EUROPEAN UNION AGENCY FOR RAILWAYS

Moving Europe towards a sustainable and safe railway system without frontiers.

Technical document

REQUIREMENTS FOR CONFORMITY ASSESSMENT BODIES SEEKING NOTIFICATION

Document History

Version	*Date*	*Comments*
1.1	14/06/2017	Minor amendments to first issue
2.0	13/12/2022	Second issue (cf. Annex K with major amendments). Endorsed by the European Union Agency for Railways by Decision ERA-ED-DEC-2110-2022 of 13/12/2022

Foreword

The European Union Agency for Railways has drafted this document within the framework of the Management Board adoption of the provisions for audits for monitoring notified conformity assessment bodies according to Agency Regulation 2016/796 Article 34(3).

On the 27th of June 2017, the Management Board of the Agency adopted the Decision n° 156 "*Provisions on auditing notified conformity assessment bodies in the framework of the monitoring as Agency Regulation 2016/796 art. 34 (3)*" to which this document refers to.

The set of detailed requirements for notified conformity assessment bodies (CABs), the provisions for inspecting CABs, the provisions for annual reporting and the provisions for a forum for exchange of best practices are fundamental elements of the system for monitoring notified CABs and are described in the Agency's internal quality management system, the Integrated Management System (IMS).

Updates in the relevant legal framework (EU legislation, ISO/EN Standards, etc.), return of experience from the Agency's audits and inspections of notified bodies, feedback from stakeholders and from other processes (e.g. railway authorisations), required the revision of the ERA technical document 000MRA1044 ver. 1.1.

This version of the ERA technical document 000MRA1044 is the result of the work of the ad-hoc Task Force composed by representatives from ERA, NSAs, EA, NB-Rail, CER, UNIFE and OTIF Secretariat.

In the context of this document:

- "shall" indicates a requirement;
- "should" indicates a recommendation;
- "may" indicates a permission;
- "can" indicates a possibility or a capability.

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Introduction

Member States shall appoint **notifying authorities** responsible for setting up and carrying out the necessary procedures for the assessment, notification and monitoring of bodies responsible for the conformity assessment of railway products. These bodies are called conformity assessment bodies (CABs).

In this context:

- **Assessment** is the process demonstrating that the CAB fulfils the requirements identified in the Interoperability Directive (EU) 2016/797.
- **Notification** is the act of the notifying authority informing the European Commission and the other Member States that a CAB meets all requirements identified by the interoperability Directive (EU) 2016/797.
- **Monitoring** is the process demonstrating that the notified conformity assessment body continuously fulfils the requirements identified in the Interoperability Directive (EU) 2016/797.

A Member State's notifying authority may decide to delegate the assessment and monitoring to:

- a national accreditation body (NAB), within the European Co-operation for Accreditation (EA) – herein referred to as **accreditation** regime, or
- a relevant national authority complying with the legal requirements identified in the Interoperability Directive (EU) 2016/797 – herein referred to as **recognition** (i.e. non accreditation) regime.

The Member State's notifying authority remains always responsible for the delegated tasks.

Article 37(5) of the Interoperability Directive (EU) 2016/797 provides that the CAB concerned may perform the activities of a notified body only where no objections are raised by the Commission or by the other Member States, within:

- two weeks of the notification, under the **accreditation** regime, or
- two months of the notification, under the **recognition** regime.

NOTE 1: The 'Blue Guide' on the implementation of EU product rules 2016 provides an exhaustive description about the above topics (see https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XC0726(02)&from=EN).

About this technical document

This technical document is composed by:

PART 1. FRAMEWORK FOR MEMBER STATES' NOTIFYING AUTHORITIES

Introduces the topic of MS assessments and accreditation/recognition regime for CABs and the overarching framework for the application of the requirements described in PART 2.

PART 2. REQUIREMENTS FOR CONFORMITY ASSESSMENT BODIES

Provides requirements for the assessment, notification and monitoring of CABs in accordance with the IOD 2016.

