

Conformity Assessment in Railways

IPA Workshop 24/03/2026

Belgrade (RS) | Jean Paul LODZINSKI



EUROPEAN
UNION
AGENCY
FOR RAILWAYS

DRAFT AGENDA

TIME	ITEM	SPEAKER(S)
09:00 – 09:30	Registration	
09:30 – 09:45	Welcome by the Transport Community Permanent Secretariat	Dejan Lasica
09:45 – 10:45	Introduction to Conformity Assessment	Jean-Paul Lodzinski
10:45 – 11:00	Coffee Break	
11:00 – 12:00	Notified Bodies, Designated Bodies and Conformity Assessment Bodies	Jean-Paul Lodzinski
12:00– 12:45	Opinion of the EU Agency for Railways for the European Commission regarding the combination of modules for assessment of conformity and suitability (ERA/OPI/2025-6)	Jean-Paul Lodzinski
12:45 – 14:00	Lunch	
14:00 – 15:00	Overview about the Modules	Jean-Paul Lodzinski
15:00 – 15:15	Coffee Break	
15:15 – 15:45	Q&A Discussion	Jean-Paul Lodzinski
15:45 – 16:30	Group Photo, Wrap up, Closure of the Workshop	Dejan Lasica Christoph <u>Kaupat</u>

FOR WHICH ORGANISATION DO YOU WORK FOR?

MS
(Ministry,
NSA, NIB)

Accreditation/
Recognition
Body

Other

INDUSTRY
(manufacturer)

Railways (RU,
IM, keeper,
etc.)

CAB



What is your experience with conformity assessment?

Are you in a position to contribute, facilitate the development of conformity assessment in your country?



Why are you here?

Expectations?



CONFORMITY ASSESSMENT

WHY

'New Approach', NLF, harmonisation, legal framework, etc.

WHAT

????????????????

HOW

Procedures, methods, CA 'Modules', etc.

CONFORMITY ASSESSMENT

WHY

'New Approach', NLF, harmonisation, legal framework, etc.

WHAT

????????????????

HOW

Procedures, methods, CA 'Modules', etc.

Definition

CONFORMITY ASSESSMENT

- Process carried out by the **manufacturer** to demonstrate whether a product, process, service fulfills **specific requirements** before it is placed on the market
- Needed to demonstrate that a product being placed on the market complies with all **legislative requirements**
- Includes **testing, inspection** and/or **certification**
- Applicable product legislation specifies procedure/s (**module/s**) for each product
- Procedure should ensure confidence of consumers, public authorities and manufacturers regarding the conformity of products

THE LEGAL FRAMEWORK: HARMONISATION & COMPLIANCE IN THE EU

The goal of harmonisation in EU legislation

- Elimination of barriers
- Free movement of goods in the single market
- Protection of EU consumers
- Level playing field
- Competitive EU single market

Policies and legislative techniques have evolved over the last 40 years of European integration



Some history...

- **Old Approach**: very detailed legislations
- **'New Approach'** (1985): defines '*essential requirements*', while the details are in '*harmonised standards*'
- Development of the conformity assessment instruments
- The **'New Legislative Framework'** (2008): built on the *New Approach*, complemented it and brought coherence (conformity assessment, accreditation, market surveillance)
- The adoption of new *Market Surveillance Regulation* and new *Mutual Recognition Regulation* (2019)

The «Old Approach»

- Traditionally, very detailed technical **national** legislation (lack of confidence in the rigorousness of economic operators, public authorities delivering certificates of conformity themselves mainly for health and safety reasons) -> very difficult, burdensome
- 1983 : information procedure between MS and EC to avoid the creation of new technical barriers to the free movement of goods (standstill period of 3 to 12 months before adoption of new rules, with some exception in case of urgency)

The «New Approach» (1985)

- Legislative harmonisation should be limited to **essential requirements** to be met by products to benefit of free movement within the EU
- Technical specifications for products meeting essential requirements set out in legislation should be laid down in **harmonised standards** applied alongside the legislation
- Products compliant with harmonised standards benefit from a **presumption of conformity** with the corresponding essential requirements
- Application of harmonised or other standards remains voluntary, manufacturers can always apply other technical specifications to meet the requirements (but it holds the burden of proof)

The «**N**ew **L**egislative **F**ramework» (2008)

Objectives of the **NLF**:

- Reinforce the New Approach
- Simple, clear and coherent legislation
- More effective market surveillance and accreditation of conformity assessment bodies
- EU framework for their accreditation
- Enhanced credibility of the CE marking

KEY CONCEPTS

Conformity Assessment

Accreditation

Market surveillance

The «New Legislative Framework» (2008)

- [Regulation \(EC\) 765/2008](#) setting out requirements for accreditation and market surveillance of products
- [Decision 768/2008](#) on a common framework for the marketing of products, includes reference provisions to incorporate in product harmonisation legislation
- [Decision 2010/713/EU](#) on modules for conformity assessment procedures in railways
- [Regulation \(EU\) 2019/1020](#) on market surveillance and compliance of products

The «New Legislative Framework» (2008)

REGULATION (EC) No 765/2008 + Regulation (EU) 2019/1020

- ❖ Accreditation
- ❖ Market surveillance
 - internal
 - imported products
- ❖ CE marking general principles
- ❖ Financing elements

DECISION No 768/2008/EC

- ❖ Definitions / obligations
- ❖ Essential requirements + Harmonised standards
- ❖ Conformity assessment procedures
- ❖ Notification (criteria / process / accreditation)
- ❖ Safeguard mechanisms (& market surveillance)
- ❖ CE marking

Basis for future legislation

New Legislative Framework – Key features (1)

- 1) **Essential requirements** – level of protection of public interests: health, safety, protection of consumers or environment
- 2) **Harmonised standards** detailing technical solutions to meet the essential requirements
 - **Voluntary** – manufacturers can use other methods
 - **Presumption of conformity with the essential requirements** they cover
- 3) **Division of responsibilities along the distribution chain**

Manufacturers, authorised representative, importer, distributor, service providers, etc.

New Legislative Framework – Key features (2)

4) Conformity assessment procedures (so-called “**modules**”)

- Choice of procedure : **Risk-based approach**
- No third-party involvement - preferred for low to medium risk products
- **Third-party conformity assessment** for safety critical products/services

5) Uniform rules for the designation and supervision of **notified bodies**

Only **notified conformity assessment bodies** can perform conformity assessment tasks

New Legislative Framework – Key features (3)

6) Accreditation – preferred method to demonstrate the competence of the notified body. As alternative, Member States can apply “**recognition**” of **NoBos**

7) Market surveillance

- The authorities’ obligation to check products covered by Union harmonisation legislation made available on the Union market
- May range from control of formal requirements to in-depth laboratory examinations

8) CE marking

- A declaration by the manufacturer that the product conforms to all the essential requirements of the relevant legislation
- Only the manufacturer can affix it on the product
- Visible, indelible

Q & A



Some NLF 'Key features' in detail...

- **Essential requirements**
- **Harmonised standards**
- **Accreditation**
- **CE marking**



- **Essential requirements**
- **Harmonised standards**
- **Accreditation**
- **CE marking**



Essential requirements

DEFINITION: mandatory requirements products must meet to be put on the market

- They define results to be attained, or risks to be dealt with
- They do not specify the technical solutions for doing so
- Suppliers are free to choose how the requirements are to be met
- They are future-proof (do not become obsolete with technical progress)

Example: Toy Safety Directive

Essential Safety Requirements for Toys

- Physical and Mechanical Properties
- Flammability
- Chemical properties
- Electrical Properties
- Hygiene
- Radioactivity



[Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys Text with EEA relevance \(europa.eu\)](#)

N.B.: This Directive shall apply to products designed or intended, whether or not exclusively, for use in play by children under 14 years of age.

Railway interoperability essential requirements

Essential Requirements

Safety

Reliability and
availability

Health

Environmental
protection

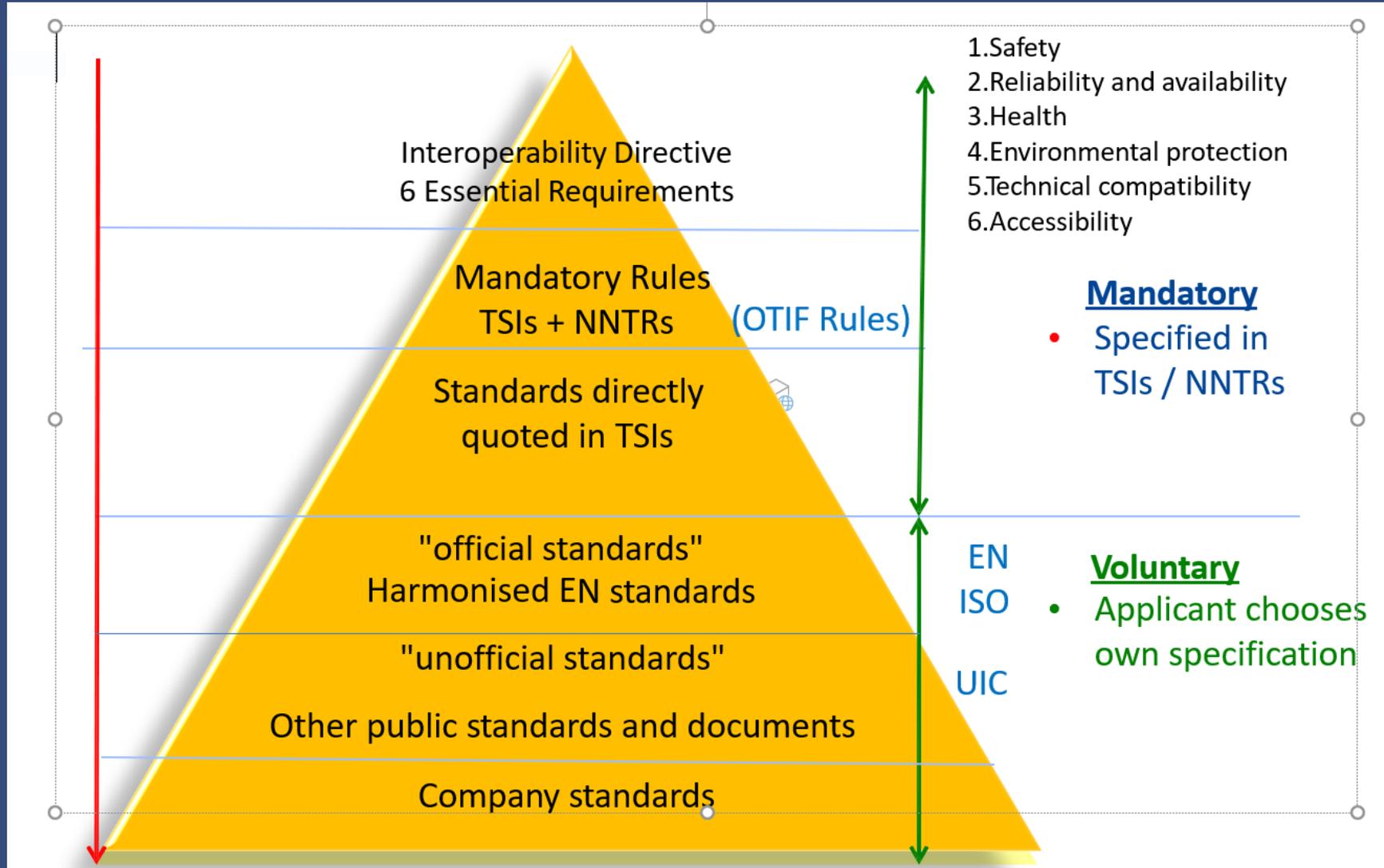
Technical
compatibility

Accessibility



Directive
EU
2016/797

Annex III



- Essential requirements
- **Harmonised standards**
- Accreditation
- CE marking



Harmonised standards

DEFINITION: European standard that provides technical solutions for compliance with legal provisions/**essential requirements**

- Elaborated on the basis of mandate from EC to a recognised European Standards Organisation (CEN-CENELEC-ETSI)
- Published in Official Journal of the EU
- Gives manufacturers presumption of conformity with respect to the applicable **essential Requirements**
- Remains voluntary: manufacturers can use other means to demonstrate conformity with the **essential requirements**, but burden of proof on person affixing the **CE marking** (producer , importer, etc.)

