

North Railway Station

Certification Framework and Procedure of European Railway Industry

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1. European Certification Framework

Need for Harmonization

EU started in 1991 after expansions from EEC established in 1957 according to Treaty of Rome. Currently 28 member states, population of 513 million



Need for harmonization and interoperability in the European Union

- Transportation policies
- New Directives:
 - Directive on Railway Safety
 - Directive on Railway Infrastructure Package
 - Directive on European high-speed Rail Network
 - Directive on European conventional Rail Network

Objectives of Harmonization

European Union for Harmonization and Interoperability aiming to achieve:

- free circulation of goods, services, capital and labor
- technical harmonization
- harmonization of standards
- comparable level of quality and safety
- cross acceptance
- interoperability of railway systems



Council Directives for Harmonization

New Approach by EU due to

- technical harmonization in the EU-member states is established by Council Directives,
- Council Directives are European laws which have to be transferred into national laws of the member states,
- a new regulatory technique and strategy was laid down by the Council Resolution of 1985 on the New Approach to technical harmonization and standardization which established principles for the New Approach directives.



New Approach Principles

New Approach directives are based on

- harmonization is limited to essential requirements
- only products fulfilling these essential requirements may be placed on the market and put into service
- the technical specifications of products meeting the essential requirements set out in the directives are laid down in harmonized standards
- products manufactured in compliance with harmonized standards benefit from a presumption of conformity with the essential requirements
- harmonized standards: CENELEC standards and marked as e.g. EN 50126, EN 50128, EN 50129
- examples for New Approach directives are:
low voltage equipment, simple pressure vessel, Toys....



Cross Acceptance

Cross Acceptance

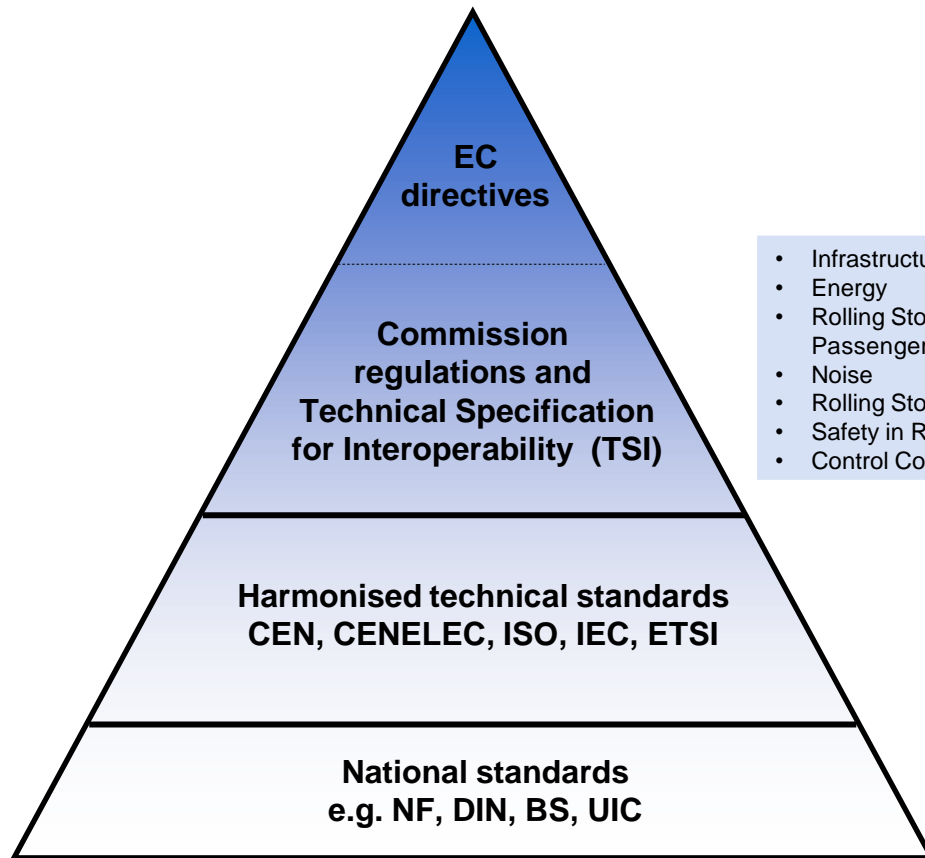
The status achieved by a product that has been accepted by one authority to the relevant European Standards and is acceptable to other authorities without the necessity for further assessment.

The Cross Acceptance may concern:

- products certifications
- management system certifications (quality, safety, environmental)
- test or inspection results / reports
- qualifications of suppliers
- competence of entities