NOTE 2: In this document the terms conformity assessment bodies (CAB) and "certification body" (in reference to the EN ISO/IEC 17065) are considered synonyms.

Abbreviations and acronyms

Table 1 : Table of abbreviations and acronyms

Abbreviation / Acronym	*Meaning*
AsBo	Assessment Body
AT	Assessment team
CAB	Conformity Assessment Body (Notified and Designated Body)
CER	Community of European Railway and Infrastructure Companies
CSM-RA	Document [19] described in *Table* 3 : Table of *reference legislation* *Ref* | *Title*
DeBo	Designated Body
Decision 2010/713/EU on railway modules	Document [18] described in in *Table* 3 : Table of *reference legislation* *Ref* | *Title*
Decision on generic modules	Documents [16] described in in *Table* 3 : Table of *reference legislation* *Ref* | *Title*
EA	European Co-operation for accreditation as defined by Article 14 of [16]
EC	European Commission
ERA, Agency	European Union Agency for Railways as defined by [15] in *Table* 3 : Table of *reference legislation* *Ref* | *Title*
ERATV	European Register of Authorised Types of Vehicles
ERA Assessment Scheme	ERA technical document “Requirements for conformity assessment bodies seeking notification - 000MRA1044”
EVR	European Vehicle Register
FAQ	Frequently Asked Questions
IAF	International Accreditation Forum The IAF is the world association of accreditation bodies and other bodies interested in conformity assessment in the fields of management systems, products, services, personnel and other similar programmes of conformity assessment
ILAC	International Laboratory Notification Cooperation The international organisation for accreditation bodies operating in accordance with EN ISO/IEC 17011 and involved in the accreditation of conformity assessment bodies
IOD 2016	Interoperability Directive, document [13] described in *Table* 3 : Table of *reference legislation* *Ref* | *Title*

Abbreviation / Acronym	*Meaning*
ISO 19011	Document [12] described in *Table 2*
ISO 9001	Document [11]described in *Table 2*
EN ISO/IEC 17011	Document [6] described in *Table 2*
EN ISO/IEC 17020	Document [4] described in *Table 2*
EN ISO/IEC 17021-1	Document [3] described in *Table 2*
EN ISO/IEC 17025	Document [5] described in *Table 2*
EN ISO/IEC 17065	Document [2] described in *Table 2*
ISO/IEC 31000	Document [7] described in *Table 2*
MS	European Union Member State
NAB	National Accreditation Body as defined by Article 4 of [17] in *Table* 3 : Table of *reference legislation* *Ref* | *Title*
NSA	National safety authority as defined by [14] in *Table* 3 : Table of *reference legislation* *Ref* | *Title*
NVR	National Vehicle Register
OTIF	Intergovernmental Organisation for International Carriage by Rail
PA VA	Document [21] described in *Table* 3 : Table of *reference legislation* *Ref* | *Title*
Q/C	Questions and Clarification
QMS	Quality Management System
Regulation on CSM-RA	Document [19] described in *Table* 3 : Table of *reference legislation* *Ref* | *Title*
RFU	Recommendation for Use
RINF	Register of Infrastructure
RSD 2016	Railway Safety Directive, document [14] described in *Table* 3 : Table of *reference legislation* *Ref* | *Title*
SRAC	Safety Related Application Condition
TSI	Technical Specification for Interoperability
UNIFE	European Rail Supply Industry Association (Union des Industries Ferroviaires Européennes)