Sectoral schemes

DEFINITION: An accreditation scheme containing criteria supplementary (amplified or detailed) to those contained in Harmonised standards (ref. [Reg. \(EC\) 765/2008](#), Art. 13.3)

Sectoral accreditation schemes should cover the fields of activity where general requirements for the competence of conformity assessment bodies are not sufficient to ensure the necessary level of protection where specific detailed technology or health and safety-related requirements are imposed (ref. [Reg. \(EC\) 765/2008](#))

A sectoral scheme has been developed for railway NoBos

- Essential requirements
- Harmonised standards
- **Accreditation**
- CE marking



Accreditation

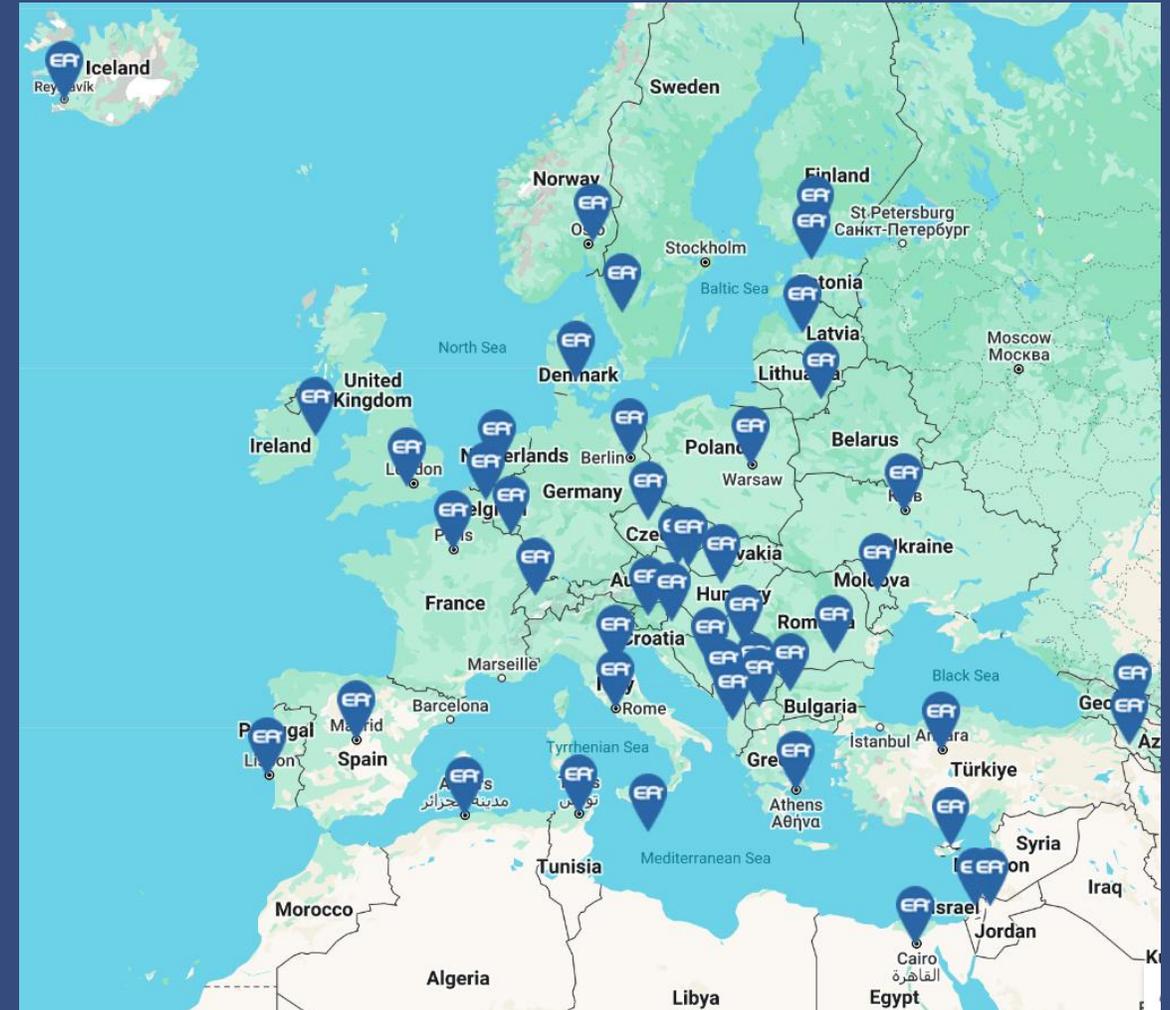
- Meant to ensure that CABs (e.g. inspection or certification bodies, laboratories) have the **technical capacity** to perform their duties
- Used in **regulated** sectors and **voluntary** areas
- Increase **trust** in conformity assessment, remove barriers for CABs
- Reinforce **mutual recognition** of **products, services, systems, and bodies** across the EU
- Requirements for **accreditation** set in Regulation (EC) 765/2008

National Accreditation Body

- The only body in a MS that performs accreditation with authority derived from the State
- Should be organised in such a way as to safeguard the objectivity and impartiality of its activities
- Should possess the relevant knowledge, competence and means for the proper performance of its tasks

EU & non-EU NABs

List available on website of European Cooperation for Accreditation (EA): [Directory of EA Members and MLA signatories - European Accreditation \(european-accreditation.org\)](https://www.european-accreditation.org/)



BALKAN NABs

ALBANIA: DPA - Directorate of Accreditation

BOSNIA & HERZEGOVINA: BATA - Institute for Accreditation of Bosnia and Herzegovina

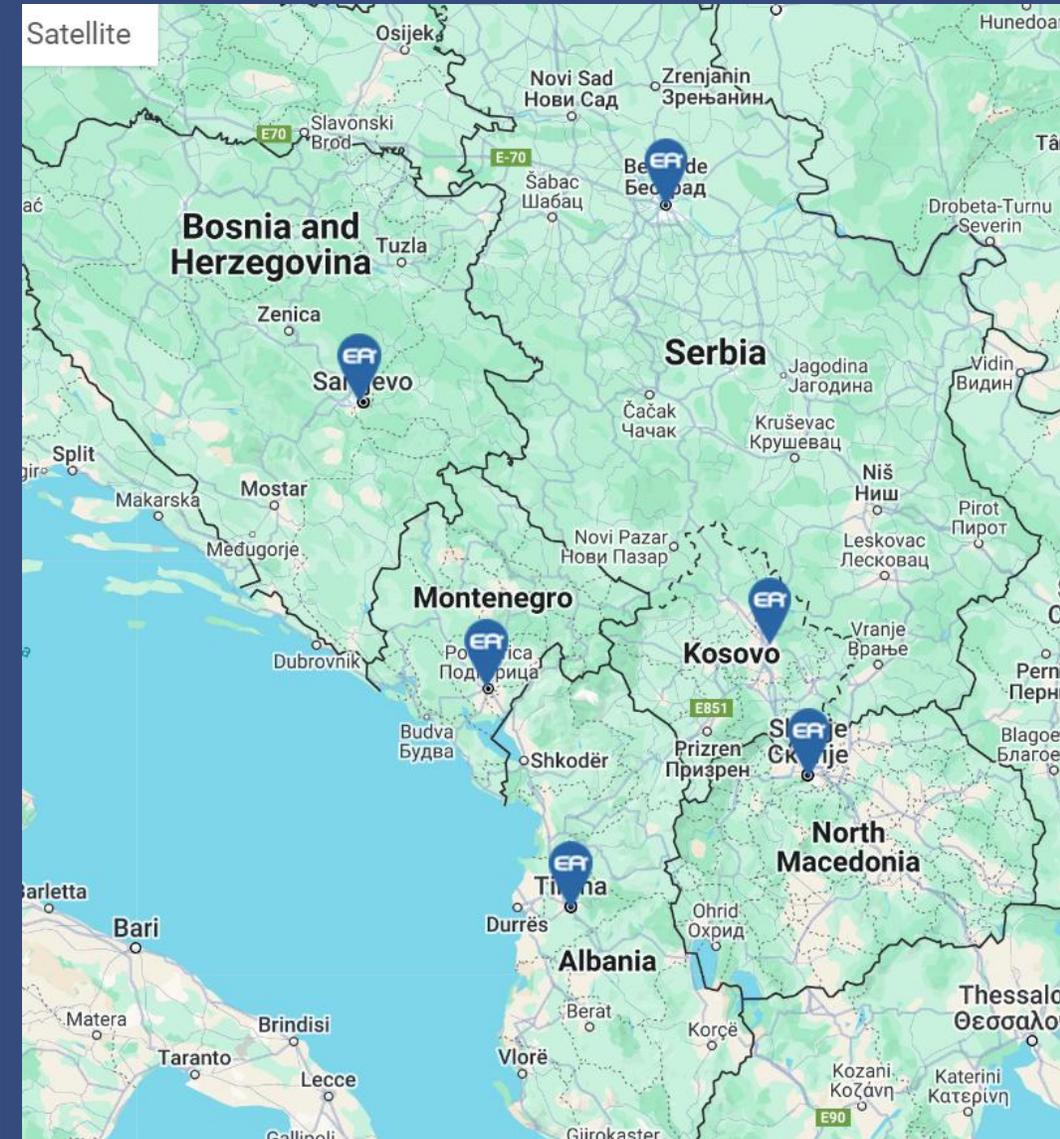
KOSOVO*: DAK - Accreditation Directorate of Kosovo

MONTENEGRO: ATCG

NORTH MACEDONIA: IARNM - Institute for Accreditation of the Republic of North Macedonia

SERBIA: ATS - Accreditation Body of Serbia

*This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ opinion on the Kosovo declaration of independence



Accreditation vs Recognition

ACCREDITATION

attestation by National Accreditation Body (NAB) that CAB meets requirements set by harmonised standards and, where applicable, any additional requirements including those in relevant sectoral schemes, to carry out specific conformity assessment activity

RECOGNITION

Not defined in EU legislation, however **Reg. (EC) No. 765/2008** allows Member State to select the specific CAB provided that it complies with requirements comparable to those applicable to CABs in the accreditation regime

NOTE: MSs may choose accreditation, recognition or apply both

Accreditation certificates



AKKREDITERING til produktcertificering

Reg. nr. 7046

Virksomhed	Scandinavia Rail & Verification ApS Kay Fiskers Plads 10, DK-2300 København S CVR: 40771158
Akkrediteringsområde	Certificering af produkter for overensstemmelse med krav i <ul style="list-style-type: none"> • IOD-direktivet (EU)2016/797 om interoperabilitet i jernbanes met, som specificeret i bilag 1
Gyldighedsperiode	19-09-2023 til 1-1-2027
Erstatter dokument af	23-08-2023
Akkrediteringsgrundlag	DS/EN ISO/IEC 17065:2012 Certificeringsorganet opfylder kravene i DS/EN ISO/IEC 17065:2012 - Overensstemmelsesvurdering - Krav til organer, der certificerer produkter, processer og serviceydelse, samt de relevante bestemmelser for den akkrediterede virksomhed for ovennævnte akkrediteringsområde.



DC0208PRD/000/CERT

CERTIFICATO DI ACCREDITAMENTO Accreditation Certificate

ACCREDITAMENTO N. ACCREDITATION N.	0208PRD REV. 000
EMESSO DA ISSUED BY	DIPARTIMENTO CERTIFICAZIONE E ISPEZIONE
SI DICHIARA CHE WE DECLARE THAT	VERICERT S.r.l.
SEDE PRINCIPALE/HEADQUARTER:	• Via L. Masotti, 5 48124 - Fornace Zarattini (RA) - Italia
È CONFORME AI REQUISITI DELLA NORMA	UNI CEI EN/ISO/IEC 17065:2012
MEETS THE REQUIREMENTS OF THE STANDARD	EN/ISO/IEC 17065:2012
QUALE ORGANISMO DI AS BODY FOR THE	Certificazione di Prodotto/Servizio/Processo (così come dettagliato negli Allegati al presente Certificato) Certification of Product/Service/Process (as stated in the Annexes to this Certificate)

Data di 1^a emissione
1st issue date
28-03-2014

Data di revisione
Review date
01-01-2023

Potvrda o akreditaciji Accreditation Certificate

Ovime se utvrđuje da je
This is to recognize that

INFRACERT d.o.o.
Odjel za certifikaciju
Ulica Ivana Zahara 7, HR-10000 Zagreb

osposobljen prema zahtjevima norme
is competent according to
HRN EN ISO/IEC 17065:2013
(ISO/IEC 17065:2012; EN ISO/IEC
17065:2012)
za/to carry out

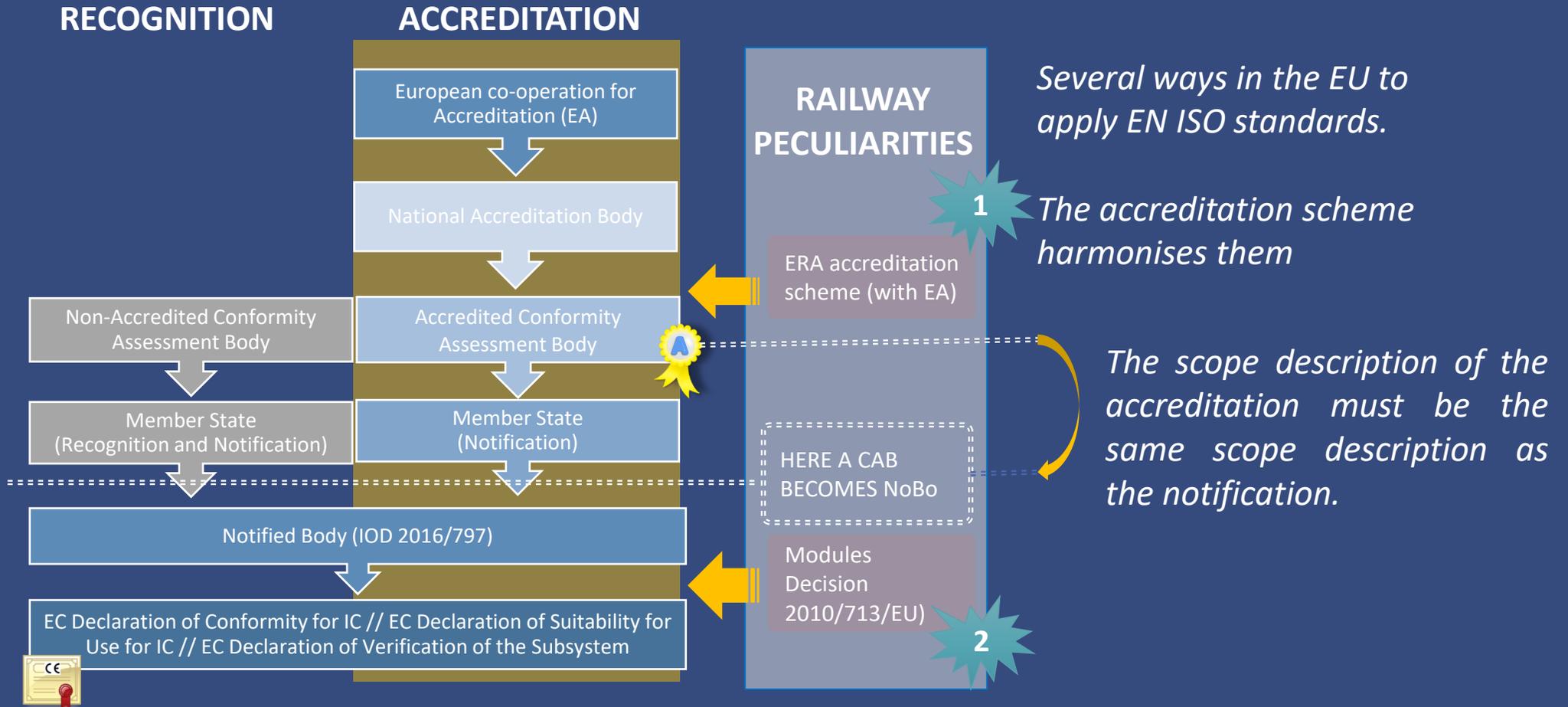
Ocjenjivanje sukladnosti podsustava i sastavnih dijelova
interoperabilnosti željezničkog sustava u EU prema
Direktivi (EU) 2016/797
Conformity assessment of subsystems and constituents of the
interoperability rail system within EU according to Directive (EU)
2016/797

u području opisanom u prilogu koji je sastavni dio ove potvrde o
akreditaciji.
for the scope described in the annex which is the constituent part of
this accreditation certificate.

