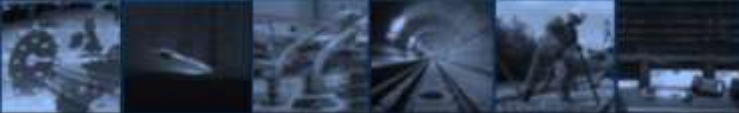


NoBo/DeBo Activity

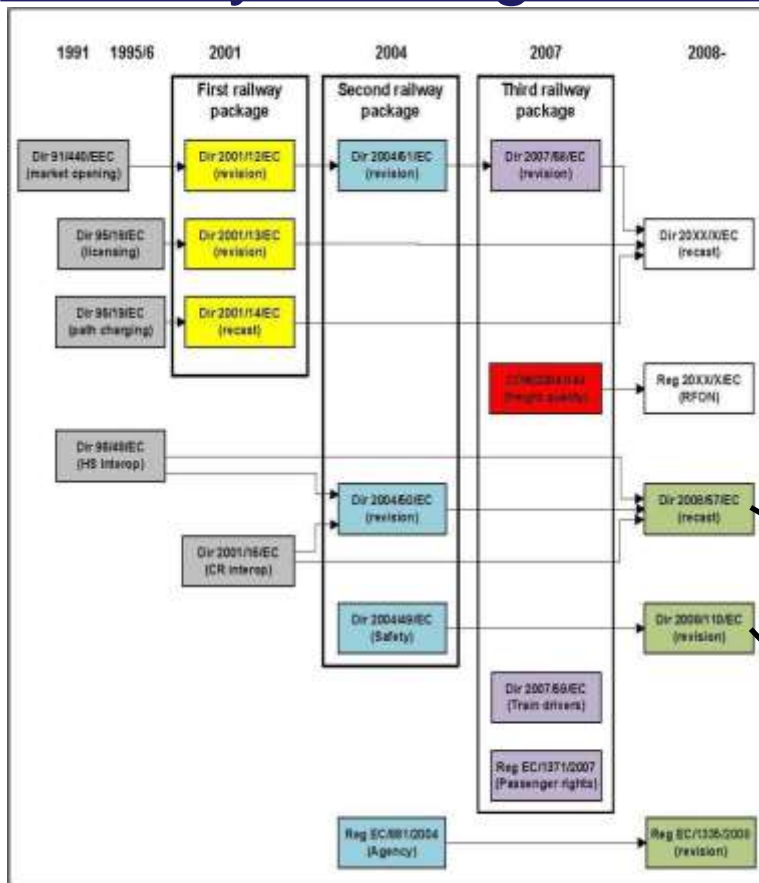




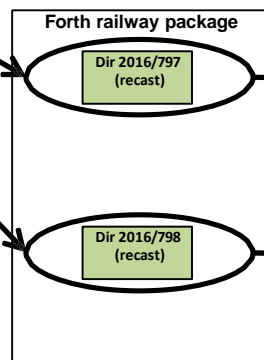
EU LEGAL FRAMEWORK



Railway EU Legislative Framework Railway Packages



Between 2001 and 2016, four legislative packages were adopted with the aim of gradually opening up rail transport service markets for competition, making national railway systems interoperable and defining appropriate framework conditions for the development of a single European railway area. These include charging and capacity allocation rules, common provisions on licensing of railway undertakings and train driver certification, safety requirements, the creation of the European Agency for railways and rail regulatory bodies in each Member State as well as rail passenger rights.



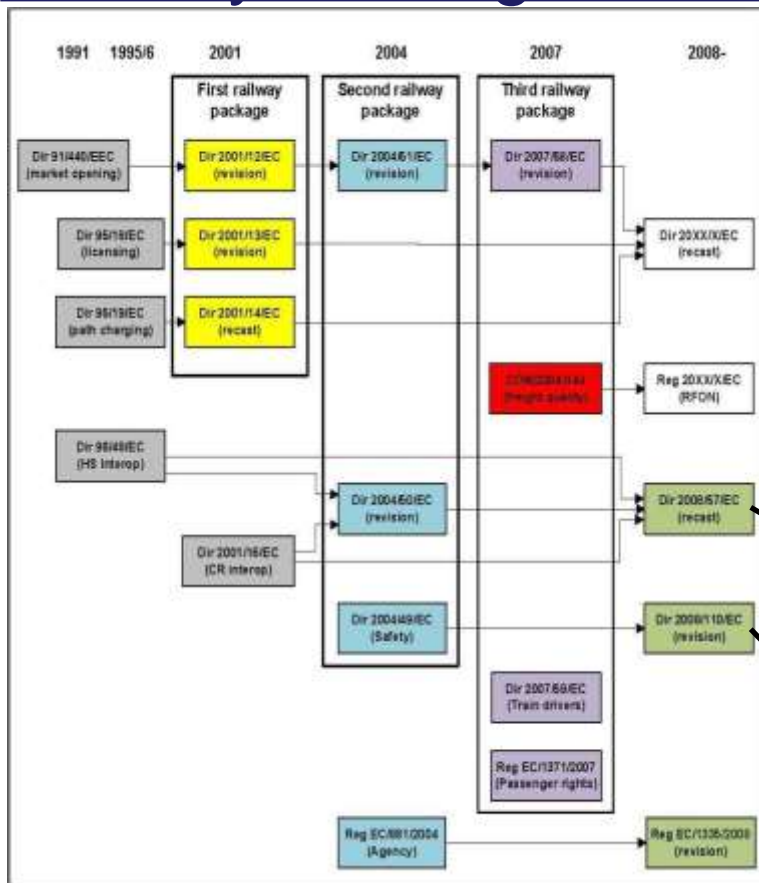
IOD (*InterOperability Directive*)