European Legislation – Hierarchy of Standards



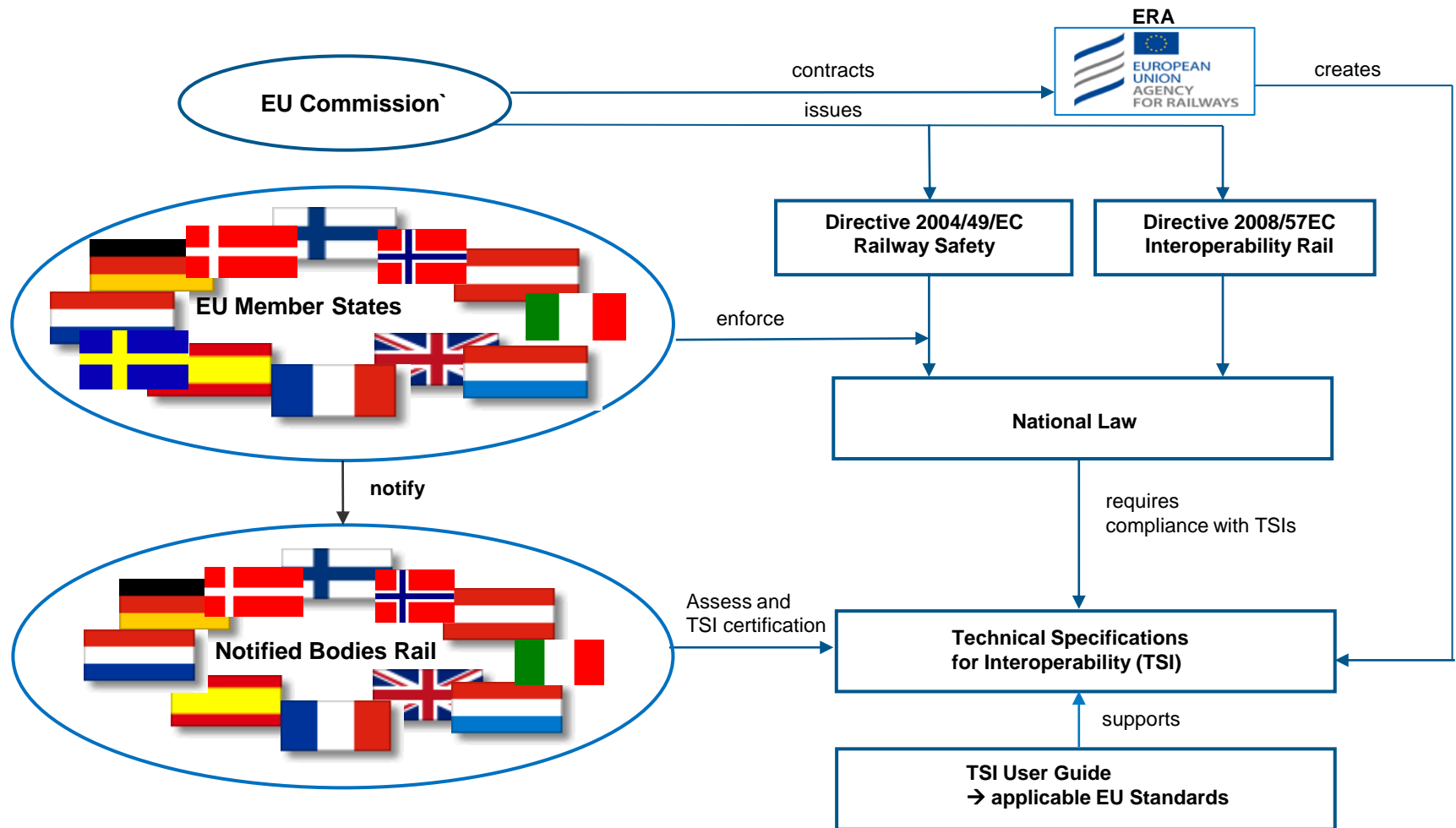
- Infrastructure
- Energy
- Rolling Stock - Locomotive & Passenger
- Noise
- Rolling Stock - Freight Wagons
- Safety in Railway Tunnels
- Control Command and Signalling

- Persons with Disabilities and with Reduced Mobility
- Operation and Traffic Management
- Telematics Application for Passenger Service
- Telematics Applications for Freight Service



CEN : Comité Européen de Normalisation
CENELEC : Committee European de Normalisation Electrotechnique
ETSI : European Telecommunication Standards Institute
UIC : International Union of Railways

Safety and Interoperability



EC Directives on Safety and Interoperability

Consequences

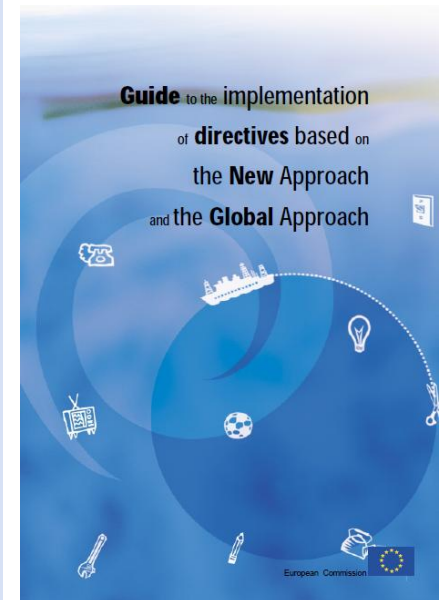
- Any rail system, subsystem or constituent crossing any European national border shall meet the Interoperability Directives plus corresponding TSIs with relevant standards
- Any operator crossing any European national border shall meet the Railway Safety Directive with TSI- CSM on Risk Assessment
- TSIs have been referred for global requirements of quality and safety as well as interoperability for EU.
(Ex. Korea national standards for rolling stock type approval)
- Certification for quality (ISO TS 22163 - IRIS) and SIL (EN 50126/50128/50129) including harmonization standards for products (EN/IEC/CENELEC/IEC/ETSI and etc.) have been recognized as essential requirements in the global market as well as European market.