Br./No.: 3705
Klasa/Ref.No.: 383-02/20-70/005
Urbroj/Id.No.: 569-03/6-23-25
Zagreb, 2023-07-24

Akkreditacija istječe Accreditation expiry: 2028-07-23
Prva akreditacija Initial accreditation: 2023-07-24

NOTIFICATION: TWO PATHS for NOBOs



- Essential requirements
- Harmonised standards
- Accreditation
- **CE marking**



CE marking



Signifies that a product sold in the European Economic Area (EEA) has been assessed to meet high **safety, health, and environmental protection requirements**

Relevant for **manufacturers, importers, distributors, consumers**

BENEFITS:

- **businesses** know that products bearing the CE marking can be traded in the EEA without restrictions
- **consumers** enjoy same level of health, safety, and environmental protection throughout entire EEA

(General principles set out in Article 30, Regulation (EC) No 765/2008)

CE marking

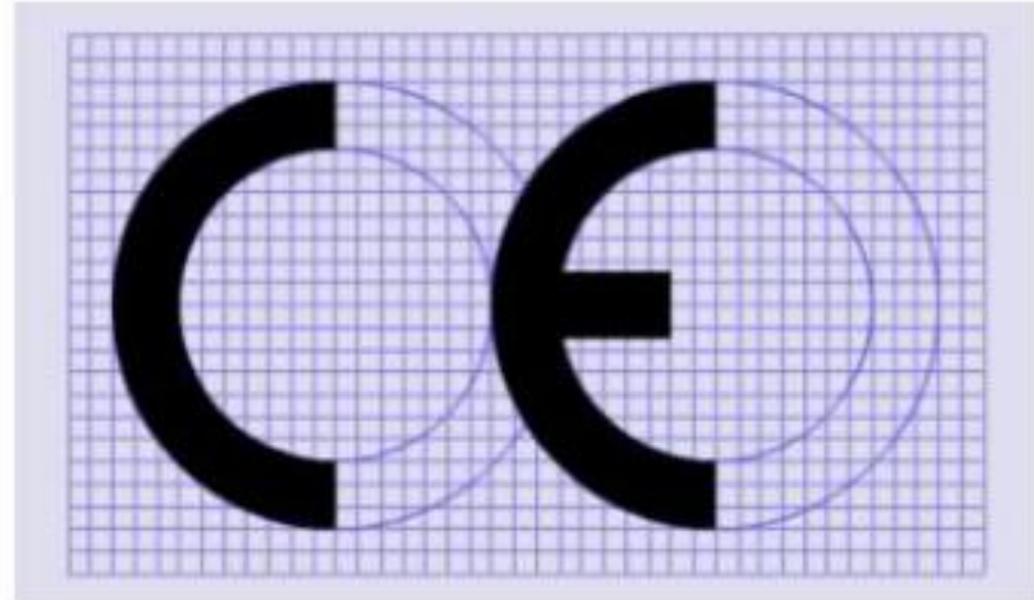


1. Affixed only by manufacturer or its authorised representative
2. Affixed only to products to which its affixing is provided for by specific EU legislation (and not on any other product)
3. Indicates the manufacturer takes responsibility for conformity of the product with all applicable requirements set out in the relevant EU legislation
4. Shall be only marking which attests conformity of the product with the applicable requirements of the relevant EU legislation
5. It is forbidden to use any other misleading markings, signs or inscriptions
6. Other markings may be affixed but shall not impair visibility of **CE marking** or create confusion
7. Infringements subject to sanctions by Member States (pecuniary or even criminal)

CE marking



- It indicates that a product has been designed and manufactured in conformity with essential requirements
- CE marking is mandatory and must be affixed before the product is placed on the market



General principles set out in Article 30, Regulation (EC) No 765/2008

CE marking in real life...



CONFORMITY ASSESSMENT & CONFORMITY ASSESSMENT BODIES (CABs)

Conformity Assessment in Railways

Accreditation/
Recognition
Bodies

MS
(Ministry,
NSA)

European
Commission
(NANDO)

ERA

Railways (RU,
IM, keeper,
etc.)

EA

CAB/
NoBo

INDUSTRY/
MANUFACTURERS

Definitions (1)

CONFORMITY ASSESSMENT

- Process carried out by the **manufacturer** to demonstrate whether a product, process, service fulfills specific requirements before it is placed on the market
- Needed to demonstrate that a product being placed on the market complies with all legislative requirements
- Includes **testing, inspection** and/or **certification**
- Applicable product legislation specifies procedure/s (**module/s**) for each product
- Procedure should ensure confidence of consumers, public authorities and manufacturers regarding the conformity of products

Definitions (2)

CONFORMITY ASSESSMENT BODY (CAB)

Body that performs conformity assessment activities including calibration, testing, certification and inspection (cf. **Reg. (EC) No. 765/2008** and IOD Art. 2(42))

Examples: **Notified Body (NoBo)**, Designated Body (DeBo) Assessment Body (AsBo)

The same approach is valid in all regulated European industrial sector
(*e.g. medical equipment, ships, **toys**, gas emissions, railways...*)

Railway CABs

Depending on assessment scope (TSIs, NNTR, CSM):

- **Notified Body (NoBo)** → Technical Specifications for Interoperability (TSIs)
- **Designated Body (DeBo)** → Notified National Technical Rules (NNTR)
- **Assessment Body (AsBo)** → Risk Assessment performed under the CSM (Reg. 402/2013)

Notified Bodies

DEFINITION

Organisation designated by EU country to assess conformity of certain products before being placed on the market (see practical example)

These bodies carry out tasks related to conformity assessment procedures (**modules**) set out in the applicable legislation, when a third party is required

Manufacturers are free to choose any notified body that has been legally designated to carry out the conformity assessment procedure

Notified Bodies

- **ROLE – Assess** conformity of certain products to applicable EU legislation before being placed on the EU market
- **NOTIFIED** by Member States (**notifying authorities**)
- To the **European Commission** ([NANDO](#) database)
- According to **Decision 768/2008/EC** (eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008D0768)

Notification

- Act whereby MS informs EC, and other MSs, that a CAB, which fulfils relevant requirements, has been designated to carry out conformity assessment according to a directive. Notification and withdrawal responsibility of notifying MS
- Concerns MSs, EFTA countries (EEA members) and other countries with which EU has concluded Mutual Recognition Agreements (MRAs)
- Information available in NANDO (New Approach Notified and Designated Organisations) database
- NANDO includes NoBo ID number as well as tasks for which it's been notified

NOTIFIED BODIES- REQUIREMENTS (1)

- Are free to offer their conformity assessment services to any economic operator **inside** or **outside** the EU
- May carry out these activities on the territory of **other EU countries** or **non-EU countries**
- Must operate in a non-discriminatory, transparent, neutral, independent, and impartial manner

NOTIFIED BODIES- REQUIREMENTS (2)

- Must employ the necessary personnel, with sufficient knowledge and experience to carry out the conformity assessment in accordance with the law(s) in question
- Must make adequate arrangements to ensure the confidentiality of the information obtained in the course of conformity assessment
- Must be adequately insured to cover their professional activities, unless liability is assured under the national legislation of the notifying EU country
- Must provide information to their notifying authority, the market surveillance authorities, and other notified bodies



How does CA work in practice (1)

A manufacturer can place a product on the EU market only if it meets all applicable requirements

Product legislation describes conformity assessment procedures (**modules**) for each product

Manufacturers may choose between different conformity assessment procedures (**modules**), if applicable

How does it work in practice (2)

The manufacturer carries out the assessment, this process may involve a CAB (e.g. **NoBo**) if required by applicable legislation

The conformity assessment procedure (**module**) is carried out before the product can be sold & placed on the market

The European Commission's main objective is to help ensure that unsafe or otherwise non-compliant products do not find their way to the EU market

How does it work in practice (3)

DECLARATION OF CONFORMITY (DoC)

As part of conformity assessment, the manufacturer or authorised representative must draw up a DoC

The declaration should contain all information to identify:

- product
- legislation according to which it is issued
- manufacturer or authorised representative
- **NoBo** if applicable
- a reference to **harmonised standards** or other normative documents, where appropriate

COMPLIANCE – PRACTICAL EXAMPLE



New Approach Notified and Designated Organisations Information System

NANDO



Single Market Compliance Space

Home Notified Bodies Market surveillance Noise emissions Glossary

Home > Notified Bodies > Free search

Free search

Refine list of bodies using search criteria below (by entering appropriate keywords) and click on body name to view details

Search options

Notification status

Active

Body number

0112

Body name

Search results (1)

NOTIFICATION STATUS Active

BODY NUMBER 0112

Items per page: 30

Body type	Body name	Country
NB 0112	Konformitätsbewertungsstelle des Landesbetrieb Mess- und Eichwesen NRW	Germany

Products	Procedures	Articles/Annexes
Active Electrical Energy Meters (Annex V MI-003)	Conformity to type based on instrument verification	Annex II - Module F
– Dimensional Measuring Instruments (Annex XI MI-009)		
Area measuring instruments	Conformity to type based on instrument verification	Annex II - Module F
Length measuring instruments	Conformity to type based on instrument verification	Annex II - Module F
Multi-dimensional measuring instruments	Conformity to type based on instrument verification	Annex II - Module F
Automatic Weighing Instruments (Annex VIII MI-006)	Conformity to type based on instrument verification	Annex II - Module F
– Thermal Energy Meter (Annex VI MI-004)		
Calculator (type of temperature sensors)	Conformity to type based on instrument verification	Annex II - Module F
Flow sensor (heat meter subassembly)	Conformity to type based on instrument verification	Annex II - Module F
Temperature sensor pair	Conformity to type based on instrument verification	Annex II - Module F
Thermal Energy meter complete	Conformity to type based on instrument verification	Annex II - Module F
– Material Measures (Annex X MI-008)		
Capacity serving measures	Internal production control plus supervised instrument checks at randoms intervals	Annex II - Module A2
Material measure of length	Conformity based on instrument verification	Annex II - Module F1
Exhaust Gas Analysers (Annex XII MI-010)	Conformity to type based on instrument verification	Annex II - Module F
Measuring Instruments for Liquids Other than Water (Annex VII MI-005)	Conformity to type based on instrument verification	Annex II - Module F
Taximeters (Annex IX MI-007)	Conformity to type based on instrument verification	Annex II - Module F
– Gas Meters and Volume Conversion Devices (Annex IV MI-002)		
Volume conversion device (gas meter subassembly)	Conformity to type based on instrument verification	Annex II - Module F
Water Meters (Annex III MI-001)	Conformity to type based on instrument verification	Annex II - Module F

Organization details

BODY VERSION 7

Body Name	Konformitätsbewertungsstelle des Landesbetrieb Mess- und Eichwesen NRW
Address	Hugo-Eckener-Straße, 14 50829 Köln; Briefpostanschrift: 40208 Düsseldorf
Country	Germany
Phone	+49 (0) 221 5 97 78-10888
Fax	+49 (0) 221 5 97 78-30101
Email	Poststelle.Direktion@LBME.nrw.de
Website	http://www.lbme.nrw.de/
Body Number	0112
Last approval date	14/11/2022



List of notifications

NOTIFICATION STATUS Active

Body type	Legislation	End date	PDF
NB	2014/31/EU Non-automatic weighing instruments		↓
NB	2014/32/EU Measuring Instruments Directive		↓

'Modules' for Conformity Assessment



CHAPTER II

Capacity serving measures

The relevant essential requirements of Annex I, and the specific requirements and the conformity assessment procedures listed in this chapter, apply to capacity serving measures defined below. However, the requirement for the supply of a copy of declarations of conformity may be interpreted as applying to a batch or consignment rather than each individual instrument. Also, the requirement for the instrument to bear information in respect of its accuracy shall not apply.

DEFINITIONS

Capacity serving measure	A capacity measure (such as a drinking glass, jug or thimble measure) designed to determine a specified volume of a liquid (other than a pharmaceutical product) which is sold for immediate consumption.
Line measure	A capacity serving measure marked with a line to indicate nominal capacity.
Brim measure	A capacity serving measure for which the internal volume is equal to the nominal capacity.
Transfer measure	A capacity serving measure from which it is intended that the liquid is decanted prior to consumption.
Capacity	The capacity is the internal volume for brim measures or internal volume to a filling mark for line measures.

MODULE A2: INTERNAL PRODUCTION CONTROL PLUS SUPERVISED INSTRUMENT CHECKS AT RANDOM INTERVALS

RECAP OF PART 1

- Old Approach
- **'New Approach'** (1985) → 'essential requirements', 'harmonised standards'
- **'New Legislative Framework'** (2008) → supports *New Approach*:
 - Essential requirements
 - Harmonised standards
 - Conformity assessment
 - Accreditation
 - CE marking
 - CA Procedures/Modules
 - Market surveillance

KEY TERMS

New Legal Framework (NLF)

ESSENTIAL REQUIREMENTS

HARMONISED STANDARD

NoBo

MODULE

ACCREDITATION



EXERCISE

Conformity assessment Entities vs. Roles/tasks

E
N
T
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Y

1. Accreditation Body

2. CAB/NoBo

3. Recognition Body

4. Notifying Authority

5. Manufacturer

6. MS/ministry

T
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K

A. Choose NoBo & procedure (module) to certify a product

B. Set up national conformity assessment framework

C. Issue EC certificates of compliance

D. Issue accreditation certificate/accredit NoBo

E. Assess product compliance to TSI requirements

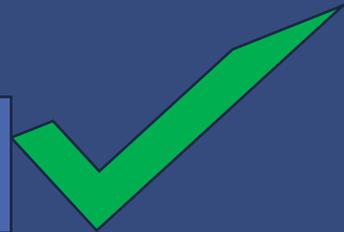
F. Assess/monitor CAB/NoBo competence

G. Notify CABs to European Commission/NANDO

CONFORMITY ASSESSMENT

WHY

'New Approach', NLF, harmonisation, legal framework, etc.