New Approach Product Directive

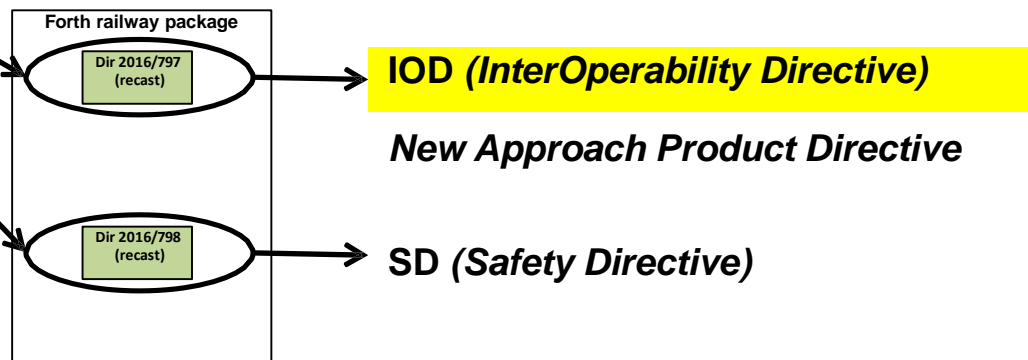
SD (*Safety Directive*)



Railway EU Legislative Framework Railway Packages



Under the New Approach directives a mechanism is in place whereby national authorities **NOTIFY** the **THIRD PARTIES (Notified Bodies)** they design to **CARRY OUT CONFORMITY ASSESSMENTS** based on recourse to these standards.





Railway EU Legislative Framework Railway Packages

ROLES AND RESPONSABILITIES OF NOTIFIED BODY

- Is a **third party conformity assessment body**, notified by Member State in charge for jurisdiction, which is recognized to be **technically competent to assess the compliance of products** with the requirements of Union harmonization legislation that applies to them.
- Carries out the **tasks pertaining to the conformity assessment procedures** referred to in the applicable technical harmonization legislation when a third party is required.

NOTE (IOD):

***‘notified bodies’** means the bodies which are responsible for assessing the conformity or suitability for use of the interoperability constituents or for appraising the ‘EC’ procedure for verification of the subsystems.*



Railway EU Legislative Framework Railway Packages

PRINCIPLES OF 'NEW APPROACH' APPLIED TO INTEROPERABILITY DIRECTIVE (IOD) AND TSIs

- Uniform conditions for product conformity assessment and testing are set out.
- To this end, EU legislation describes **modules** for the different phases of the conformity **assessment procedures** and lays down criteria for the use of these procedures and for the designation of bodies carrying out these procedures.
- **2010/713/EU** *Commission Decision of 09/11/2010 on modules for the procedures for assessment of conformity, suitability for use and EC verification to be used in the technical specifications for interoperability adopted under Directive 2008/57/EC of the European Parliament and of the Council.*



INTEROPERABILITY DIRECTIVE HOMOLOGATION



Rail Systems IOD Homologation

ROLE OF TSIs

TSIs clarify the relationship between the **essential requirements** and the **European standards (EN)** and **other documents of a normative nature**.

In particular, a **clear distinction** should be drawn between:

- the standards indicated in the TSIs (or parts of standards) which are **mandatory** in order to achieve the objectives of IOD;
- the 'harmonized' standards, developed in the spirit of the new approach to technical harmonization and standardization (**not mandatory**).

Meeting the requirements of the TSI is sufficient to assume compliance with the essential requirements of IOD



Rail Systems IOD Homologation

Interoperability constituents

- All ICs shall be subject to the procedure for **assessing conformity and suitability for the use indicated in the relevant TSI** and accompanied by the corresponding certificate.
- Member States shall consider that **an IC meets the essential requirements if it complies with the conditions laid down by the corresponding TSI or the corresponding European specifications developed to comply with these conditions.**
- **‘EC’ Declaration** applies to the ICs involved in the interoperability of the rail system.



Rail Systems IOD Homologation

Interoperability constituents

➤ **'EC' declaration** covers:

- either the assessment by a notified body (or bodies) of the intrinsic conformity of an IC, considered in isolation, to the technical specifications to be met (**CONFORMITY**),
- or the assessment/judgement by a notified body (or bodies) of the **SUITABILITY FOR USE** of an IC, considered within its railway environment and, in particular in cases where the interfaces are involved, in relation to the technical specifications, particularly those of a functional nature, which are to be checked.

The **assessment procedures** implemented by the notified bodies, at the **design and production stages**, will draw upon the **modules defined in Decision 2010/713/EC**, in accordance with the conditions referred to in the TSIs.



