in the first order when technical solutions had to be chosen and implemented. This had been mainly the case for fire protection aspects. The assessment has formed the basis for approval by the French Authority.

The second project is an ongoing project regarding the regional train ITINO which is supplied to Sweden. It is presented in section four. Again, the CENELEC standards form the basis for safety assessment, supplemented by some additional requirements stated by the Swedish authorities Järnvegsinspektion and Banverket. Several systems have been classified into different Safety Integrity Levels by the Swedish authorities and requirements have been derived. Partially, EN 50129 has been used outside its original area of application (signalling), if this had been useful. The results of the assessment process are intended to be used for approval of the train in Sweden.

As a main result, experience shows that the CENELEC standards act as a driver towards easier assessment. Experience from the assessment and approval process in France have been used regarding preparation of documents and analysis methods for the ITINO.

Nevertheless, the current assessment and approval process is still far away from simple re-using approval obtained in one country in another one.

2. Players in Safety Assessment in Rail Technology

Within the Thematic Network ProM@in [1] which is sponsored by the European Commission within the 5th Framework Programme, an overview of the current situation in safety assessment has been carried out. The main results are presented here.

Safety assessment in rail technology is an activity that has to be carried out prior to application for safety approval, preferably in close contact with the safety authority. It is an analysis and judgement on the activities of a manufacturer or operator especially dealing with the safety case, regarding activities that are dedicated to a safe railway system and a safe exploitation of the railway system, regarding product and process inspections rather as pre-supposition than as a main subject of work.

Safety assessment is closely connected with other processes and activities. In many cases, safety assessment is carried out by a competent body that is acknowledged / approved by an authority. Therefore, the authorities acknowledging / approving competent bodies play a role in safety assessment. Based on safety assessment, safety approval is given by authorities for technical systems and parts of them. The authorities pose certain requirements on the process of safety assessment.

Manufacturers and operators of safety relevant systems and their organisation also play an important role, since safety is achieved via design and operation.

The following main areas of different kinds of technology can be considered regarding safety assessment. First of all, three areas are identified for railways:

- European wide regulated area
Activities in this area are based on European wide specifications. Here, the interoperability directive for high speed lines together with the TSIs (Technical Specifications Interoperability) have to be mentioned as well as the safety directive and the directive on Transeuropean Networks. This part is evolving. The interoperability directive for high speed lines is in place. The Technical Specifications for Interoperability will be published mid 2002. The interoperability directive for the Transeuropean network (conventional rail) is in preparation. A directive on safety is in progress..

On the basis of the high speed interoperability directive, notified bodies are currently nominated by national, governmental organisations. National organisations as well as the European Commission are in the course of preparing means of co-ordination of notified bodies. A secretariat has been set up by the European Commission. Assessment is carried out by notified bodies that are accredited by national authorities. Some countries have already accredited notified bodies, others are in the course of doing so.

- Nationally regulated area

This area is based on national regulations. Approval of competent bodies is carried out according to national law by national authorities that are not necessarily the same as for the European wide regulated area. Currently, part of the nationally regulated area is taken over by European wide regulations.

- Voluntary area

In this area neither national nor international regulations need to be applied. However, assessment is done on a voluntary basis, mostly because regulations are expected to become mandatory or to have an advantage on the market. In some countries accreditation based on the EN 45000 series is offered.

The European standards EN 50126, EN 50128, EN 50129 play an important role in safety assessment and approval in all three areas. They are intended to enhance harmonisation in safety assessment.

In addition, a close connection exists with other transport systems, especially with urban mass transport systems. This connection arises due to several reasons. First, manufacturers are the same for many systems used in urban mass transport and railway systems. Second, interoperable systems are becoming active, e.g. trams using railway line as well as their own lines. In this area, other national authorities are acting as accrediting bodies or giving approval for safety. However, the European standards EN 50126, EN 50128 and EN 50129 are partially also applied here.