WHAT

????????????????????



HOW

Procedures, methods, CA 'Modules', etc.

INTEROPERABILITY CONSTITUENTS & SUBSYSTEMS (1)

INTEROPERABILITY CONSTITUENT (IC): *any elementary component, group of components, subassembly or complete assembly of equipment incorporated or intended to be incorporated into a **subsystem**, upon which the interoperability of the rail system depends directly or indirectly, including both tangible objects and intangible objects*

SUBSYSTEM: *the **structural or functional** part of the Union rail system, as set out in Annex II (Directive (EU) 2016/797)*

INTEROPERABILITY CONSTITUENTS & SUBSYSTEMS (2)

ICs: Axle, Bogie & Running gear, Brake blocks, Contact strips, Head lamp/light, Over-head contact line, Pantograph, Rail steel, Railhead profile, Tail lamp/light, Track sleepers, Wheel, Wheelset, etc.

SUBSYSTEMS (STRUCTURAL):

- Control Command and Signalling (**on-board**)
- Control Command and Signalling (**track-side**)
- Energy
- Infrastructure
- Rolling Stock

VEHICLES - LIST OF ICs IN THE TSIS

LOC&PAS TSI

- Automatic centre buffer coupler
- Manual end coupling
- Rescue couplers
- Wheels
- Wheel slide protection system (WSP)
- Head lamps
- Marker lamps
- Tail lamps
- Horns
- Pantograph
- Contact strips
- Main circuit breaker
- Driver's seat
- Toilet discharge connection
- Inlet connection for water tanks

WAG TSI

- Running gear
- Wheelset
- Wheel
- Axle
- Rear-end signal

NOI TSI

- Friction element for wheel tread brakes

PRM TSI

- Interface of the door control device
- Standard and universal toilets: common parameters
- Standard toilet
- Universal toilet
- Baby nappy changing table
- Interface of the call for aid device
- Boarding aids: movable steps and bridging plates
- Boarding aids: on-board ramps
- Boarding aids: on-board lifts

SRT TSI

- [no ICs]

CCS TSI (on-board)

- ETCS on-board
- Odometry equipment
- Standardised interface Specific Transmission Module (STM)
- GSM-R voice cab radio
- GSM-R data radio
- GSM-R SIM card
- ATO On-Board
- FRMCS On-Board voice application
- On-board FRMCS
- FRMCS Profile

Fixed installations - LIST OF ICs IN THE TSIS

INF TSI

- Rail
- Rail fastening systems
- Track sleepers

ENE TSI

- Overhead contact line

PRM TSI

- Platform ramps
- Platform lifts

SRT TSI

- [no ICs]

CCS TSI (trackside)

- Radio Block Centre (RBC)
- Radio infill unit
- Eurobalise
- Euroloop
- LEU Eurobalise
- LEU Euroloop
- Axle Counter
- Marker Board
- ATO Trackside

RAILWAY SUBSYSTEMS*

STRUCTURAL SUBSYSTEMS

INF

- TSI INF
- TSI SRT
- TSI PRM

ENE

- TSI ENE
- TSI SRT

CCT & CCO

- TSI CCS
- TSI SRT

RST

- TSI
LOC&PAS
- TSI WAG
- TSI NOI
- TSI SRT
- TSI PRM

FUNCTIONAL SUBSYSTEMS

OPE

- TSI OPE
- TSI SRT

MAI

- TSI INF
- TSI ENE
- TSI CCS
- TSI WAG
- TSI
LOC&PAS
- TSI SRT
- TSI PRM

TA

- TSI TAF
- TSI TAP

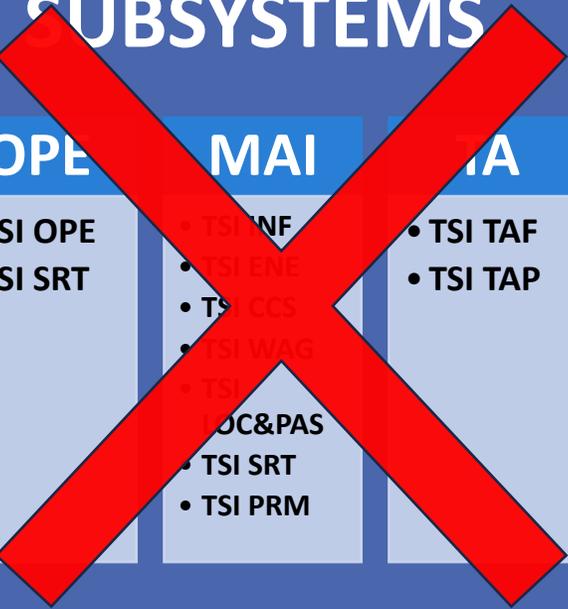
* see Directive 2016/797/EU, Annex II

RAILWAY SUBSYSTEMS*

STRUCTURAL SUBSYSTEMS

INF	ENE	CCT & CCO	RST
<ul style="list-style-type: none"> • TSI INF • TSI SRT • TSI PRM 	<ul style="list-style-type: none"> • TSI ENE • TSI SRT 	<ul style="list-style-type: none"> • TSI CCS • TSI SRT 	<ul style="list-style-type: none"> • TSI LOC&PAS • TSI WAG • TSI NOI • TSI SRT • TSI PRM

FUNCTIONAL SUBSYSTEMS



OPER	MAINT	TAF
<ul style="list-style-type: none"> • TSI OPE • TSI SRT 	<ul style="list-style-type: none"> • TSI INF • TSI ENE • TSI CCS • TSI WAG • TSI LOC&PAS • TSI SRT • TSI PRM 	<ul style="list-style-type: none"> • TSI TAF • TSI TAP

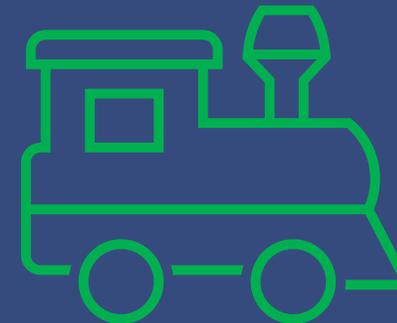
Only **STRUCTURAL** SUBSYSTEMS are
in scope of conformity assessment

RAILWAY MODULES APPLY ONLY TO

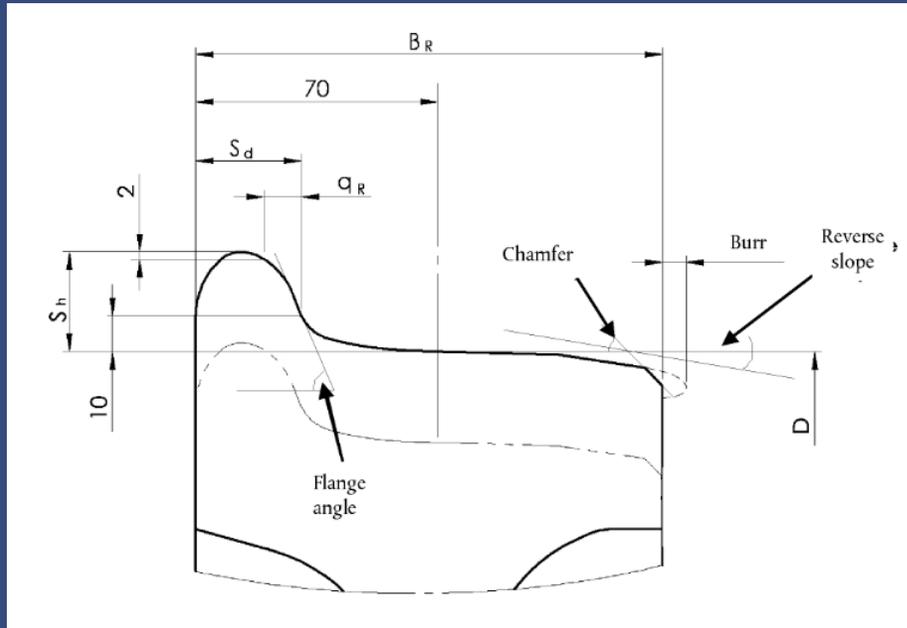
**INTEROPERABILITY
CONSTITUENTS**



**STRUCTURAL
SUBSYSTEMS**

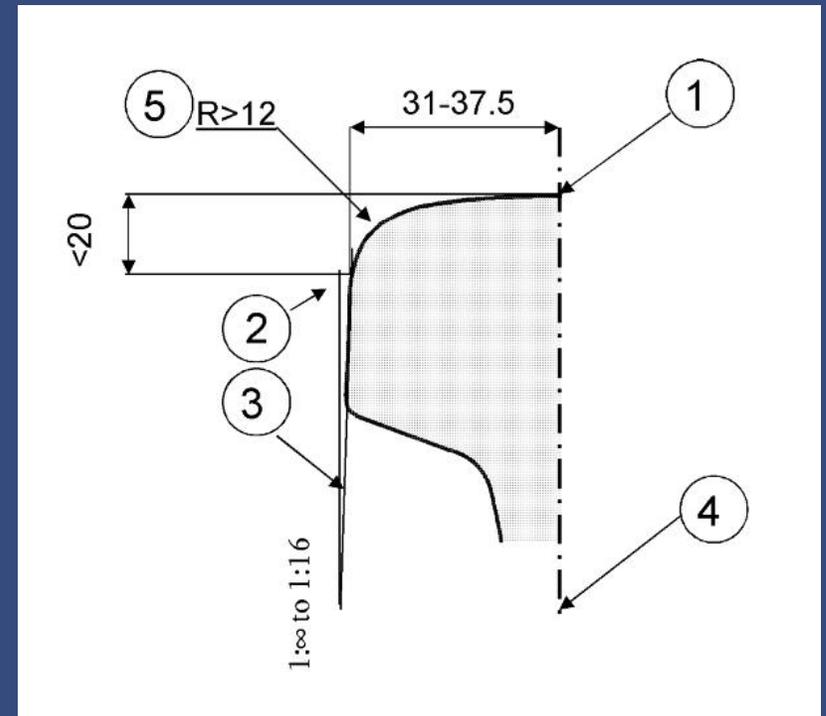


INTEROPERABILITY CONSTITUENTS



Wheel profile

Railhead profile



CASE STUDY: THE RAIL AS IC (1)

High-Speed Infrastructure TSI 2002

(Commission Decision 2002/732/EC, superseded)

- the railhead profile shall comprise a side slope on the flank of the head angled at between $1/20$ and $1/17,2$ with reference to the vertical axis of the head, followed in moving towards the top surface of the head by a succession of curves with a radius of 12,7 or 13 mm, then 80 and 300 mm as far as the vertical axis of the railhead (railhead profile defined in an Annex to the TSI)
- minimum mass of the rail shall be more than 53 kg/m
- steel grade of rail shall be as defined by the CEN standard applicable (steel composition defined in an Annex to the TSI)

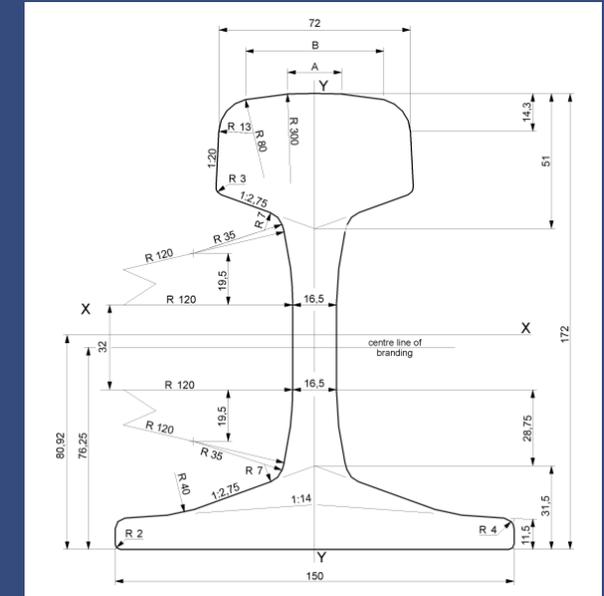


Table 2(a)
Chemical composition/mechanical properties

Steel sample grade		% by mass								10 ¹⁰ % (appn) max		Rm min N/mm	Min elong %	Centre line ramming surface hardness HBW	
		C	Si	Mn	P max	S	Cr	Al max	V max	N max	O				H
200	Liquid	0,40/0,60	0,15/0,58	0,70/1,20	0,035	0,008/0,035	< 0,15	0,004	0,030	0,009	20	3,0			
	Solid	0,38/0,62	0,13/0,60	0,65/1,25	0,040	0,008/0,040	< 0,15	0,004	0,030	0,010	20	3,0	680	14	200/240
220	Liquid	0,50/0,60	0,20/0,60	1,00/1,25	0,025	0,008/0,025	< 0,15	0,004	0,030	0,008	20	3,0			
	Solid	0,50/0,60	0,20/0,60	1,00/1,25	0,025	0,008/0,025	< 0,15	0,004	0,030	0,008	20	3,0	770	12	220/260
260	Liquid	0,62/0,80	0,15/0,58	0,70/1,20	0,025	0,008/0,025	< 0,15	0,004	0,030	0,009	20	2,5			
	Solid	0,60/0,82	0,13/0,60	0,65/1,25	0,030	0,008/0,030	< 0,15	0,004	0,030	0,010	20	2,5	880	10	260/300
260 X	Liquid	0,40/0,60	0,20/0,45	1,20/1,60	0,025	0,008/0,030	0,40/0,60	0,004	< 0,06	0,009	20	2,5			
	Solid	0,40/0,60	0,20/0,45	1,20/1,60	0,030	0,008/0,030	0,40/0,60	0,004	< 0,06	0,010	20	2,5	880	10	260/300
260 Mn	Liquid	0,55/0,75	0,15/0,60	1,30/1,70	0,025	0,008/0,025	< 0,15	0,004	0,030	0,009	20	2,5			
	Solid	0,53/0,77	0,15/0,60	1,25/1,75	0,030	0,008/0,030	< 0,15	0,004	0,030	0,010	20	2,5	880	10	260/300
320 Cr	Liquid	0,60/0,80	0,50/1,10	0,80/1,20	0,020	0,008/0,025	0,80/1,20	0,004	0,18	0,009	20	2,5			
	Solid	0,58/0,82	0,48/1,12	0,75/1,25	0,025	0,008/0,030	0,75/1,25	0,004	0,20	0,010	20	2,5	1 080	9	320/360