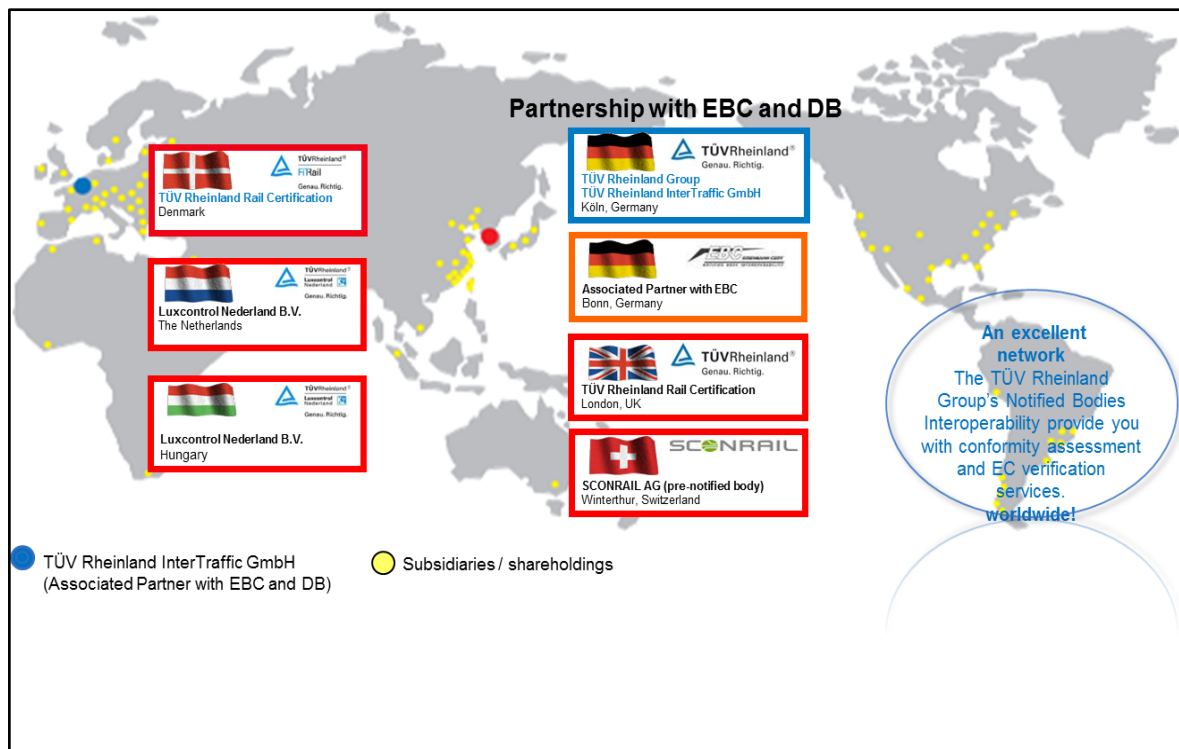


Conformity Assessment and EC Verification

Definition and Methods

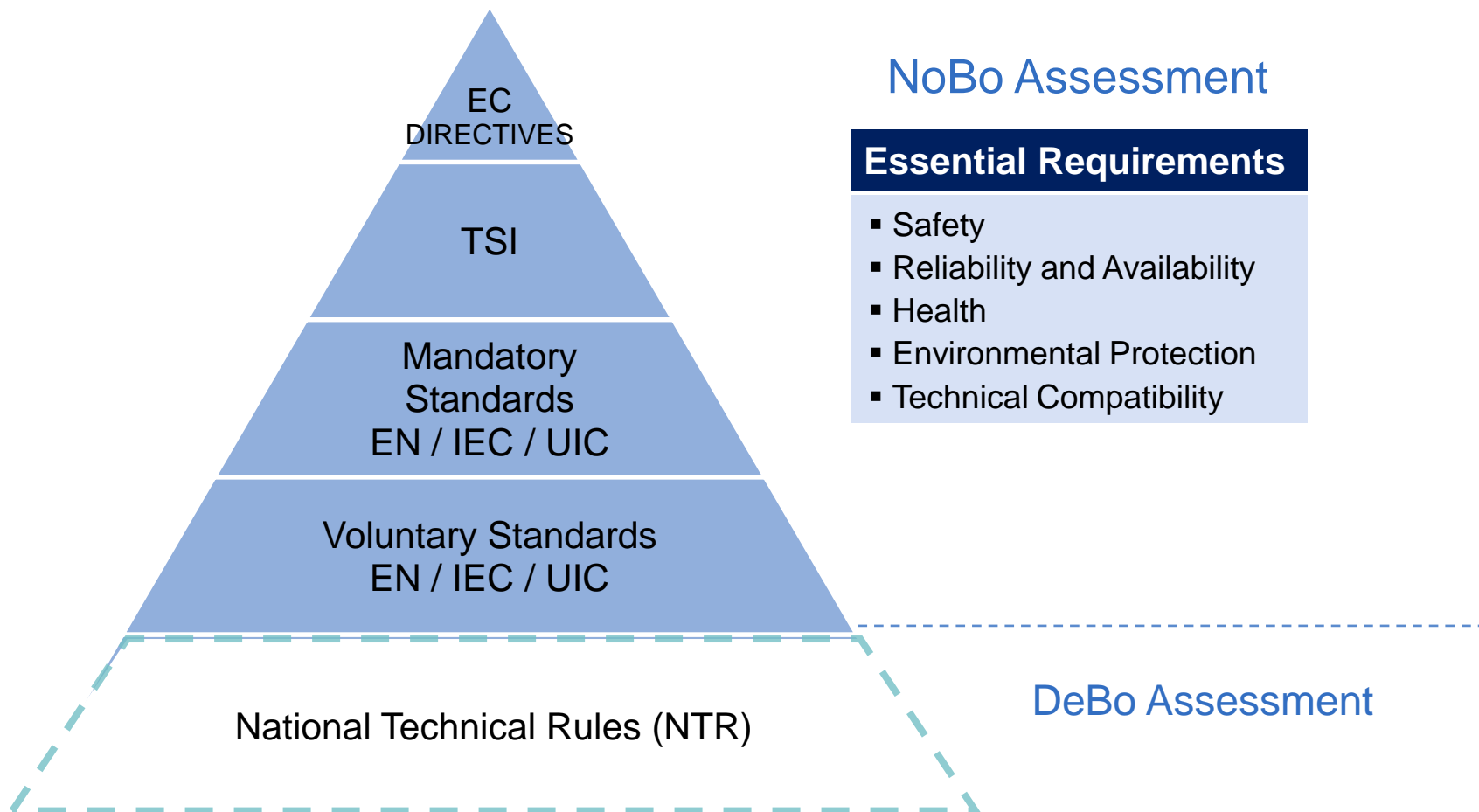
- The conformity with the harmonized rules and standards has to be demonstrated.
- The demonstration of conformity is called assessment for interoperability constituents.
- For subsystems the demonstration of conformity is called EC verification.
- The assessment procedure is described in modules.
- The modules relate to the design phase of products/subsystems, their production phase or both.
- The basic modules and their possible variants can be combined in a variety of ways in order to establish complete conformity assessment procedures.
- Each New Approach directive describes the range and contents of possible conformity assessment procedures and the modules to be applied.