The authorities in the different areas are different national authorities. That means, for safety approval, different authorities have to agree for different areas. Within the nationally regulated area, there are different authorities for different countries. Regarding "other

transport systems” there might even be different authorities in the same country, as e.g. in Germany.

In Europe, national accreditation bodies co-operate in EA (European Accreditation). That means, that accreditation of inspection bodies, testing laboratories and certification bodies is carried out nationally, but on a basis of a European series of standards, EN 45000. Accreditation delivers confidence in certificates and reports by implementing widely accepted criteria set by the European (CEN) or international (ISO) standardisation bodies. The standards address issues such as impartiality, competence and reliability; leading to confidence in the comparability of certificates and reports across national borders. Governments have confidence in testing and certification in support of regulatory functions.

Assessment bodies are acknowledged / approved within the different areas: European wide regulated, nationally regulated, voluntary area and area of urban and mass transport. Within the European wide regulated area, acknowledged assessment bodies are the notified bodies. In the other areas, the acknowledged /approved bodies are called authorised bodies. Partially, the organisations that act in different areas in the role of a notified body or authorised body are the same. That means, an organisation works in several areas as a competent body, holding acknowledgements / approval /accreditations in some of these areas.

Besides notified bodies and authorised bodies, there exist other competent bodies which are also involved into the work of safety assessment. These can be organisations acting as testing laboratories, bodies carrying out verification activities and others. The competent bodies (not being formally acknowledged or approved within a certain area) are involved in the work of the authorised bodies, in some cases as sub-contractors.

The difference between authorised and competent bodies is not clear, since a competent body might be authorised in one area, but might work in another area solely as a competent body, without being authorised therefore. E.g. a competent body is authorised within the nationally regulated area, but has no authorisation in the European wide regulated area (is not a notified body). However, in the European wide regulated area, the competent body works together as a partner or subcontractor with another competent body which is a notified body. So, each competent body holds a set of authorisations, acknowledgements and

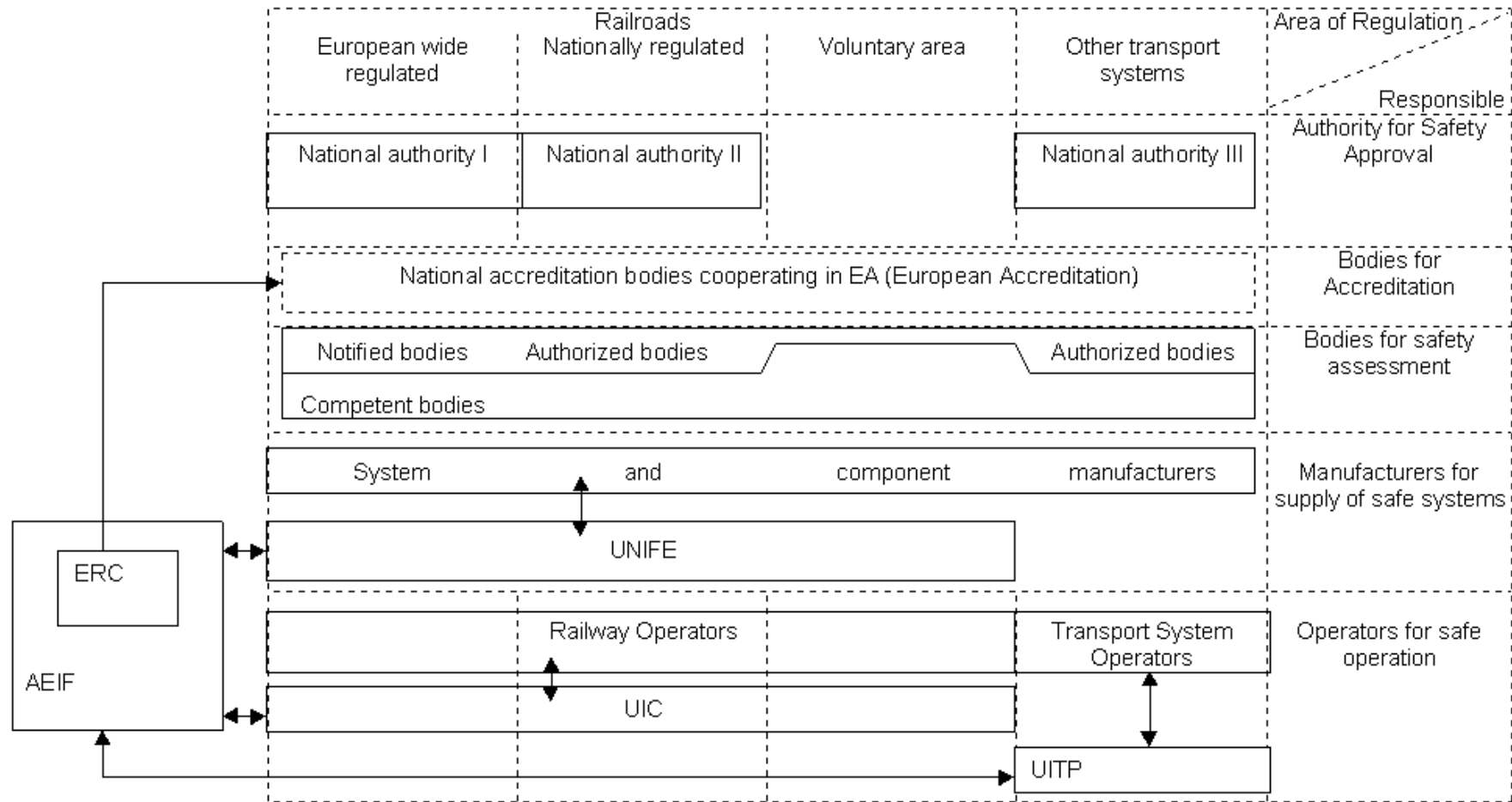
accreditations in different areas, sub-areas and countries. Generally this set is different for different competent bodies.