CASE STUDY: THE RAIL AS IC (1)

High-Speed Infrastructure TSI 2002 (Commission Decision 2002/732/EC, superseded)

- the railhead profile shall comprise... on the flank of the head angled at between... with reference to the vertical... in moving towards the... by a succession of curves with a... then 80 and 300 mm as far as... railhead (railhead profile defined in the TSI)
- minimum... shall be more than 53 kg/m
- steel grade... shall be as defined by the CEN standard applicable (steel composition defined in an Annex to the TSI)

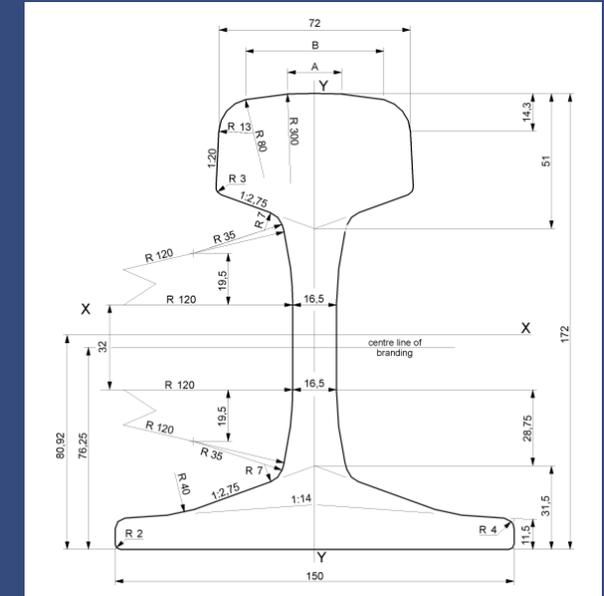


Table 2(a)
Chemical composition/mechanical properties

Steel sample grade		% by mass								10 ¹⁰ % (appn) max		Rm min	Min elong	Centre line transverse surface hardness HBW	
		C	Si	Mn	P max	S	Cr	Al max	V max	N max	O				H
200	Liquid	0,40/0,60	0,15/0,58	0,70/1,20	0,035	0,008/0,035	< 0,15	0,004	0,030	0,009	20	3,0			
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220	Liquid	0,50/0,60	0,20/0,60	1,00/1,25	0,025	0,008/0,025	< 0,15	0,004	0,030	0,008	20	3,0			
	Solid	0,50/0,60	0,20/0,60	1,00/1,25	0,025	0,008/0,025	< 0,15	0,004	0,030	0,008	20	3,0	770	12	220/260
260	Liquid	0,62/0,80	0,15/0,58	0,70/1,20	0,025	0,008/0,025	< 0,15	0,004	0,030	0,009	20	2,5			
	Solid	0,60/0,82	0,13/0,60	0,65/1,25	0,030	0,008/0,030	< 0,15	0,004	0,030	0,010	20	2,5	880	10	260/300
260 X	Liquid	0,40/0,60	0,20/0,45	1,20/1,60	0,025	0,008/0,030	0,40/0,60	0,004	< 0,06	0,009	20	2,5			
	Solid	0,40/0,60	0,20/0,45	1,20/1,60	0,030	0,008/0,030	0,40/0,60	0,004	< 0,06	0,010	20	2,5	880	10	260/300
260 Mn	Liquid	0,55/0,75	0,15/0,60	1,30/1,70	0,025	0,008/0,025	< 0,15	0,004	0,030	0,009	20	2,5			
	Solid	0,53/0,77	0,15/0,60	1,25/1,75	0,030	0,008/0,030	< 0,15	0,004	0,030	0,010	20	2,5	880	10	260/300
320 Cr	Liquid	0,60/0,80	0,50/1,10	0,80/1,20	0,020	0,008/0,025	0,80/1,20	0,004	0,18	0,009	20	2,5			
	Solid	0,58/0,82	0,48/1,12	0,75/1,25	0,025	0,008/0,030	0,75/1,25	0,004	0,20	0,010	20	2,5	1 080	9	320/360

CASE STUDY: THE RAIL AS IC (2)

TSI INF (2023)

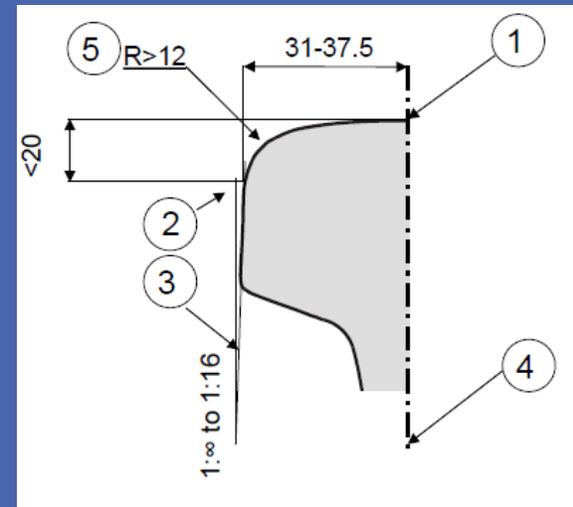
5.3.1. THE RAIL

The specifications of the “rail” interoperability constituent concern the following parameters:

(a) railhead profile (clause 4.2.4.6)

(b) rail steel shall meet the following requirements:

- The rail hardness shall be at least 200 HBW
- The tensile strength shall be at least 680 MPa
- Minimum number of cycles at fatigue test without failure shall be at least 5×10^6



CONFORMITY ASSESSMENT

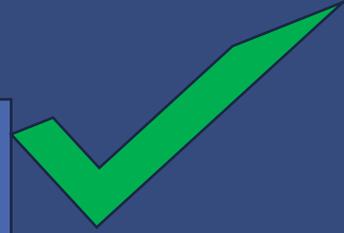
WHY

'New Approach', NLF, harmonisation, legal framework, etc.



WHAT

????????????????????



HOW

Procedures, methods, CA 'Modules', etc.



CONFORMITY ASSESSMENT PROCEDURES: GENERIC MODULES & RAILWAY MODULES

FLASHBACK

CONFORMITY ASSESSMENT: Process/activity carried out by **manufacturer** to demonstrate if a product fulfills specific requirements

MODULE: Procedure for manufacturers to demonstrate compliance of products with requirements in applicable law. May cover both **design** and **production** phases of a product.

LEGAL FRAMEWORD: [Decision 768/2008/EC](#), besides setting down rules for EC marking of products, lays down the **modules** that can be used for all regulated sectors

MODULES – WHAT ARE THEY

On the basis of international standards, Europe developed conformity assessment procedures and rules for their selection and use, these procedures are called “**modules**” and are defined in **Decision 768/2008**, ANNEX II

Majority of industrial sectors adopt the modules described

Choice of modules ranges from ‘lightest’ (“*internal control of production*”), for simple products or products not necessarily presenting serious risks, to most comprehensive (full quality assurance), where the risks are more severe or products/technologies more complex

LEGAL FRAMEWORK (1)

GENERIC MODULES

[Decision 768/2008/EC](#)



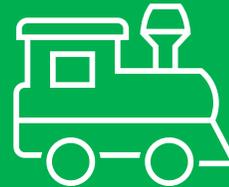
The specific nature of railway sector & TSIs (ICs & SS) make it necessary to have specific set of “modules” implementing the generic provisions of [Decision 768/2008/EC](#)

LEGAL FRAMEWORK (2)

GENERIC MODULES

[Decision 768/2008/EC](#)

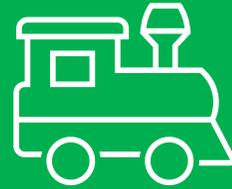
**'RAILWAY MODULES'
for ICs & Subsystems**



[Decision 2010/713/EU](#)

LEGAL FRAMEWORK (2)

‘RAILWAY MODULES’
for ICs & Subsystems



Decision 2010/713/EU

Most railway specific modules require a **3rd party** independent conformity assessment performed by bodies notified by MSs to the European Commission

These bodies are known as **Notified Bodies** (NoBos)

RAILWAY MODULES

Decision 2010/713/EU provides a wide range of modules according to the level of **risk** involved and the level of **safety** required

Railway modules relate to compliance with TSI provisions

TSIs identify the relevant modules which shall be used by applicants (e.g. manufacturers) in collaboration with NoBos (**see dedicated slide**)

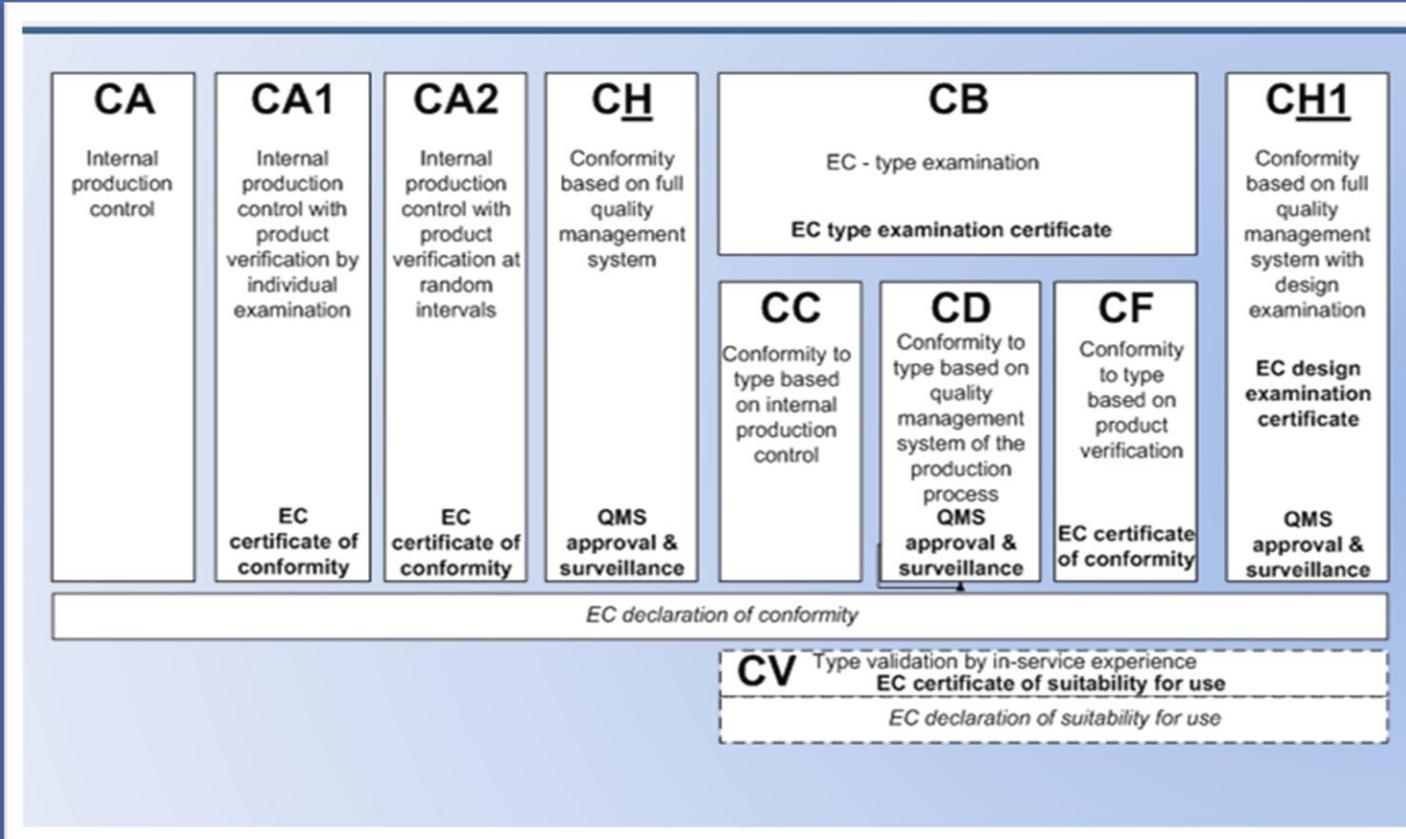
Part of the procedure necessary to place a vehicle or a railway line in service

RAILWAY MODULES: SCOPE & PURPOSE

- Procedures for conformity assessment (**ICs**) & EC verification (**subsystems**)
- Define responsibilities of participants in the procedures:
Manufacturer, applicant, notified body, authorised representative, national authorities
- Specify necessary documents to attest conformity:
Technical documentation, certificates, declarations, etc.