Rail Systems IOD Homologation

RAILWAY SUBSYSTEMS

Each Member State shall authorize the **placing in service** of structural subsystems only if they are:

- **DESIGNED**
- **CONSTRUCTED** and
- **INSTALLED**

in such a way as to **meet the essential requirements** concerning them **when integrated into the rail system**.

In particular, they shall check:

- the **technical compatibility** of these subsystems **with the system into which they are being integrated**
- the **safe integration** of these subsystems in accordance with SD (2004/49/EC)



Rail Systems IOD Homologation

RAILWAY SUBSYSTEMS TSIs

Structural Subsystems

- Infrastructure
- Energy
- Rolling Stock (Loc&Pas – Wagon – Noise)

Common TSIs

- Command, Control and signalling
- Persons with reduced mobility
- Safety in railway tunnels

Functional Subsystems

- Operation and traffic management
- Telematics application for freight service
- Telematics application for passenger service
- Maintenance



Rail Systems IOD Homologation

TSIs

Open Points

Technical aspects corresponding to the essential requirements not explicitly covered in a TSI. They are identified in an annex to the TSI as ***open points***.

When a TSI conform vehicle has already been authorized in one MS, additional authorizations should only consider those open points that relate to technical compatibility between the vehicle and the network.

Derogations

Authorization granted by a MS not to apply one or more TSIs (or parts).

Derogations are possible only in regulated circumstances, and are to be notified and approved by EU Commission.

Specific Case

A part of the rail system which needs **special provisions in the TSIs**, either temporary or definitive, because of geographical, topographical or urban environment constraints or those affecting compatibility with the existing system.



TSI CERTIFICATION PROCESS



TSI Certification Process

Modules

- Module SG – EC verification based on unit verification
- Module SB – EC - type examination
- Module SF – EC verification based on product verification
- Module SD – EC verification based on quality management system of the production process
- Module SH1/SH2 – EC verification based on full quality management system plus design examination



TSI Certification Process

Module SB. EC-type examination

In the EC-type examination the notified body examines the technical design of a subsystem and verifies and attests that the technical design of the subsystem meets the requirements of the relevant TSI(s).

EC-type examination shall be carried out by:

- design type
- production type

A type may cover several versions of the subsystem provided that the differences between the versions do not affect the provisions of the relevant TSI(s).

Phases of the activity involved:

- *Design*
- *Manufacture*
- *Testing*



TSI Certification Process

Module SD. EC verification based on quality management system of the production process

The notified body shall assess the quality management system for production to determine whether it assures conformity with the type and issue a QMS approval certificate.

The quality management system shall ensure by means of QMS documentation that the subsystem is in conformity with the type described in the EC-type examination certificate and therefore complies with the requirements of the relevant TSI(s).

The notified body does not have to take part in any tests performed in the production phase, because he can rely on the approved quality management system.

If the manufacturer of a part of the subsystem or the whole subsystem is changed during the project than a new assessment of the quality management system for production of this manufacturer has to be carried out.



TSI Certification Process

Module SF. EC verification based on product verification

EC verification based on product verification (module SF) follows module SB.

The notified body shall carry out appropriate examinations and tests in order to check the conformity of the subsystem with the approved type as described in the EC-type examination certificate. This then implies conformity with the requirements of the relevant TSI(s).

All subsystems shall be individually examined and appropriate tests set out in the relevant TSI(s), harmonised standard(s) and/or technical specifications shall be carried out in order to verify conformity with the approved Type.



TSI Certification Process

Module SH1/SH2. EC verification based on full quality management system plus design examination

The design, manufacture and final inspection and testing of the subsystem concerned shall be covered by an approved quality management system that is checked against all the requirements of the relevant TSI(s) by a notified body.

The notified body has to examine the design of the subsystem and, where the design meets the requirements of the relevant TSI(s) that apply to the subsystem, it shall issue an EC-design examination certificate.

The EC-design examination certificate must not be confused with the EC-type examination certificate of module SB that attests the conformity of a specimen “representative of the production envisaged”, so that the conformity of the products may be checked against this specimen.

By the full quality management system (QMS) the NoBo has to take into account the QMS of the applicant as the QMS of the main contractors. Indeed, the NoBo has to evaluate all the QMS supporting the compliance of the constituent/subsystem with the requirements of the relevant TSI's.