Assessment bodies can have different backgrounds. Railway or transport system operators are acting as competent bodies. Also, manufacturers or genuine technical expert organisations which neither operate nor manufacture railway systems act as competent bodies. Whereas a manufacturer in its function as an assessment body mostly works on assessment and expertise of his own products and of his sub-suppliers, operators and technical expert organisations can also assess systems and constituents of competing manufacturers. Transport system operators usually assess only those systems they use themselves.

A main role is played by manufacturers. The manufacturers supply systems and constituents for all four said areas. In many cases, the same piece of equipment might be intended to be used in different areas. The manufacturers have their organisation UNIFE. It represents the supply industry and supports the development of the railway supply industries and promotes rail transport initiatives. It monitors and influences EU policies and supports members with products and services.



Organisations involved in Safety Assessment



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Another main group are the railway operators. In the area of safety, they are responsible for safe railway operation and must ensure that only safe technology is used. They work closely together with their national authorities, manufacturers and other competent bodies. UIC is the worldwide organisation of the railway operators for co-operation among railway companies. Its activities encompass all fields related to the development of rail transport.

The situation is analogous regarding operators within the area of mass transport systems. However, usually they act in an area or a region, rather than in a whole country. In several cases there is also a close co-operation with railway operators. UITP is a world wide association of urban and regional passenger transport operators, their authorities and suppliers. It seeks to promote a better understanding of the potential of Public Transport. It provides information, research and analysis on all aspects of Public Transport including infrastructure, rolling stock, organisation and management.

AEIF is a joint organisation of UIC, UNIFE and UITP to put forward activities that are in the interest of all partners and to co-ordinate work in this area. In particular, AEIF has drafted the TSIs for high speed and conventional rail.