MODULES FOR ICs

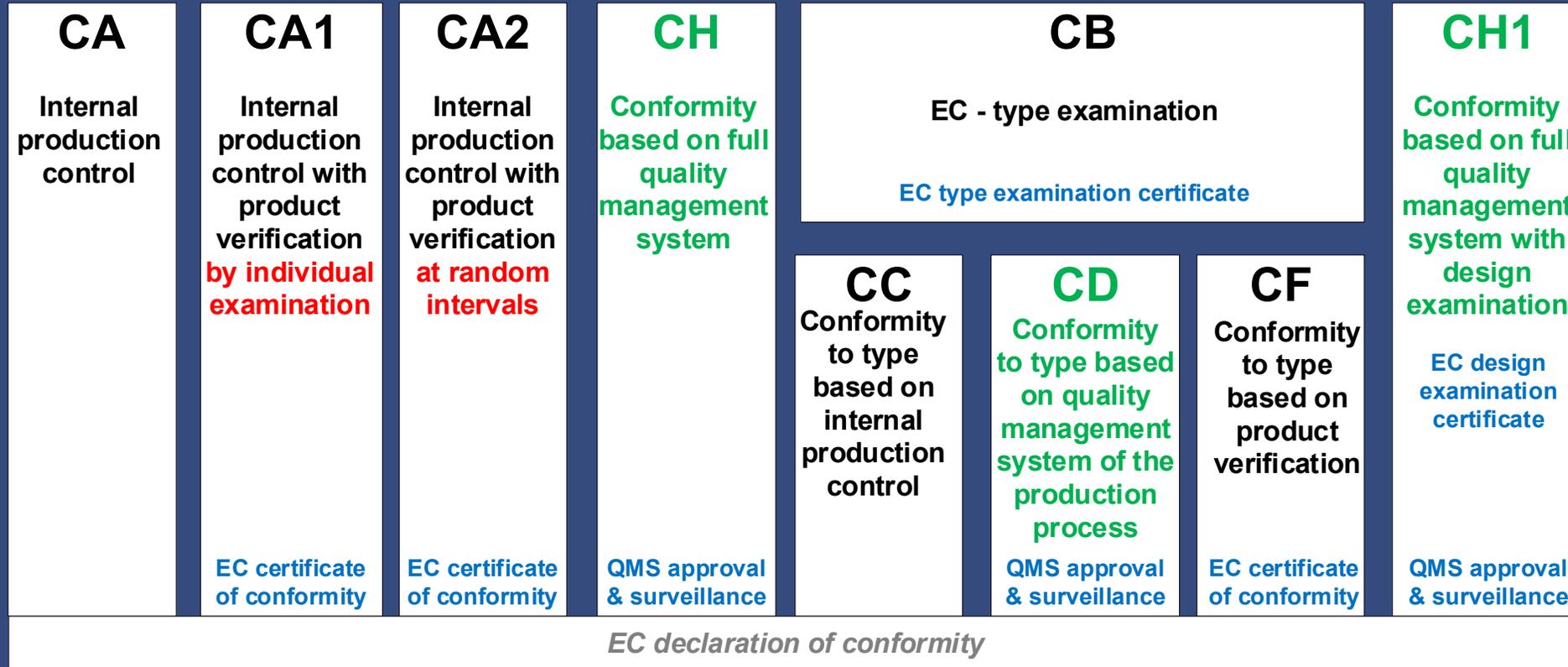
Defined in the TSIs from the **Decision 713/2010/EU**



The “C” at the beginning indicates the reference to “constituents”

The modules are “in principle” the same as the general modules for other industrial sectors

Menu of rail modules for ICs*



CV Type validation by in-service experience
EC certificate of suitability for use

EC declaration of suitability for use

QMS modules

Documents issued by notified bodies

Documents issued by manufacturers

Rail modules for ICs – Which ones require tests to be carried out by NoBo?

Module	Tests by the Manufacturer	Other testing body	Tests by the NoBo ¹
Module CA	yes	-	-
Module CA1	yes (by accredited in-house body) ²	-	yes ²
Module CA2	yes (by accredited in-house body) ²	-	yes ²
Module CB	yes ³	yes ³	yes
Module CC	yes, if necessary	-	-
Module CF	yes ⁴	-	yes
Module CV	yes	IM and/or RU ⁵ , and, if nec., other test body	monitoring & inspection, assessment of the (test) reports

¹ Tests carried out by NoBo or subcontracted

² Choice between 2 options for testing – accredited in-house body or NoBo

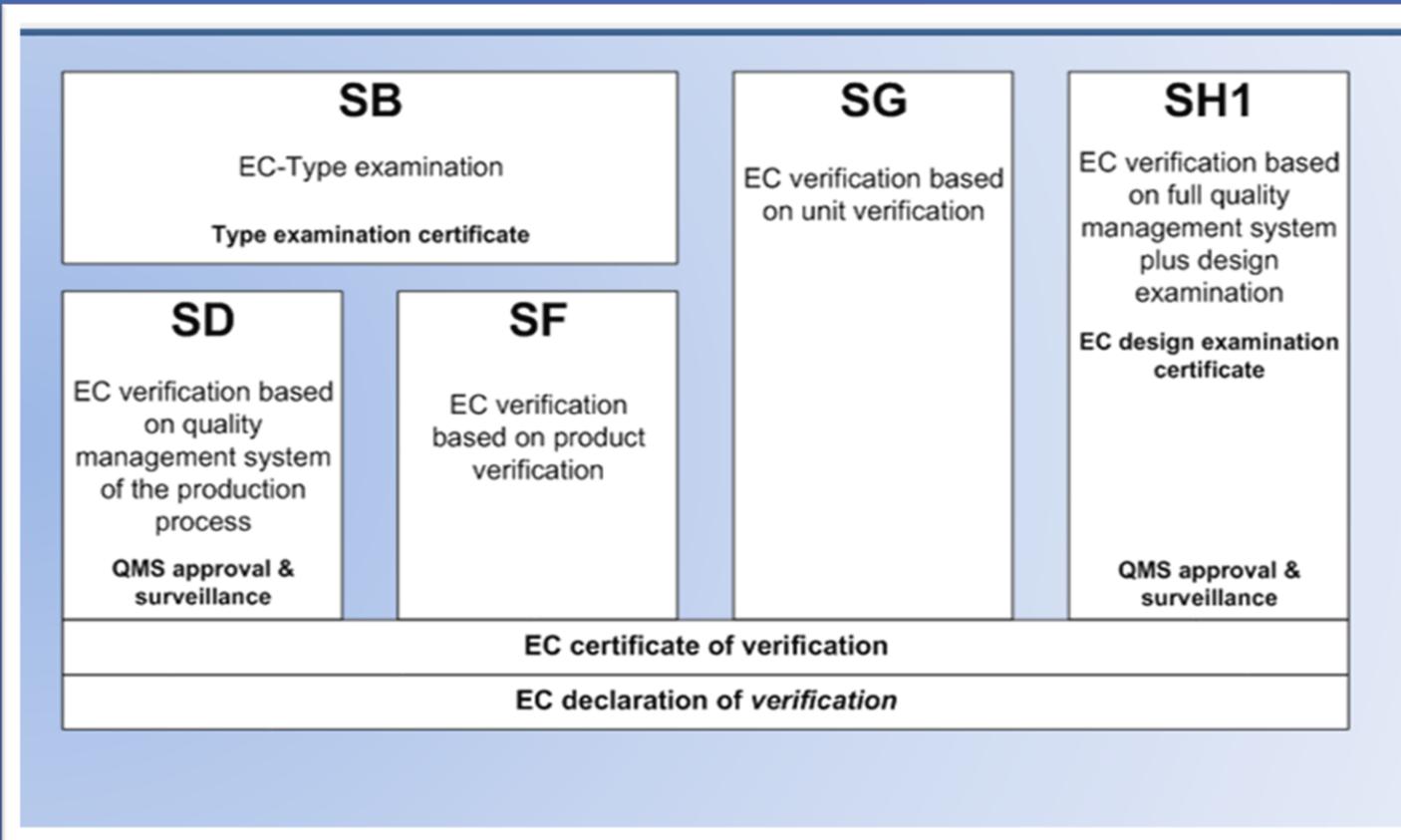
³ Tests may be carried out by a laboratory of the manufacturer or another laboratory on his behalf and under his responsibility

⁴ When a test is not set out in the TSI, harmonised standard(s) and technical specification(s), the appropriate tests to be carried out shall be decided between the manufacturer and the NoBo

⁵ IM and/or RU, with which the applicant has obtained an agreement to contribute to a suitability for use assessment by in-service experience

MODULES FOR SUBSYSTEMS

Defined in the TSIs from the **Decision 713/2010/EU**



The “S” at the beginning indicates the reference to “subsystems”

The modules are “in principle” the same as the general modules for other industrial sectors, Some additional verifications are introduced to take into account rail specific provisions in IOD

Menu of rail modules for subsystems

SB

EC-Type examination

Type examination certificate

SG

EC verification
based on unit
verification

SH1

EC verification
based on full quality
management
system plus design
examination

EC design examination
certificate

SD

EC verification
based on quality
management
system of the
production process

QMS approval &
surveillance

SF

EC verification
based on
product
verification

QMS approval &
surveillance

EC certificate of verification

EC declaration of verification

QMS modules

Documents issued by notified bodies

Documents issued by applicant



Rail modules for subsystems – Which ones require tests to be carried out by NoBo?

Module	Tests by the Manufacturer/Applicant	Other testing body	Tests by the NoBo ¹
Module SB	yes ²	yes ²	yes
Module SF	yes ³	-	yes & supervision and attendance of tests ⁴
Module SG	yes ⁵	yes ⁶	yes & supervision and attendance of tests ⁴

¹ Tests carried out by NoBo or subcontracted

² Tests may be carried out by a laboratory of the manufacturer or another laboratory on his behalf and under his responsibility

³ When a test is not set out in the TSI, harmonised standard(s) and technical specification(s), the appropriate tests to be carried out shall be decided between the manufacturer and the NoBo

⁴ Whenever required in the relevant TSI(s), tests or validation under full operating conditions, are carried out by the applicant under direct supervision and attendance of the notified body

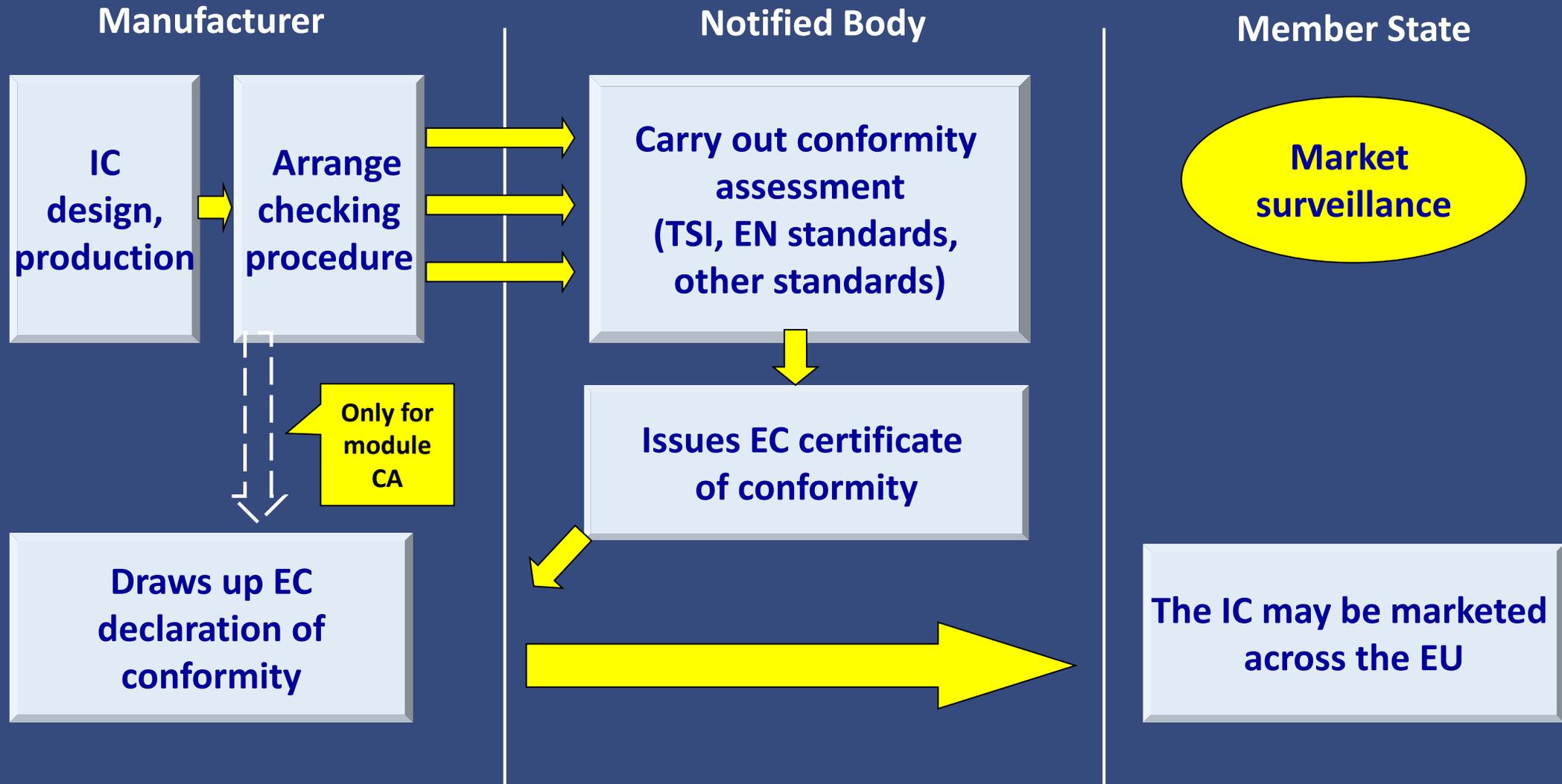
⁵ When this is specified by the relevant TSI(s)

⁶ **The conditions to entrust checking and test must be similar to the conditions, respected by a notified body to subcontract activities**