TSI Certification Process

Module SG. EC verification based on unit verification

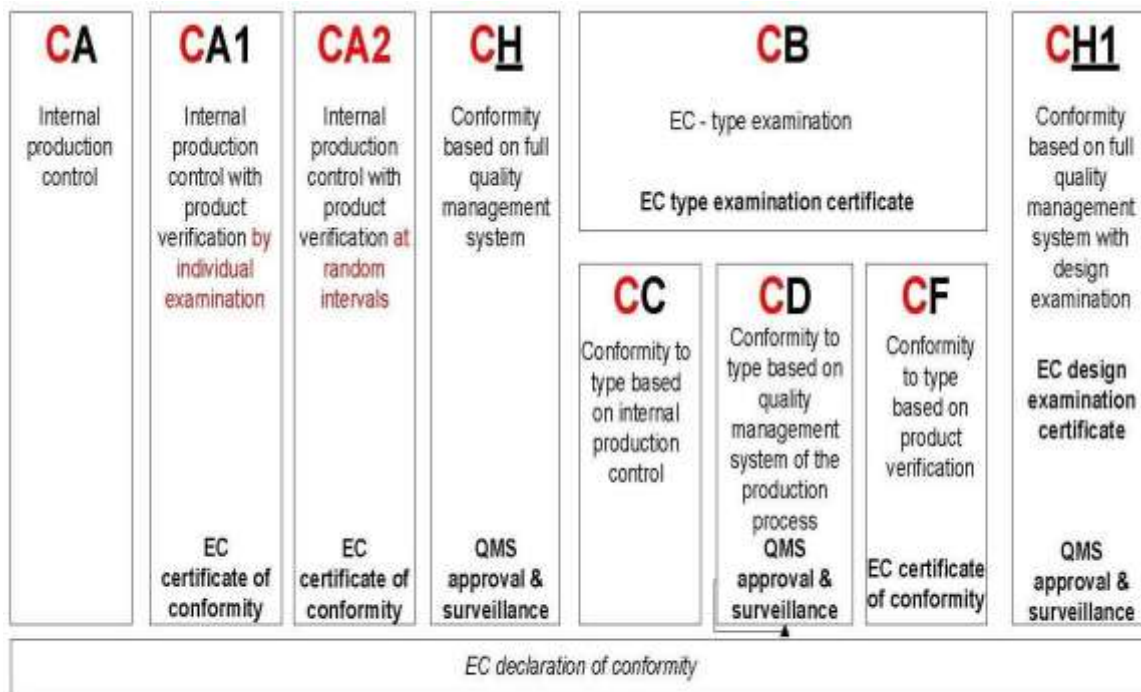
The task of the notified body in module SG is to assess all different subsystems in a project according against all applicable TSI requirements.

In the production phase each subsystem has to be checked regardless of identical design, because there is no quality management system to rely on.