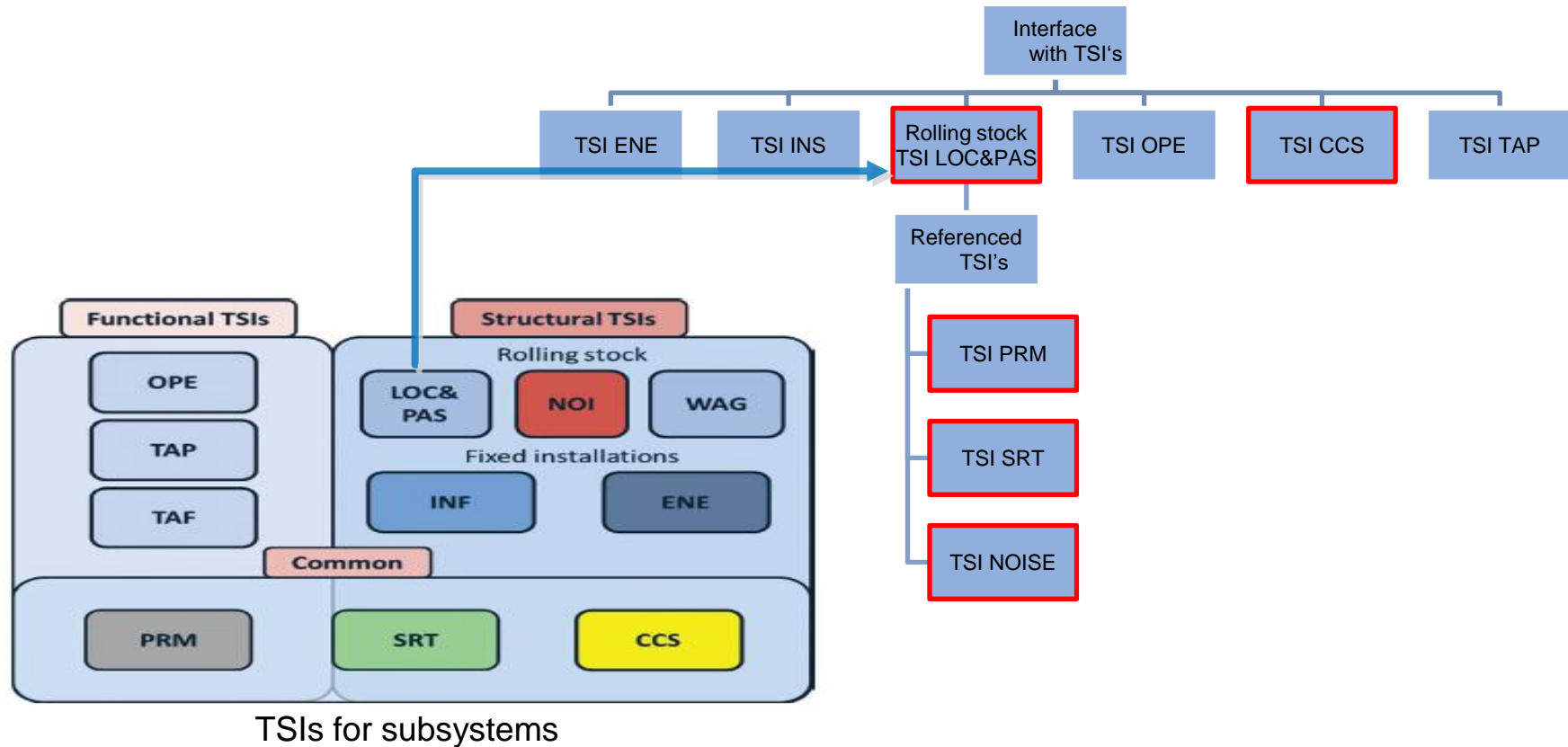
2. TSI Certification : Interoperability

Notified Body Assessment – Responsibility

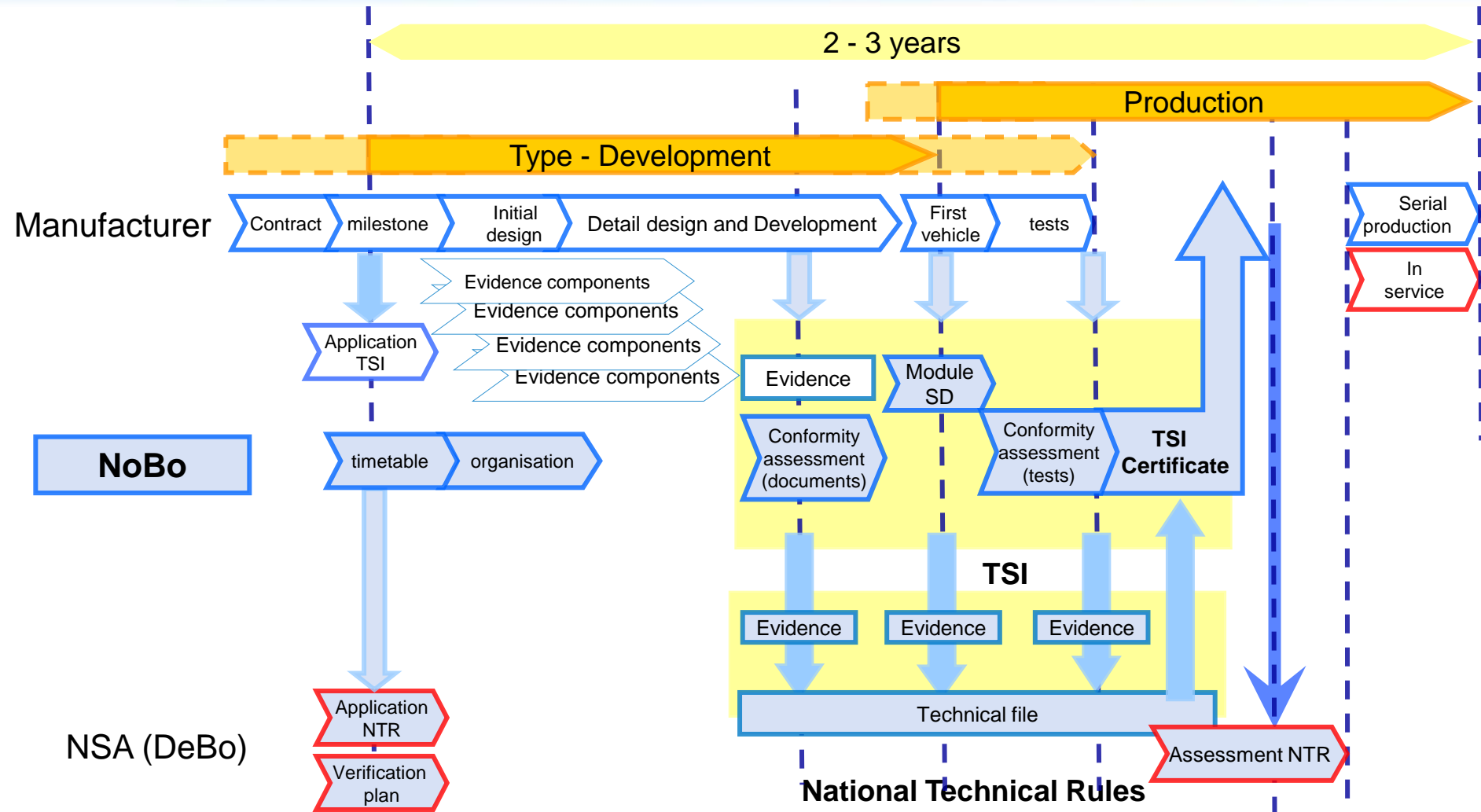


TSIs for Subsystems

- TSIs for subsystems and TSIs related to Rolling Stock (TSI LOC&PAS)



TSI Certification Process of Rolling Stock System



TSI Certification Example

■ Application Form and TSI Certificate with Assessment Report

Application for Certification	
The	
CLIENT (Applicant)	
hereby applies at the certification body	
CONTRACTOR (Notified Body)	TÜV Rheinland Rail Certification B.V. (NB 1010) Arthur van Schendelstraat 600 3511 MJ Utrecht, The Netherlands
for the certification of	<input checked="" type="checkbox"/> the constituent <input type="checkbox"/> the subsystem
PRODUCT	Front LED Monitor (DIF), External Side LED Monitor (DIS), Internal Sliding LED Monitor (PID), Internal LCD Monitor – Single/Twin (PID-S / PID-D)
on basis of Quotation no. TRRC/26418-TO of 2018-06-12 including any appendices (including the certification regulations) according to procedures as defined in European Interoperability Directive 2008/57/EC on:	
<input checked="" type="checkbox"/> the issue of one of the following types of certificates for interoperability constituent(s) in compliance with annex IV: <ul style="list-style-type: none"><input checked="" type="checkbox"/> EC type examination certificate (Module B, CB).<input type="checkbox"/> EC certificate of conformity (Module F, CF).<input type="checkbox"/> EC design examination (Module H2, CH1)<input type="checkbox"/> EC certificate of suitability for use (Module V, CV)	
<input type="checkbox"/> the issue of one of the following types of certificates for the subsystems in compliance with annex V: <ul style="list-style-type: none"><input type="checkbox"/> EC type examination certificate (Module SB)<input type="checkbox"/> EC design examination certificate (Modules SH1, SH2)<input type="checkbox"/> EC certificate of verification (Modules SD, SF, SG, SH1, SH2)<input type="checkbox"/> EC intermediate statement of verification (Modules SB, SD, SF, SG, SH1, SH2)	