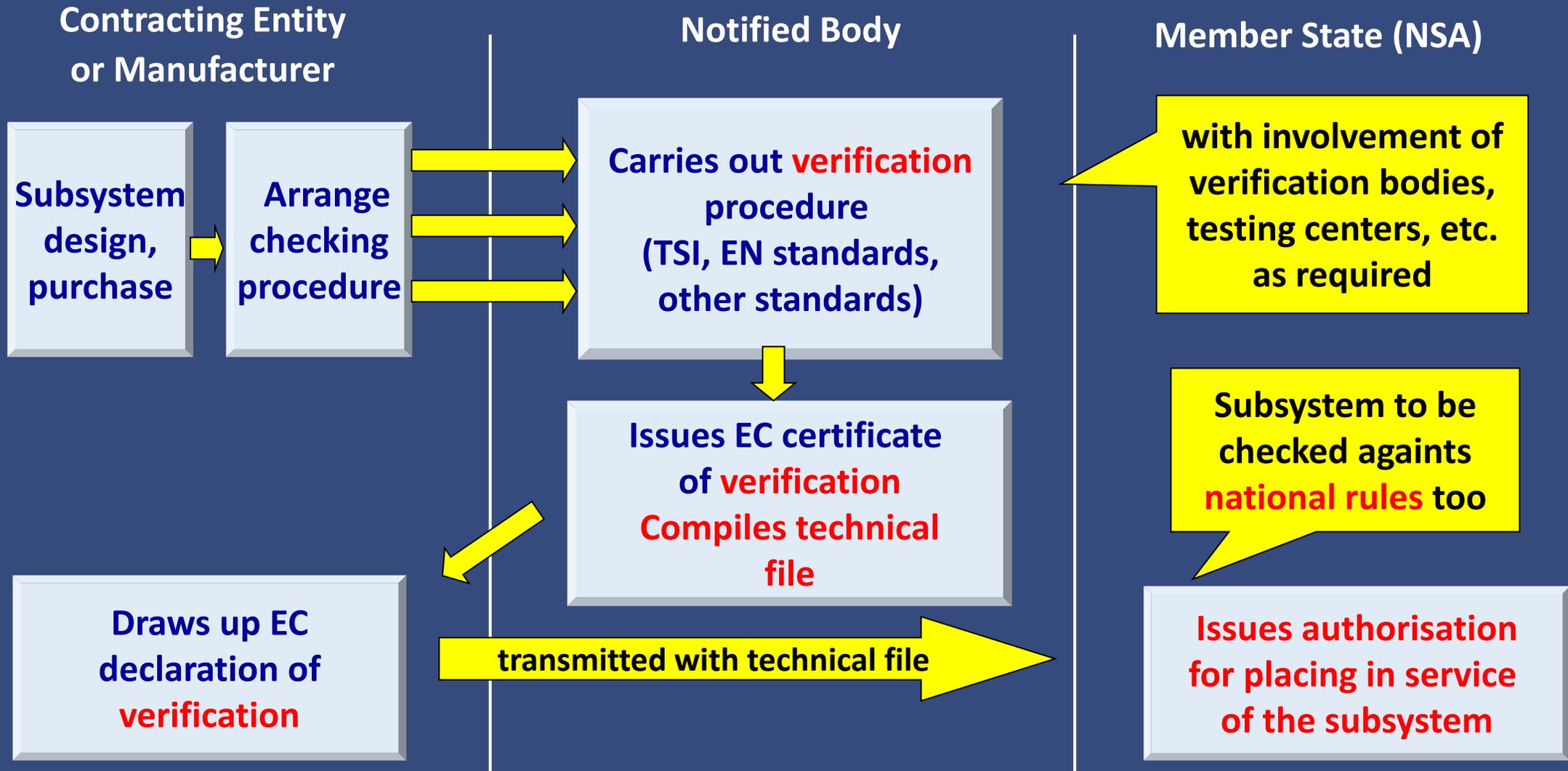
TO SUMMARIZE

- **9** modules for **Interoperability Constituent (ICs)**
- **5** modules for **Subsystems**
- Some modules can be used only in combination with others
- Range of modules to ensure proportionate procedures to the objectives
- Modules may involve 3rd party assessment (NoBo) or self-assessment (modules CA, CC)

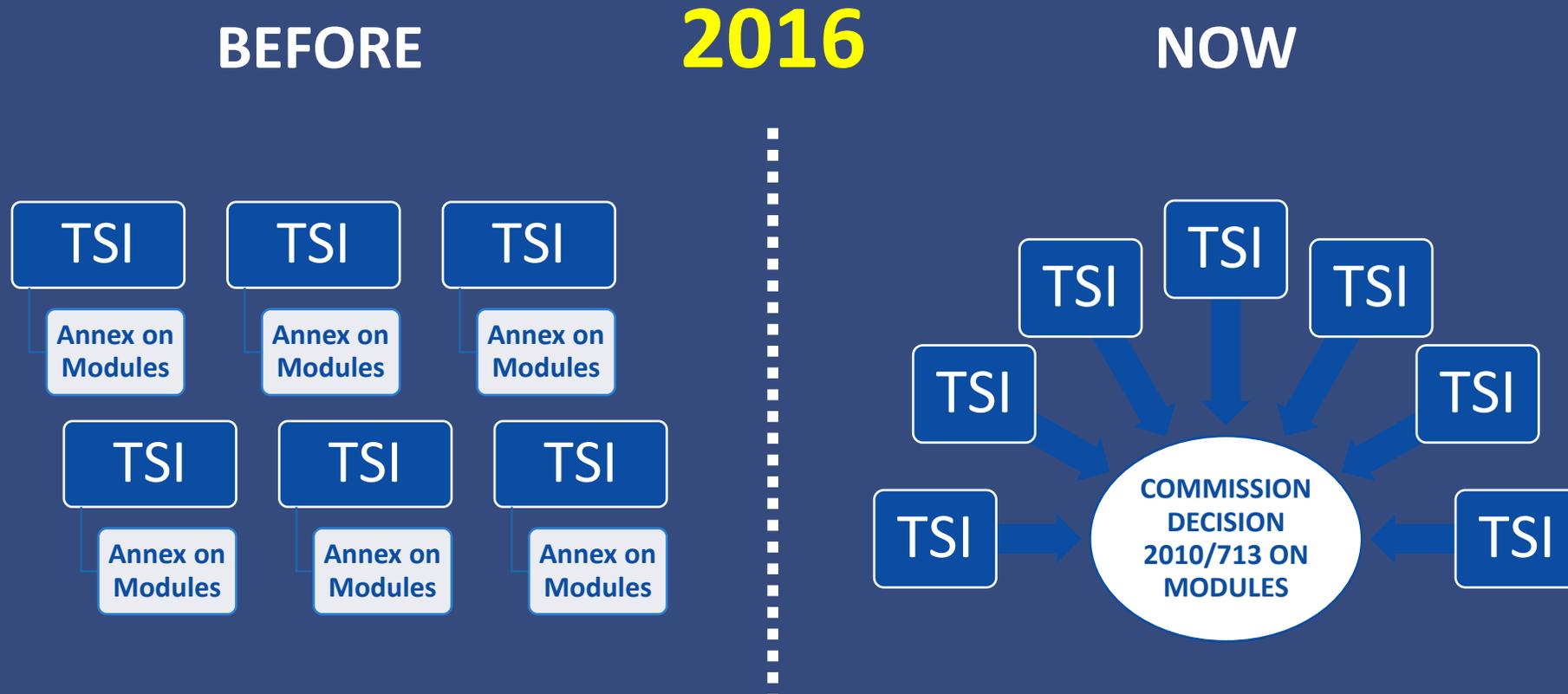
PROCESS: IC conformity assessment



PROCESS: Subsystem verification



TSIs & MODULES



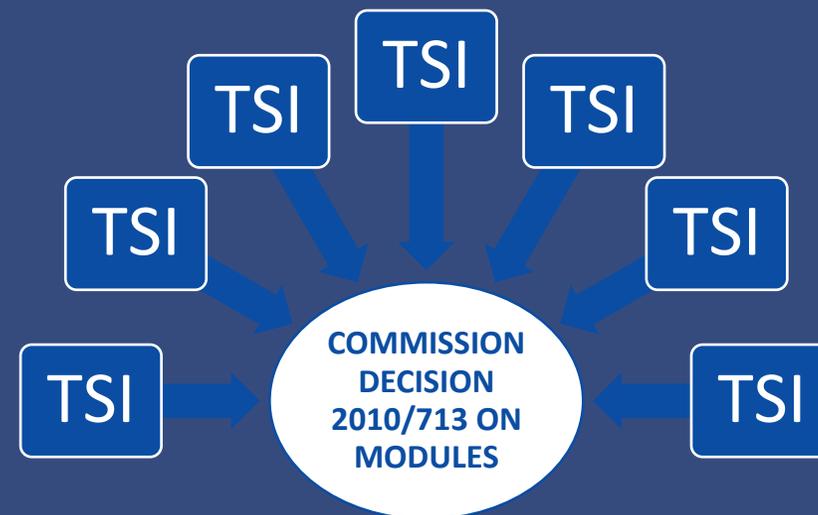
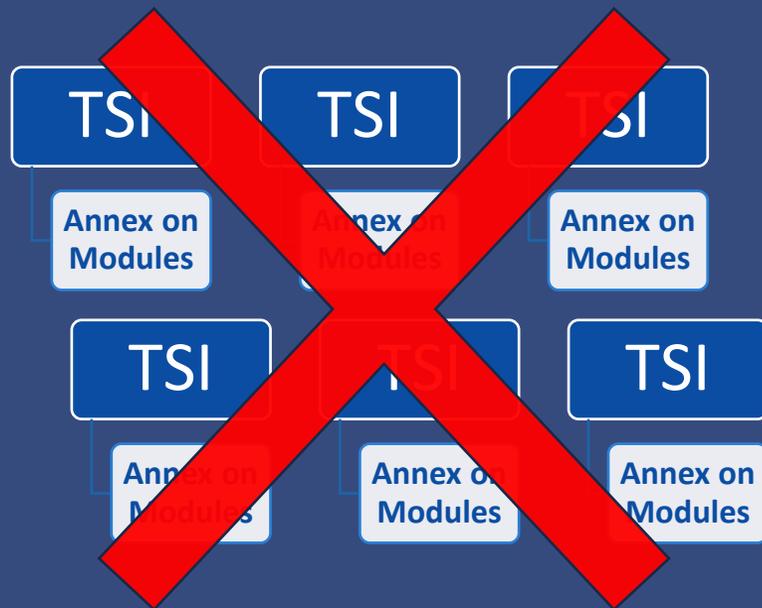
New and revised TSIs refer to [Decision 2010/713/EU](#) on modules
instead of including Annex with modules description

TSIs & MODULES

BEFORE

2016

NOW



New and revised TSIs refer to [Decision 2010/713/EU](#) on modules
instead of including Annex with modules description

TSIs & MODULES

- Each TSI indicates which modules may be used for the conformity assessment of an **IC** or verification of a **Subsystem**
- The manufacturer of the **IC** or applicant for the verification of the **Subsystem** to choose, from those indicated in the TSIs, the module or combination of modules

1 dedicated section for conformity assessment in each TSI

“Chapter 6”

- specifies which modules can be used for ICs and the subsystem
 - (1) For the EC verification procedure of the infrastructure subsystem, the applicant may choose either:
 - (a) Module SG: EC verification based on unit verification, or
 - (b) Module SH1: EC verification based on full quality management system plus design examination.
- defines particular assessment procedures and technical solutions giving presumption of conformity

CHOICE OF MODULES

- Some modules have higher fixed costs (e.g. SB+SD or SH1 imply costs before the first unit is produced) and smaller marginal costs for each new unit → The bigger the size of serial production, the more suitable these modules are
- Some other modules have small fixed costs, but higher marginal costs (e.g. application of SG implies individual verification for every unit) → These modules are more appropriate for one-off products

CHOICE OF MODULES

Some useful questions to ask:

- ❖ Is my product:
 - an IC → Which TSIs are applicable for my IC?
 - a Subsystem → Which TSIs are applicable for my subsystem?
 - a vehicle or
 - none of the above?

- ❖ What is the size of my serial production?

- ❖ Do I have a Quality Management System in my organisation? (QMS based modules may be used)

CHOICE OF MODULES

❖ What stages does my QMS cover?

Design and/or Production/final product/susystem inspection and testing?

ICs

If both stages are covered, modules CH or CH1 or the combination CB+CD may be used

If the design stage is not covered, CH and CH1 cannot be used, but the combination CB+CD may be used

SUBSYSTEMS

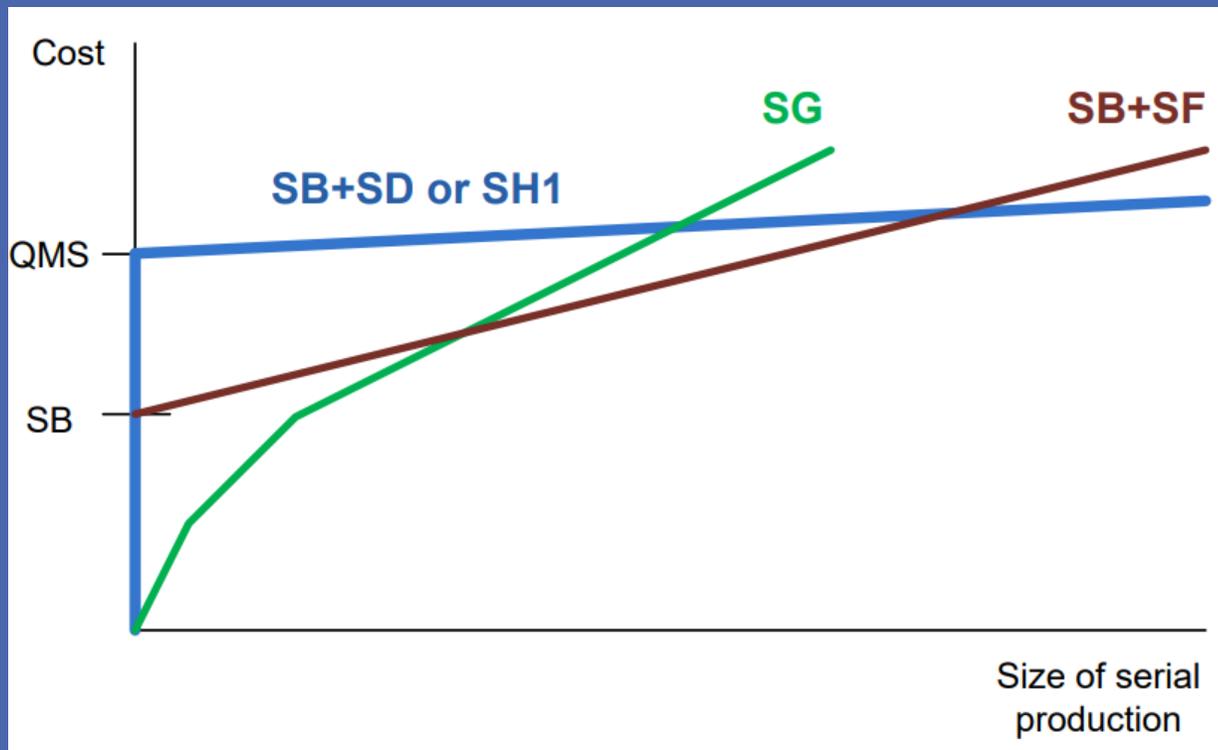
If all three stages are covered, module SH1 or combination SB+SD may be used.