TSI Certification Process

IC Modules

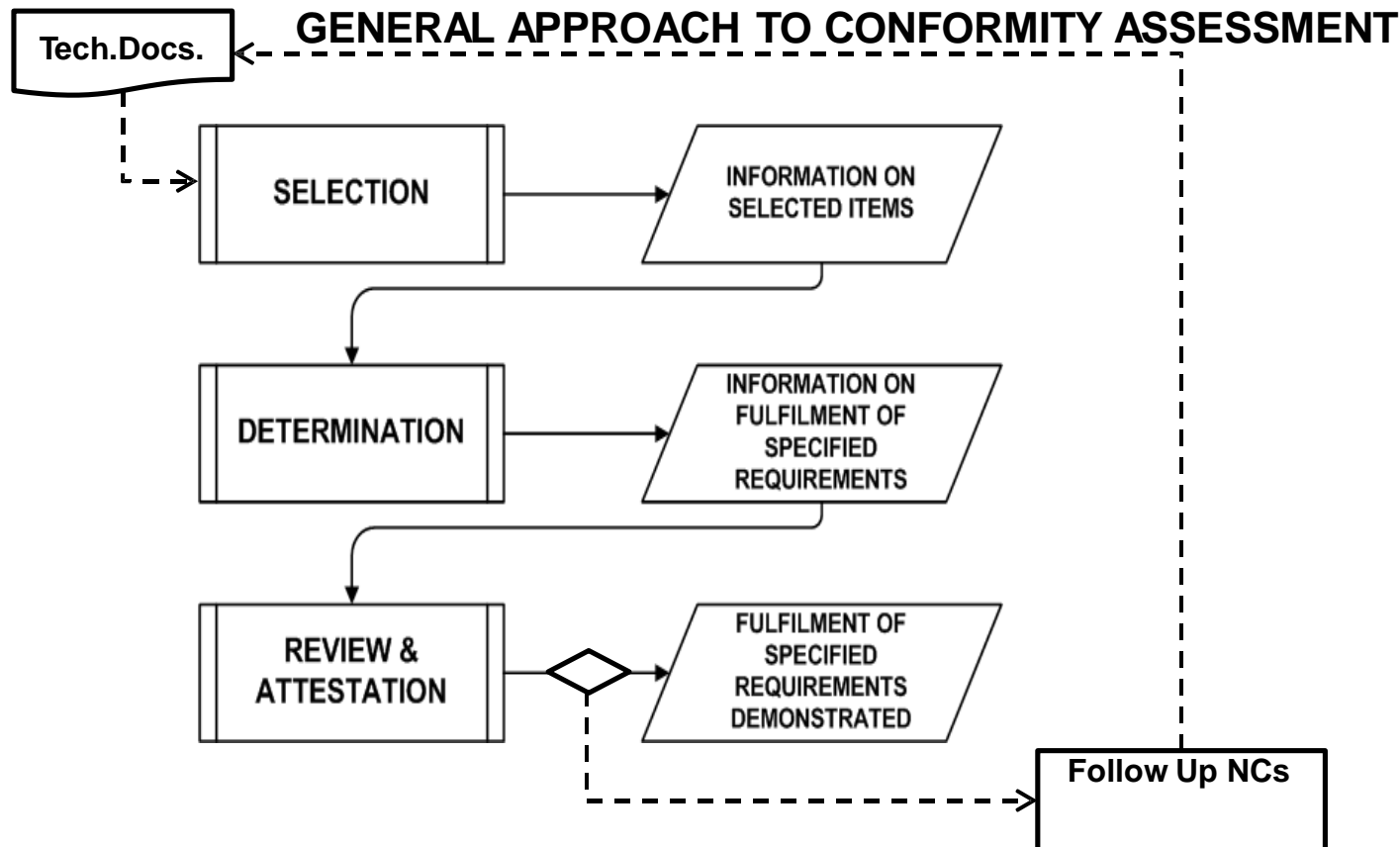


Documents issued by notified bodies

Documents issued by manufacturers or their authorised representatives



TSI Certification Process





TSI Certification Process

Certification request

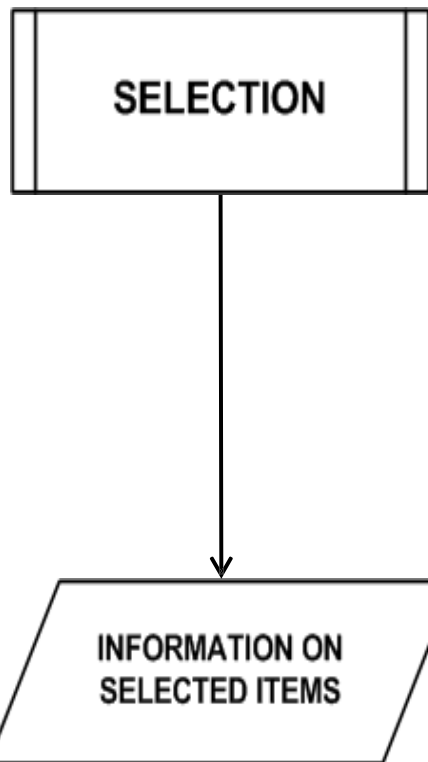
In order to be able to proceed with the formulation of an offer, the certification request must be formalized by filling out an instance which must contain at least:

- customer's general information
- the scope of the required certification
- an exhaustive description of the product to be certified
- the indication of the production sites concerned with its manufacture
- a statement by the applicant in which it agrees to comply with the requirements of the certification system to be applied and agrees to provide any information necessary to support the assessment process.



TSI Certification Process

Selection involves **planning and preparation activities** in order to collect or produce all the information and input needed for the subsequent determination function.

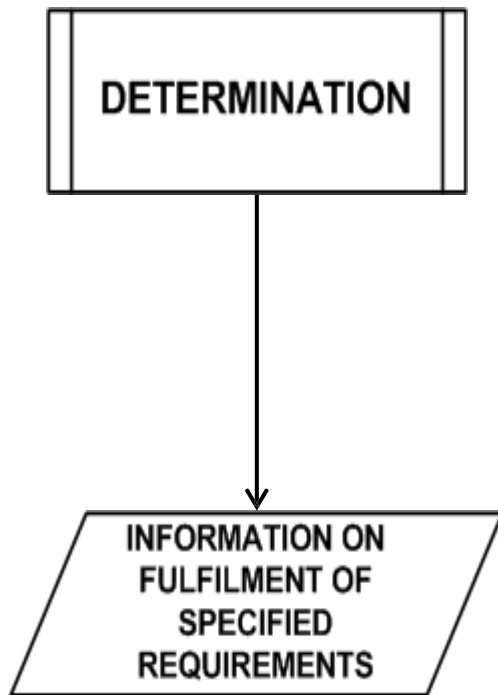


Selection include:

- **sampling** of requirements and/or specimens (e.g. selection of critical parts or requirements)
- choice of most appropriate **assessment procedures** (testing, audits, inspections) and related methods
- selection of proper **locations and/or conditions** to perform procedures (development stage, on-site, laboratories, etc.).



TSI Certification Process



Determination activities are undertaken to develop complete information regarding fulfilment of the specified requirements by the object of conformity assessment or its sample.

Determination include:

- **examination or analysis of design, or other documentation**
- **inspections**
- **testing**
- **audit**

Determination generally require the exercise of **professional judgement**, in particular when assessing conformity with **general requirements**.



TSI Certification Process



Review is the final stage of checking before taking decisions as to whether or not the object of conformity assessment has been reliably demonstrated to fulfil the specified requirements.

Attestation results in issuing a “Statement of Conformity” which refers to any means of communicating that fulfillment of specified requirements has been demonstrated.



If fulfillment of the specified requirements has not been demonstrated, the finding of nonconformity may be reported.

A **follow up** (iteration of process) can be needed to check that critical non conformities have been effectively fixed.



TSI Certification Process

Conformity Assessment Process generally ends when attestation is issued.

- In some cases, systematic iteration of the process may be needed **to maintain the validity of the statement** resulting from attestation (depends on assessment methods and/or provisions of applicable norms).
- Iterations can also be needed in other non-systematic cases (e.g. changes in object or other elements relevant for its conformity to specified requirements)
- In these cases, validity of the attestation is subject to **SURVEILLANCE** activities, performed in a similar way.