European Rules for Certification (ERC) is part of AEIF. ERC is working towards harmonisation of conformity assessment, certification and assessment procedures. ERC, is elaborating guidelines for certification to be applied in Europe, thus promoting uniform testing and certification in the railway area, taking the EN 45000 series as a base. The guidelines are intended to promote multilateral acceptance of railway product certificates and regard competence of certification, inspection and testing bodies. The work already done by ERC can be very useful to enhance certification especially in the nationally regulated area and the voluntary field.

3. Project Nantes

In the following, the experience of the application of the new standard EN 50126 will be described with the help of two projects serving as examples. The first is the project Nantes. Bombardier Transportation delivered INCENTRO trams to the French city Nantes. In the contract, a safety process according to the – at that time: preliminary – European Standard EN 50126 was required. Besides the application of relevant French law, the BO Strab was agreed as a basis for the design of the trams.

These were the fundamental criteria for the homologation stated by the responsible authority, the local department of the transport ministry. The customer SEMITAN, the mass transport company of the city, was responsible to receive the homologation (approval) from the authority. The necessary documents and certificates had to be brought in by the manufacturer. So, a common responsibility for getting the homologation was defined in the contract. This gave the whole process a positive momentum.

An independent assessor (third party) was required by the authority for the certification of the vehicles. The certification included the evaluation of the Safety Case. The task of the assessor comprised the certification of all characteristics of the vehicles necessary for the homologation. The TÜV Rheinland – Berlin / Brandenburg was accepted for this task by the authority. However, it was also required, that a French consultant has to be involved in responsibility of the customer to ensure the application and fulfilment of specific French requirements and experiences.

The certification was carried out on the basis of the BO Strab as it is usually done in Germany. This was also accepted. The checks were extended due to the results of the safety analysis. The process for the Safety Case was carried out on the basis of the Standard EN 50126. This process is described here shortly.

First, a Safety Plan was created and a Preliminary Hazard Analysis (PHA) was worked out. The Safety Plan defined the safety criteria, the safety organisation and the process. On the results of the PHA it was decided, for which systems Safety Analysis and Safety Cases were necessary. The requirements on the Safety resulting from the Safety Plan and the PHA were described in the specifications and also given to the sub-suppliers.

The most frequently used means for the safety analysis was the FMECA. If necessary, FTAs were elaborated. For every system analysed, a Safety Case was given. The safety relevant characteristics of the systems were checked during first article inspections and typtests. Typtests were also carried out on the entire vehicle. Especially, some failure procedures were checked.

Additional demands on service and maintenance arose by the analysis, because some of the safety characteristics can only be maintained by the right procedures. This was realised in the manuals and by the training.

The actions and results of the safety work related to certain hazards were documented in the Hazard Log, which was continued during the whole safety process. Also, new hazards were found by the investigations and inserted into the Hazard Log. Finally, it had to be demonstrated for all identified hazards, that the risk was avoided or reduced to an acceptable

level by suitable solutions. So, the Hazard Log was the central document for the Safety Case. The whole process was carried out in close relationship with the Engineering department, the sub-suppliers and the Quality Management.

The assessor accompanied the work during the complete design and production process. The first activity was the assessment of the Safety Plan and the PHA, especially the evaluation of the safety criteria. The necessary work, tests and certificates were agreed on a regular basis. The task comprised also the participation on the safety relevant typtests.

In accordance with his task, the work of the assessor was finished with the recommendation of the vehicles for homologation by the authority.

The French consultant asked critically for a lot of results and brought in his specific knowledge on safety. Some hints led to deeper analysis and additional tests and last but not least to a higher level of Safety.

4. Project ITINO - Motorvagn 2002

Within this project, regional trains of the new product platform ITINO have to be delivered to two Swedish customers. The customers act only as the owners of the vehicles. They use other companies as operators for the service. So, the customer itself is not acquainted with the operation and service, but his subcontractors, which were not known at the contract effective date. It has also to be considered, that the operators could be changed in the future. Accordingly, there was only one contractual condition for the homologation of the vehicles, i.e. passing the responsibility for homologation to the manufacturer. The manufacturer has to reach an agreement on the conditions and procedures for homologation with the authorities. There are two Swedish authorities, Jämvägsinspektionen and Banverket. The first one is responsible for the aspects of safety in service. The second authority is responsible for track. It checks, whether the vehicles comply with the given track conditions, the technical realisation and the fulfilment of standards.