If the design stage is not covered, SH1 cannot be used, but the combination SB+SD may be used

❖ Does my QMS cover different design & production sites?

CHOICE OF MODULES

According to the choice given in the TSI, there are always two possibilities:
with QMS or without QMS



Cost of application of different conformity assessment modules
depending on size of serial production

Choice of module may have an important impact on cost & time

Choice depends on particular situation of each company and specific characteristics of the products

CHOICE OF MODULES

Balance between fixed cost, mass production and marginal cost

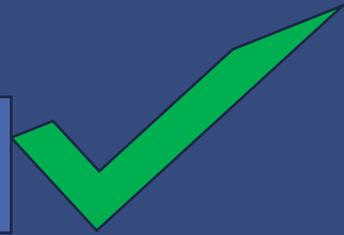
Rule of thumb:

- SB modules for mass production (vehicles)
- SG for specific developments (fixed installation)

CONFORMITY ASSESSMENT

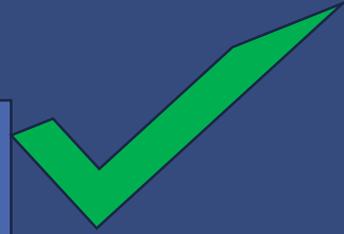
WHY

'New Approach', NLF, harmonisation, legal framework, etc.



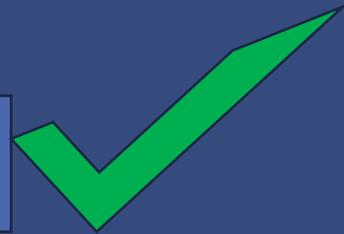
WHAT

????????????????



HOW

Procedures, methods, CA 'Modules', etc.



Q & A



TECHNICAL OPINION ERA/OPI/2025-6 ON COMBINATION OF MODULES FOR ASSESSMENT OF CONFORMITY & SUITABILITY

DESCRIPTION OF PROBLEM

SB (Type examination)

The **application** shall include:

- [...]
- a written declaration that the **same application** has not been lodged with any other notified body,
- the technical documentation
 - 17 sub-points!
 - **conditions for use** of the subsystem

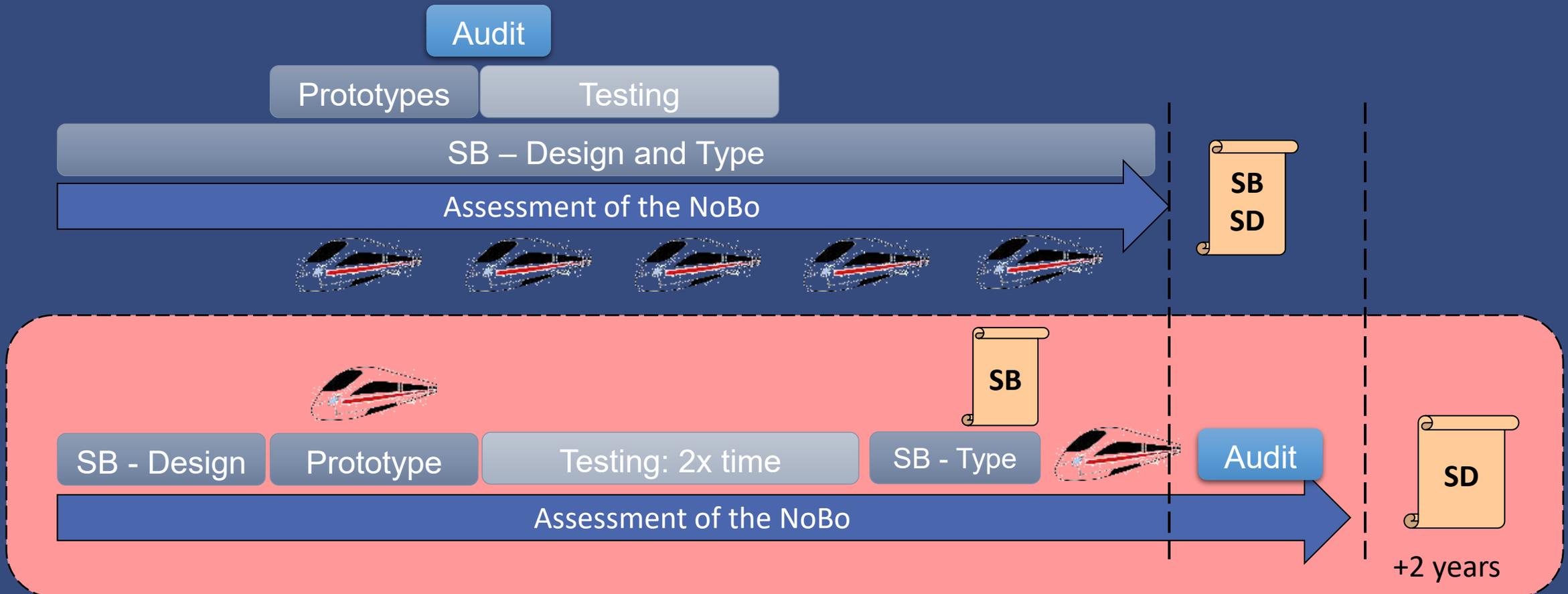
SD (QMS Audit)

The **application** shall include:

- [...]
- the technical documentation of the approved type and a copy of the **EC-type examination certificate** and its annexes.

DESCRIPTION OF PROBLEM

From design to certification...



MODULES IN SCOPE OF TO

For ICs

- **Module CB:** EC type examination
- **Module CD:** Conformity to type based on QMS of production process
- **Module CF:** Conformity to type based on product verification

For subsystems:

- **Module SB:** EC type examination
- **Module SD:** EC verification based on QMS of production process
- **Module SF:** EC verification based on product verification

ERA OPINION

- Activities performed NoBos in the context of modules xD/xF can be done in parallel to those related to modules xB
- The Notified Body responsible for the modules xD/xF shall ensure that:
 - At the time the inspections/audits are made, the design is mature enough to allow the verification/QMS assessment. Documentary evidence of these activities shall be part of documentation accompanying the certificate

continues...

ERA OPINION

- Changes brought to the design and/or the manufacturing process between the inspection/audit and the delivery of the EC Type examination certificate are assessed as well as their implementation on the object of assessment. Documentary evidence of these activities shall be part of documentation accompanying the certificate.
- The EC Type examination certificate (module xB) is released before of the certificates related to production and final testing (module xD or xF).

ERA OPINION

- It should be noted that xH1 modules (full QMS with design examination) might be preferred by applicants in case of parallel activities
- Decision 2010/713: Wording for module SD point 5.2 and for module SF point 4.2 “*The notified body chosen by the applicant shall first examine the application concerning the validity of the EC type examination certificate and its annexes*” should be rephrased in a future revision to better reflect gradual delivery of the required documentation all along the project

USEFUL READING

[‘Blue guide’](#) on the implementation of EU product rules 2022

Very exhaustive guide on these
and other related topics

THE 'BLUE GUIDE'

- A hands-on document explaining EU product legislation
- 1st edition published in 1994 with a blue cover
- Subsequent editions: 2000, 2014 and 2016

Update 2022:

- Market Surveillance Regulation 2019/1020
- Complementary information on certain issues (substantial modifications)
- Withdrawal of the UK from the EU



[EUR-Lex -
52022XC0629\(04\) - EN -
EUR-Lex \(europa.eu\)](#)

USEFUL INTERNET LINKS

[New Legislative Framework](#)

[Accreditation](#)

[CE marking](#)

[Conformity assessment](#)

[NoBos](#)

[Harmonised Standards - European Commission \(europa.eu\)](#)

Glossary

Accreditation Body (AB) / National Accreditation Body (NAB)

The (single) body in a Member State with authority derived from the state to perform accreditation

Accreditation

Attestation by a NAB that a conformity assessment body (CAB) meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity

Conformity Assessment Body (CAB)

A body that performs one or several elements of conformity assessment, including one or several of the following activities: calibration, testing, certification and inspection (see Reg. (EC) No. 765/2008 and IOD Art. 2(42))

Conformity assessment

Process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled

Glossary

European Harmonised Standard

A European standard developed by a recognised European Standards Organisation: CEN, CENELEC, or ETSI. Manufacturers, other economic operators, or conformity assessment bodies can use harmonised standards to demonstrate that products, services, or processes comply with relevant EU legislation

European co-operation for Accreditation (EA)

A not-for-profit association set up to coordinate and lead the European accreditation infrastructure

NANDO

New Approach Notified and Designated Organisations

New Approach

Introduced in 1985, a 'new approach' to technical harmonization and standards, to eliminate technical barriers to the free circulation of goods

New Legislative Framework (NLF)

Regulation (EC) No 765/2008 and Decision 768/2008/EC

Glossary

Notified Body (NoBo)

A conformity assessment body officially designated by the national authority to carry out the procedures for conformity assessment within the meaning of applicable Union harmonisation legislation

Notification

An act whereby a Member State informs the Commission and the other Member States that a body, which fulfils the relevant requirements, has been designated to carry out conformity assessment according to a directive

Notification Procedures

The procedures of a Notifying Authority for the assessment and notification of conformity assessment bodies, and the monitoring of notified bodies, under a specific directive/regulation

Notifying Authority (NA)

The national authority responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies

Glossary

Procedure/Module

Conformity assessment procedure as set out in Annex II of Decision 758/2008/EC, and in the relevant EU product legislation

Technical Specification for Interoperability (TSI)

A Commission Decision or Regulation that prescribes the technical requirements to be fulfilled by a product, process or service ('sub-system') in order to meet the essential requirements of the Directive on Interoperability of the rail system within the European Union

Sources & droits d'auteur

Sources

[EC Website](#)

[ERA Website](#)

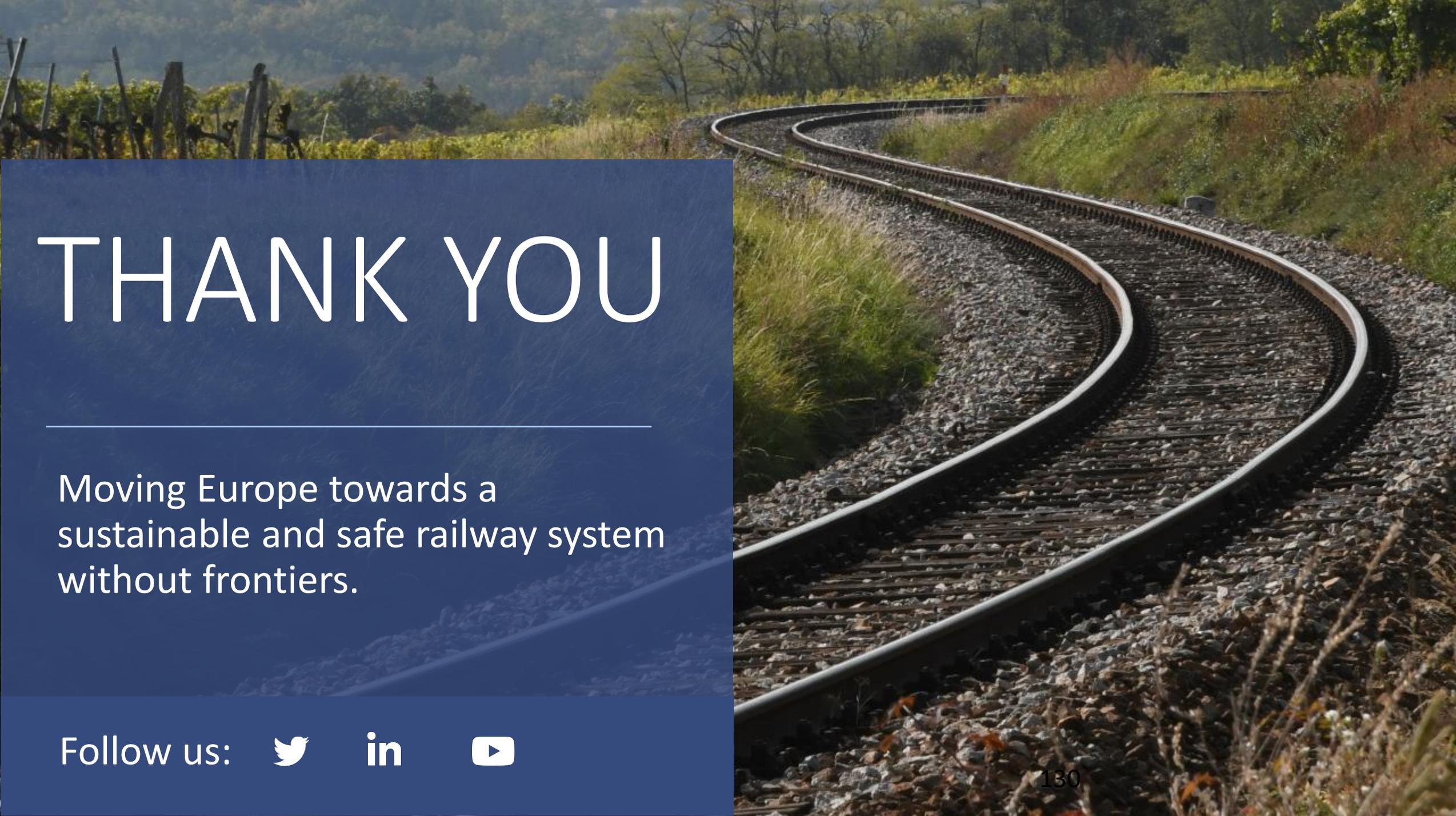
From the CEN website : [The 'New Approach' \(cen.eu\)](#)

From the Commission website : [EUROPA – European Commission – Growth – Regulatory policy - SMCS](#)

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