TSI Certification Process

ISARail Methodology

Phases	Outputs
Planning	Activity planning
	Taking charge of the activity
	Assessment Activities Planning
	Assessment Specification
Determination	Activity Folder
	Sheets of the activities
Review and attestation	ISA Report(s)
	Inspection Certificate / EC Certificate of verification
Follow-up Non Conformities	Management of Non Conformities Module



TSI Certification Process

ISARail Methodology – External Commitment

If the execution of part of the activities expected by the assessment specification requires commitment to an external subject (subcontracting), this is selected from among those in possession of appropriate qualification.

Qualification requirements: relevant ISO / IEC 17000 series standards and accreditation regulations.

Impartiality requirements: always applied.

Customer guarantee: legally binding contractual arrangements for the parties.



TSI Certification Process

Subcontracting of Inspection Activities

The subcontractor is selected, where possible, among the bodies accredited in accordance with ISO / IEC 17020 issued by one of the recognized body at level of EA (European Cooperation for Accreditation), with a scope of accreditation relevant to the subject of subcontracting.

In the absence of such accreditation, the suitability of the subcontractor in relation to the requirements of ISO / IEC 17020, and to the requirements of competence and experience related to the scope of the activities entrusted to it, have been provisionally demonstrated by conducting a qualification audit .

The documentation relating to this audit is kept at the disposal of the accreditation, recognition or notification bodies to which the subcontractor is required to guarantee the possibility to carry out verifications and attend the activities with their own observers.



TSI Certification Process

Subcontracting of Test Activities

If the activity falls within the "analytical testing" field, to be performed under controlled environmental conditions and using sophisticated equipment and methods, outsourcing is defined as the acquisition of a laboratory service whose activity falls within the scope of EN ISO / IEC 17025.

Laboratory selection criteria:

- 1) Laboratory accredited according to EN ISO / IEC 17025 for the specific test
- 2) Laboratory in possession of a qualification obtained by one of the Notified Bodies for tests and checks similar to those to be carried out in the course of the inspection activity
- 3) The qualification of the lab carried out through a second-party audit



TSI Certification Process

Subcontracting of Test Activities

In the case where the customer intends to perform some of the tests specified, the use of the results obtained for the purposes of the formulation of conformity judgments is subject to the prior verification of possession of suitable requirements by the laboratory used.

In case of EA and / or ILAC-accredited laboratory for the type of test performed, the verification is limited to the congruence between the test performed and the assessment specification prepared for the inspection.

In case of a not accredited laboratory, the possession of competence, independence, testing and material handling processes, facilities and equipment and other processes relevant to the contribution to the subsystem are verified directly through an audit, verifying in particular the suitability of the methods applied and the proper and competent execution of the activities carried out. This last verification is obtained by attending the tests (witnessing).

ECM Activity



ISARail group

TRUST IN SKILL • INDEPENDENCE • IMPARTIALITY • INTEGRITY



EU LEGAL FRAMEWORK



EU Legal Framework - ECM

Entity in Charge of Maintenance (ECM)

Introduced by Directive 2008/110 / EC

Each vehicle, before it is placed in service or used on the network, shall have an entity in charge of maintenance assigned to it and this entity shall be registered in the NVR

The entity shall ensure that the vehicles for which it is in charge of maintenance are in a safe state of running by means of a system of maintenance

The entity in charge of maintenance shall carry out the maintenance itself or make use of contracted maintenance workshops

In the case of freight wagons, each entity in charge of maintenance shall be certified by a body accredited or recognised or by a national safety authority.



Requirement and Certification

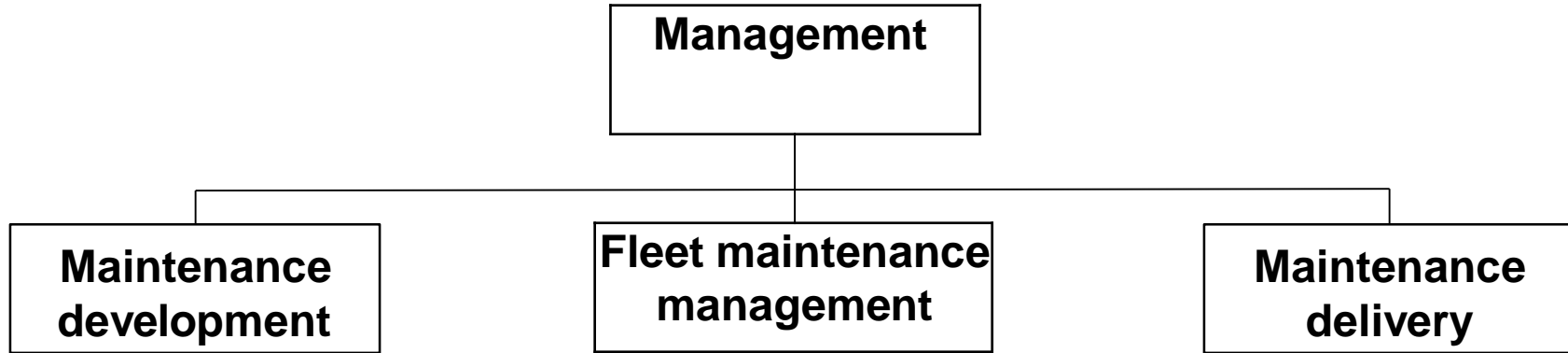
Regulation 445/2009/CE – System of Certification of Entities in Charge of Maintenance for freight wagons