<input type="checkbox"/> approval and surveillance of the quality management system according to the Technical Specifications for Interoperability TSI (Module CD, CH, CH1, D, SD, H1, H2, SH1, SH2)	
<input type="checkbox"/> the issue of an NNTR-certificate for a subsystem in compliance with annex VI, cl. 3.	

EC Type Examination Certificate	
Certificate no.: 1010/1/CB/2019/RST/ENTRRC4322940	
In accordance with Directive 2016/797/EU of 11 May 2016	
Object of Assessment	Interoperability Constituent Internal displays (LCD), PID-47000 according drawing M-TUV444-PID, S-0001, 2019-03-13 and PID-47000 according drawing M-TUV444-PID, D-0001, 2019-03-13
Applicant / Manufacturer	Inter-M Corporation Seoul OFFICE 603-6 Banghak-Dong Dobong-KU, Seoul, Republic of Korea
Assessment Requirements	TSI PRM Regulation (EU) No 13002014 in combination with those Harmonised Standards, Voluntary Standards (or parts thereof), other European or national rules authorized by TSI, and Alternative Solutions as identified in the EC Technical File (Section 5.1)
Module applied	CB of 2019/13/EU
Assessment Result	The Assessment Results are provided in detail within the attached EC Assessment Report. The Essential Requirements have been assessed as being met through compliance with the requirements of the relevant TSI(s) only.
Conditions and Limits of use	TRRC/B 19/432-TF section 3, 2019-06-24
EC Assessment Report	TRRC/B 19/432, 2019-06-24 The report is an integral part of this Certificate
EC Technical File	TRRC/B 19/432-TF, 2019-06-24 The Technical File is an integral part of this Certificate
Validity	This Certificate is valid until 2024-06-23 for the Object of Assessment as mentioned above as long as the Object of Assessment and the relevant technical documentation are not modified. The NB must be informed about any modifications without delay.
Date of Issue	2019-06-24
TÜV Rheinland Rail Certification B.V. Arthur van Schendelstraat 600 3511 MJ Utrecht The Netherlands EC Identification No. 1010	
Center Thomas Nevelstein	
TÜV Rheinland® Precisely Right.	
www.tuv.com	

