

# **Players in Safety Assessment in Rail Technology, Accreditation, Approval, Manufacturing and Operation of Safety Relevant Systems**

- DRAFT PAPER -

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 Trans-European 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 Trans-European 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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Administrative secretariate

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Web: <http://www.iseb.com>

### **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): <http://promain.server.de>

Interoperability directive on high speed:

[http://www.europa.eu.int/eur-lex/en/lif/dat/1996/en\\_396L0048.html](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](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'Équipement, des Transports et du Logement, Direction des Transports Terrestres, Sous-Direction des Transports Ferroviaires, 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	Subsystems, Consituents

					Waletr Tel +44 171 557 8746 Fax +44 171 557 9070	
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
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	Bundesminsterium für Verkehr	N	BENNANTE STELLE INTEROPERABILITÄT BEIM EISENBAHN-BUNDESAMT BONN Mr A. Thomasch Tel +49 228 9826 701 Fax +49 228 9826 711	Subsystems, Consituents
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, Consituents
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.	Subsystems, Consituents

					Holthuis Tel +31 10 414 5088 Fax +31 10 411 5105	
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	

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

**P:** pre-notification  
**N:** notification

### Organisations involved in Safety Assessment