During a kick-off meeting, the Swedish authorities required a safety process and Safety Case in accordance with EN 50126. Two general requirements were given. First, the systems on the vehicle shall have a level of safety at least as good as on comparable vehicles. Thus, a vehicle with an improved overall safety characteristic was expected. Second, a single point failure must not lead to hazardous consequences. Additional requirements have been stated for certain systems. The numerical definition of the Safety Integrity Level (SIL) as from EN 50129 has been used as a means for safety classification. The design principles

associated with the SILs have been defined separately for each subsystem by the Swedish authorities.

For this project, the check of the safety case for the complete vehicle and the homologation will be carried out by the authorities themselves. Independent assessors – third parties - were required only for those systems, for which special conditions were defined. For systems with lower required safety level, also third parties related to the manufacturer were accepted. The only condition to be fulfilled is, that those third parties had to be independent from organisations within the manufacturer, which are involved on the project.

The manufacturer decided to use for all systems external third parties due to the lack of competent resources to evaluate the safety analyses. After consultation with the authorities, the TÜV Rheinland – Berlin / Brandenburg (in the following: the assessor) was ordered for the most systems. For some systems, other companies were more suitable due to different reasons.

The task of the assessor is to check the fulfilment of the safety criteria for the defined systems. However, not only the documents for those systems have been considered, but also documents on vehicle-level have been evaluated, e.g. the safety analysis of the electrical equipment, although this system has not been required for assessment.

The safety process was carried out like described for the Nantes project. The efficiency was increased due to the experience of the first project.

Difficulties arose due the requirement “ at least as good as comparable vehicles”. Partially, the manufacturer had to ask for the technical solutions of comparable vehicles and had to evaluate the safety characteristics of those vehicles in order to be able to check fulfilment of this condition. A safety expert of the Swedish subsidiary of the manufacturer supported this process. So, some of the conditions were not really known during the start of the safety process.

Due to the fact, that the project is in progress, not all results can be reported yet.

Finally, it can be summarised, that the second contract was related with higher commercial risk for the manufacturer due to the unclear definitions in the contract regarding homologation. The authorities partially require solutions to guarantee a safe operation, which are different from those foreseen in the contract.

Another risk is the late involvement of the operators. In accordance to the EN 50126 the PHA has normally to be created together with the operator. The operator is responsible for the safe operation of the vehicles. So, there is a risk, that they could require solutions, which can only be realised with high effort at a late stage of the project. This is a general problem. In

such a case, it must be the aim to use as much as possible of the operations experience together with the customer, the authorities and the assessor for the design of a commonly acceptable vehicle.. Specific requirements for the operation should be minimised.

5. Conclusions

The homologation of both projects has been essentially based on the application of EN 50126. Additional specific requirements have been fulfilled, partially by the help of national experts. Also, language obstacles have been overcome, in one case by translation of all documents, in the other case by agreement on English as the business language. Moreover, it is worthwhile to note that the standard has been used for a tram as well as for a regional train. The application of the standard has proved to be very helpful. However, due to the novelty of the standard and its application and the lack of other examples, the partners were often forced to find practical solutions. Last but not least, it should be mentioned, that the application of the standard does not mean to formally carry out the required process steps. Using the new method prescribed in the standards, which is different from the traditional approaches, first risks were identified and then measures for avoiding or reducing the risks to a acceptable level were taken. This has led to improvements of technical solutions, which are at the state of the art or even better.

In Europe, still national regulations are widely used for safety assessment and safety approval. However, the CENELEC standards act as a driver towards easier assessment. This was clearly shown by our experience in both projects. On the other hand, still many additional agreements are necessary between manufacturer, authority and assessor to close existing gaps in the new standards.

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