TÜV Rheinland® Precisely Right.		
TÜV Rheinland Rail Certification B.V. Notified Body Interoperability Rail (NB 1010) according to Directive 2016/797/EU		
Assessment Report for the EC Type Examination of the Interoperability Constituent Call for aid devices PEI - 4700 according module CB		
TSI PRM (VO (EU) Nr. 1300/2014) Subsystem "rolling stock"		
Report No.	TRRC/B 19/430	
Report Date	2019-06-24	
Role	Name	Signature ¹
Lead Assessor	Dipl.-Ing. Grzegorz Kamac	<i>Grzegorz Kamac</i>
Reviewer	Dipl.-Ing. Knut Meierjürgen	<i>Knut Meierjürgen</i>
Approved by	Dipl.-Ing. Achim Hochrath	<i>Achim Hochrath</i>
¹ Advanced electronic signature, if used, in accordance with §25 and §26 of eIDAS (EU) regulation 910/2014 Report No. TRRC/B 19/430 page 1 of 12		



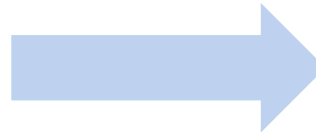
3. ISO TS 22163 Certification : Quality

IRIS - Global Quality Standard for the Railway Industry

IRIS
= **I**nternational **R**ailway **I**ndustry
Standard



IRIS Rev 0 in 2006 launched by
*UNIFE (international Railway
Industry Association)*



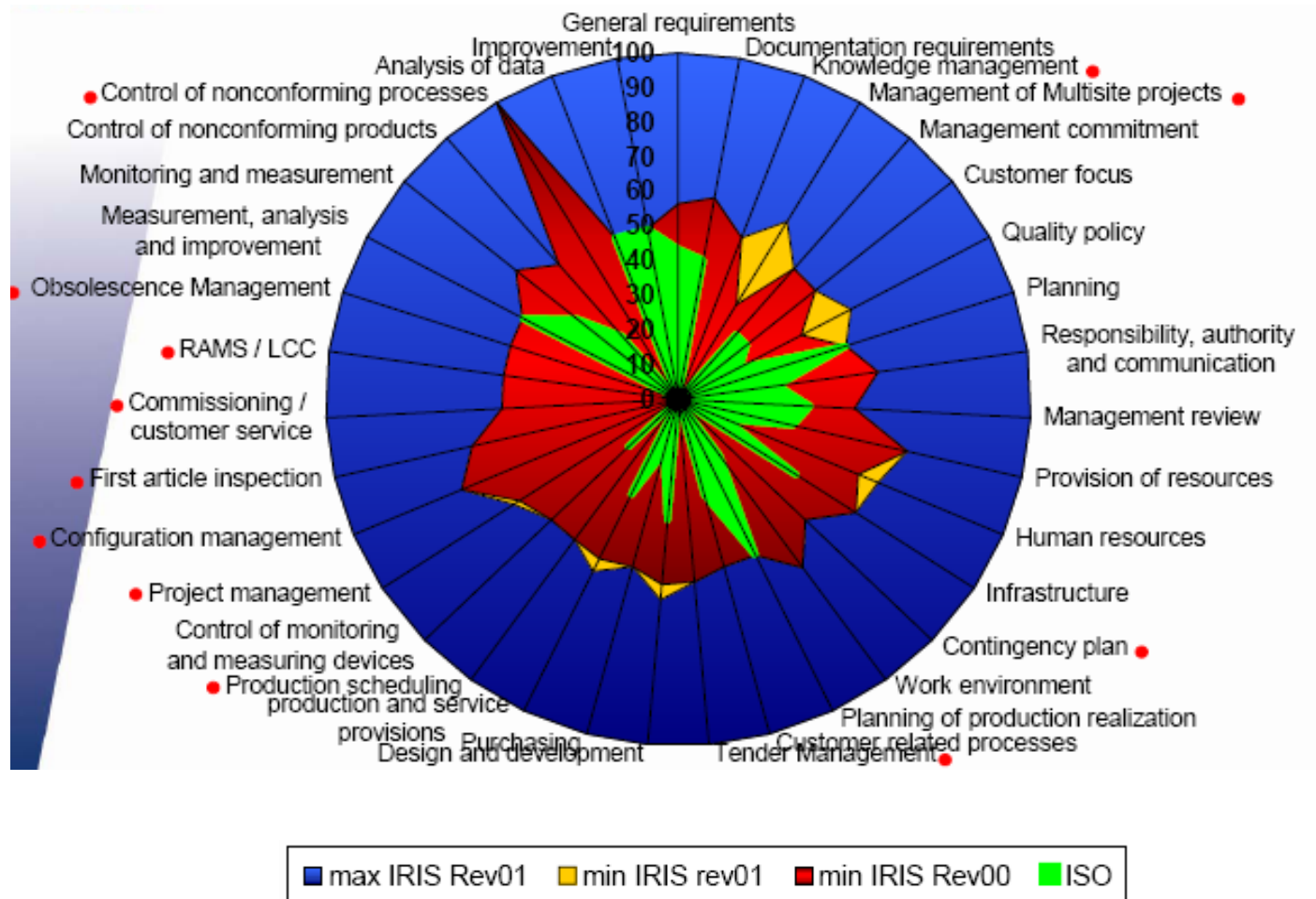
Agreement between
UNIFE and ISO in
2015



IRIS Objectives

- IRIS aims to continue to develop and implement a common global systems for the evaluation of Business Management Systems specific to the railway industry, comprising :
 - **International standard** based on the principles of ISO 9001 for the business management systems requirements in the railway industry
 - Derived from the standard **questionnaire**
 - **Evaluation process** with an assessment guideline to be performed by qualified auditors of approved certificate bodies
 - A web-based **IRIS Portal** (database) and Audit –**Tool** (software)

What makes the difference to ISO 9001?