The maintenance system shall be composed of the following functions:

- (a) **the management function**, which supervises and coordinates the maintenance functions referred to in points (b) to (d) and ensures the safe state of the freight wagon in the railway system;
- (b) **the maintenance development function**, which is responsible for the management of the maintenance documentation, including the configuration management, based on design and operational data as well as on performance and return on experience;
- (c) **the fleet maintenance management function**, which manages the freight wagon's removal for maintenance and its return to operation after maintenance;
- (d) **the maintenance delivery function**, which delivers the required technical maintenance of a freight wagon or parts of it, including the release to service documentation.



Requirement and Certification



The purpose of the system of certification is to provide evidence that an entity in charge of maintenance has established its maintenance system and can meet requirements to ensure the safe state of running of any freight wagon for which it is in charge of maintenance.

The assessment by a certification body of an application for an ECM certificate is an assessment of the applicant's ability to manage maintenance activities and to deliver the operational functions of maintenance .

It is configured as a PRODUCT certification and not a management system certification.



Requirement and Certification

Phases

Planning \longrightarrow *Audit Plan*

Audit + Inspection \longrightarrow *DAV – Inspection report – NC list*

Evaluation on corrections and corrective actions \longrightarrow *Assessment*



TECHNICAL ASSESSMENT ON RST



Subjects

Shunters



RST (Vehicle)

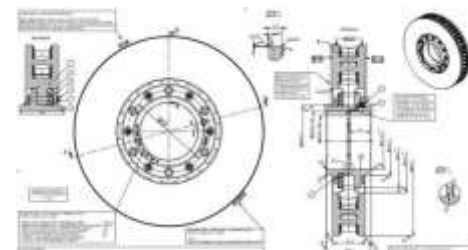
On track machines



Wagons



RST (Constituent)

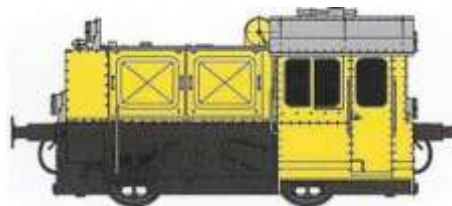
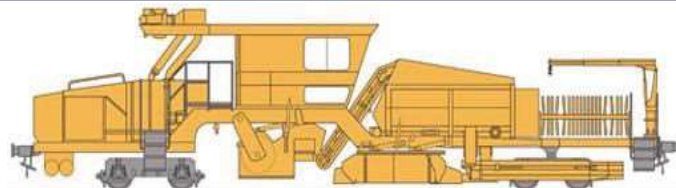




Technical Assessment

Rolling Stock

Traction
Wheel set
Car Body
Braking System
Maintenance

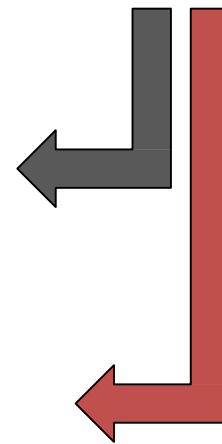
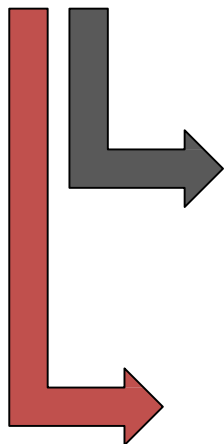


Authorization
for
Circulation

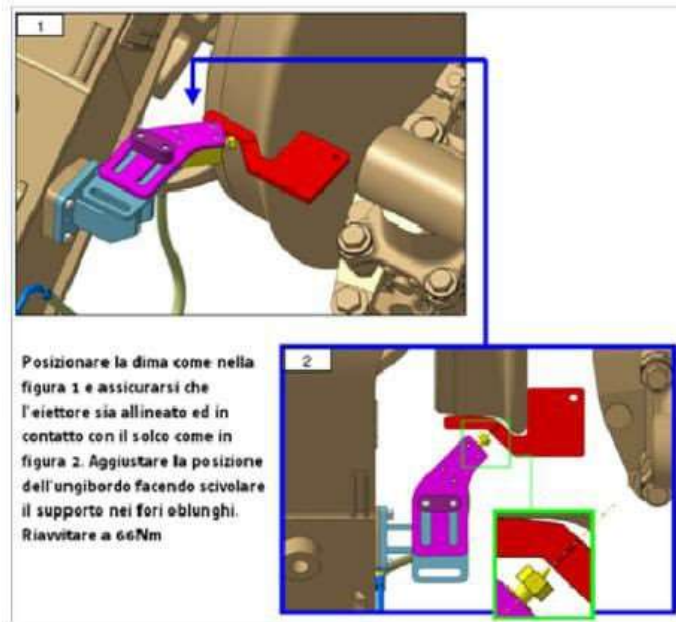
Possible Prescription
(maximum speed...
minimum curvature
radius...)