Certification Process

1. Company will sign up for a **UINIFE member** at IRIS Portal
2. Company will apply for certification by the **Certification body** of their choice.
3. IRIS Certificate is issued when Initial Audit and Second Audit passed
 - 1) Initial Audit is performed based on **12 key criteria** (“knockout” criteria)
 - 2) Second Audit can be performed subject to “**initial audit passed**”.
4. **IRIS Certificate** will be issued for a maximum validity of **three years by UNIFE**.
5. **Surveillance audits** shall be successfully held on a regular basis, as a minimum once **every 12 months**.
6. Upon expiry, the companies shall be re-certified, constituting a **renewal of the IRIS Certificate**.

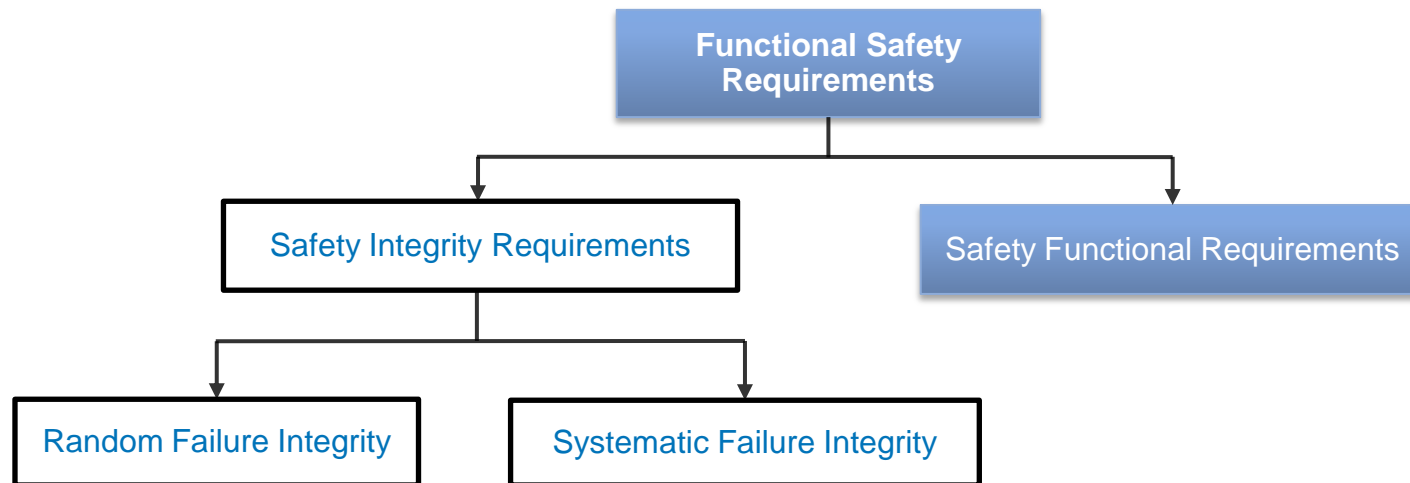




4. SIL Certification : Safety

Safety Function and Safety Integrity

- “What safety function has to be performed?”
 - **the safety functional requirements**
- “What degree of certainty is necessary that the safety function will be carried out?”
 - **the safety integrity requirements (dependability)**
- Together, these are the foundations of functional safety.



Safety Integrity

- Concept of **Safety Integrity** is described in IEC 61508 and then further applied in second tier standards to specific industries e.g.:
 - IEC 61511 : Process industry (Chemical Industry)
 - IEC 62061 : Safety of machinery
 - **EN 50126/50128/50129 : Rail industry**
 - IEC 61513 : Nuclear power plant instrumentation & control
 - ISO 26262 : Road vehicles

Safety Integrity Level (SIL)

- Random Failure Integrity : quantitative hardware (random) failure rate arising from failed or degraded components
- Systematic Failure Integrity : non-quantitative systematic failure integrity – hardware and software (represented by SIL)

The diagram illustrates the hierarchy of Safety Integrity Requirements. It branches into two main categories: Random Failure Integrity and Systematic Failure Integrity. Below these, a table maps Safety Integrity Levels (SIL) to Tolerable Hazard Rates (THR). The table is labeled 'Table A.1 – SIL-table'.

SIL	Random Failure Integrity	Systematic Failure Integrity
	Tolerable Hazard Rate THR per hour and per function	Safety Integrity Level
	$10^{-9} \leq \text{THR} < 10^{-8}$	4
	$10^{-8} \leq \text{THR} < 10^{-7}$	3
	$10^{-7} \leq \text{THR} < 10^{-6}$	2
	$10^{-6} \leq \text{THR} < 10^{-5}$	1

Table A.1 – SIL-table

SIL Certification Process

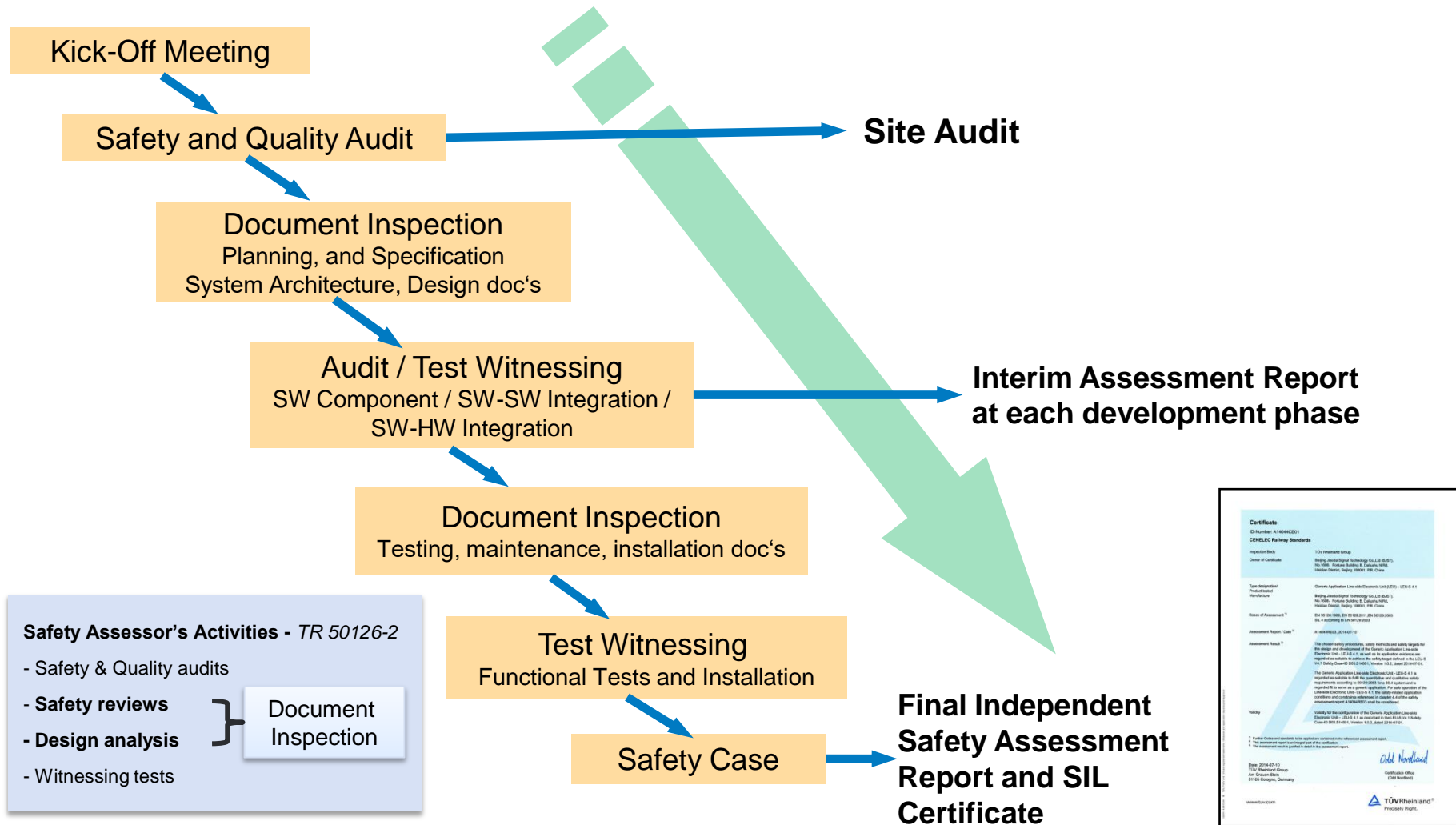
■ Documents for Inspection

Phase	Documentation Name	GA	SA
0. Planning Phase	Concept / System Description		
	Safety Plan		✓
	Verification Plan		✓
	Validation Plan		✓
	Quality Assurance Plan		✓
1. System Definition Phase	Configuration Management Plan		✓
	System Description		✓
2. Requirements Phase	PHA		✓
	System Requirements Specification		✓
	System Safety Requirements Specification (can be covered in SRS)		✓
	System Requirements Test Specification		✓
	Hazard Log and update		✓
3. Appointment of System Requirements Phase	System Architecture Design		✓
	Interface Description		✓
	System Integration Test Specification		✓
	SHA		✓
	CCFA (Common Cause Factor Analysis)		✓
	O&SHA		✓
	Hardware Requirements Specification		
	Hardware Requirements Test Specification		
	Hardware SSHA		
	Software Requirements Specification		
4.1 Hardware Design & Implementation	Overall Software Test Specification		
	Hardware Functions Description		
	Hardware Schematic Diagram		
	Hardware PCB Design		
	Hardware Bill of Material		
	Hardware Assembly documents		
	Hardware Failure Analysis		
	Hardware Failure Test Report		
	Hardware Test Report		
	Hardware Validation Report		
4.2 Software Design & Implementation	Software Architecture Design Specification (incl. Software Interface Specifications)		
	Software Integration Test Specification		
	Software Component Design Specification		
	Software Component Test Specification		
	Software Component Test Report		
	Software Integration Test Report		
	Overall Software Test Report		
	Software Validation Report		

Phase	Documentation Name	GA	SA
4.3 Application Data/Algorithm Design & Implementation	Application Requirements Specification (can be covered in SWRS)		
	Application Preparation Plan (incl. preparation & verification procedure)		
	Application Test Specification		
	Application Architecture and Design (can be covered in SWAD)		
	Application Preparation Verification Report		✓
4.4 Software Deployment	Application Test Report		✓
	Source Code of Application Data/Algorithms		✓
	Application Data/Algorithms Verification Report		✓
	Software Release and Deployment Plan		
	Software Deployment Manual		
4.5 Software Maintenance	Release Notes		✓
	Deployment Records		✓
	Deployment Verification Report		✓
5. [GA] System Integration	Software Maintenance Plan		
	Software Change Records		✓
	Software Maintenance Records		✓
6. [GA] System Validation	Software Maintenance Verification Report		✓
	Environmental/EMC Test Report & Certificate		
	System Integration Test Report		
7. [SA] Manufacture	Operation & Maintenance Manuals		
	System Requirements Test Report		
	Fault Tree Analysis (FTA)		
8. [SA] Installation, Testing and Commissioning	System Validation Report		
	GA Safety Case		
	GA Safety Assessment Report		✓
9. [SA] System Validation	Manufacture Records		✓
	Installation Manuals		✓
	Installation Records		✓
Others	Test Procedures		✓
	Test Reports		✓
	Environmental/EMC Test Report & Certificate		✓
	Operation & Maintenance Manuals		✓
	Fault Tree Analysis (FTA)		✓
	System Validation Report		✓
	Hazard Log		✓
	SA Safety Case		✓
	Verification Reports		✓
	Tool Validation Reports		

SIL Certification Process

– Document Inspection and Site Audit



*Thank
you*