Reference Documentation

Nationals Norms
Technical Specification
Technical unit of the railways
UIC Fiches
EN Norms
Project Documentation



Inspection services on the execution of the maintenance on the high speed train “Italo”





SCMT Homologation (ALS, ASF, BT, GETS)

- ALe126+Le126 Firema - Metro Campania Nord Est
- Alfa2 Firema – EAV
- ALn668 Fiat - Metro Campania Nord Est
- ALe601 Ansaldo Breda - Trenitalia
- Ale200+Le 200 Firema - Ferrovie del Gargano
- Ale80 Firema - Ferrovie del Gargano
- ALe088+Le088 Firema - Ferrovie Emilia Romagna
- E640 Ansaldo Breda - Ferrovie Emilia Romagna
- ATR220 Pesa - Ferrovie Emilia Romagna
- ALn 776 Fiat - Ferrovie Centrali Umbre
- EU43 Bombardier - Rail Traction Company
- D753 Sistemi Territoriali
- E402B Ansaldo Breda - RFI
- BB36300 Alstom SNCF
- D100 Vossloh
- G2000 Vossloh
- E190 Siemens OBB
- BR189 Siemens RTC



SCMT Homologation (ALS, ASF, BT, GETS)

Onboard Technological System (STB):

Systems, sub-systems, instruments and devices to perform the train protection and control

Features:

- Train Protection and Control
- Driver's presence and vigilance
- Speed / time measurement and visualization to driver
- Aid to driving
- Event and Parameters recording (related to driving)

SSB **STB**



Assessment Process



Alimentazione loop
Max Ø conduttore del loop = 4 mm
Lati del loop = 1500 mm



Test & Measurement

An Example

Signal-Noise Ratio on Receivers

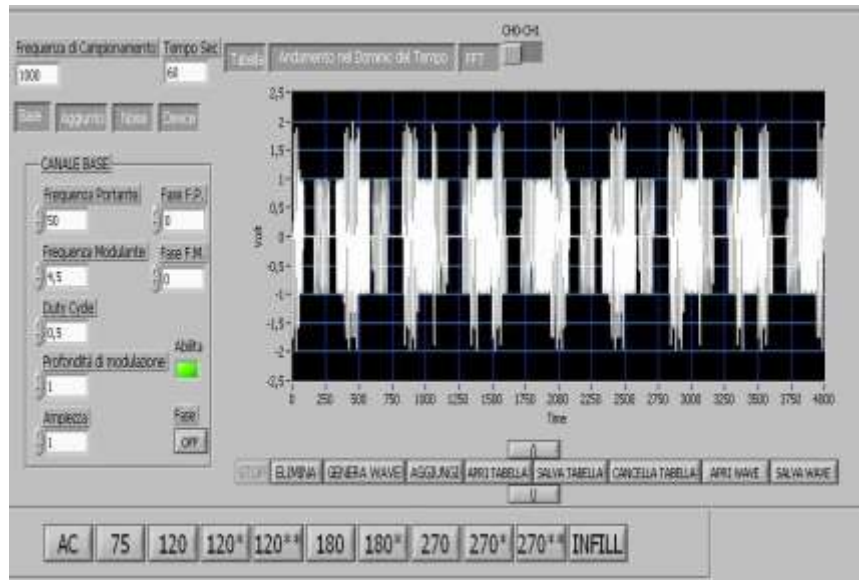
Dynamic Test – Track Analysis



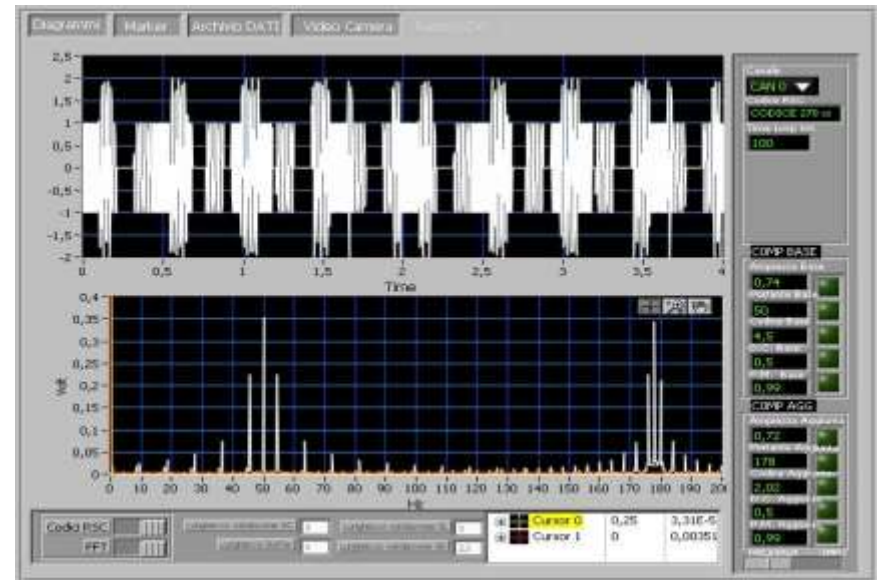


Test & Measurement

Signals Generation



Acquisition and Analysis RT





ISARail group

Via Gorizia, 1 | 80033 – Cicciano (NA) – Italy
www.isarail.com | marketing@isarail.com