Reference documents and legislation

Table 2 : Table of reference documents

Ref	Title	Version
[1]	Standard EN ISO/IEC ISO 17000 – Conformity assessment — Vocabulary and general principles	2020
[2]	Standard EN ISO/IEC 17065 - Conformity assessment — Requirements for bodies certifying products, processes and services	2012
[3]	Standard EN ISO/IEC 17021-1 - Conformity assessment - Requirements for bodies providing audit and certification of management systems	2015
[4]	Standard EN ISO/IEC 17020 - Conformity assessment — Requirements for the operation of various types of bodies performing inspection	2012
[5]	Standard EN ISO/IEC 17025 - General requirements for the competence of testing and calibration laboratories	2017
[6]	Standard EN ISO/IEC 17011 - Conformity assessment - General requirements for notification bodies accrediting conformity assessment bodies	2017
[7]	Standard ISO/IEC 31000 – Risk management - Guidelines	2018
[8]	IAF MD 5 - Determination of Audit Time of Quality and Environmental Management Systems - Issue 4, issued on 11 November 2019; Application from 07 May 2020	2019
[9]	EA-2/17 M: 2020 - EA Document on Accreditation for Notification Purposes	2020
[10]	ISO 9000 - Quality management systems — Fundamentals and vocabulary	2015
[11]	ISO 9001 - Quality management systems — Requirements	2015
[12]	ISO 19011 - Guidelines for auditing management system	2018

Table 3 : Table of reference legislation

Ref	Title	Reference
[13]	Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (recast)	OJ L 138/102, 26.5.2016
[14]	Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety (recast)	OJ L 138/102, 26.5.2016
[15]	Regulation (EC) 2016/796 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Railways and repealing regulation (EC) No 881/2004	OJ L 138, 26.5.2016
[16]	Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC	OJ L 218, 13.08.2008
[17]	Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for notification and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93	OJ L 218, 13.08.2008
[18]	Commission Decision 2010/713/EU of 9 November 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	OJ L 319, 04.12.2010

Ref	*Title*	*Reference*
[19]	Commission Implementing Regulation (EU) No 402/2013 of 30 April 2013 on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009	OJ L 121/8, 3.5.2013
[20]	Commission Implementing Regulation (EU) 2019/250 of 12 February 2019 on the templates for 'EC' declarations and certificates for railway interoperability constituents and subsystems, on the model of declaration of conformity to an authorised railway vehicle type and on the 'EC' verification procedures for subsystems in accordance with Directive (EU) 2016/797 of the European Parliament and of the Council and repealing Commission Regulation (EU) No 201/2011	OJ L 42, 13.2.2019
[21]	Commission Implementing Regulation (EU) 2018/545 of 4 April 2018 establishing practical arrangements for the railway vehicle authorisation and railway vehicle type authorisation process pursuant to Directive (EU) 2016/797 of the European Parliament and of the Council	OJ L 90, 6.4.2018
[22]	Commission Recommendation of 18 July 2018 on guidance for the harmonised implementation of the European Rail Traffic Management System in the Union	OJ C 253, 19.7.2018
[23]	Regulation (EC) 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents	OJ L 145/43 31.05.2001
[24]	Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data	OJ L 8/1 12.1.2001
[25]	Commission Regulation (EU) No 1299/2014 of 18 November 2014 on the technical specifications for interoperability relating to the 'infrastructure' subsystem of the rail system in the European Union	OJ L 356/1 12.12.2014
[26]	Commission Regulation (EU) No 1302/2014 of 18 November 2014 concerning a technical specification for interoperability relating to the 'rolling stock — locomotives and passenger rolling stock' subsystem of the rail system in the European Union	OJ L 356/228 12.12.2014
[27]	Commission Regulation (EU) No 321/2013 of 13 March 2013 concerning the technical specification for interoperability relating to the subsystem rolling stock — freight wagons of the rail system in the European Union and repealing Decision 2006/861/EC	OJ L 104 12.4.2013
[28]	Commission Regulation (EU) 2016/919 of 27 May 2016 on the technical specification for interoperability relating to the 'control-command and signalling' subsystems of the rail system in the European Union, amended by Commission Implementing Regulation (EU) 2019/776 of 16 May 2019	OJ L 158/1 15.6.2016
[29]	Commission Regulation (EU) No 1303/2014 of 18 November 2014 concerning the technical specification for interoperability relating to 'safety in railway tunnels' of the rail system of the European Union	OJ L 356, 12.12.2014

NOTE 1: The legislation listed above includes all the applicable amendments.

PART 1. FRAMEWORK FOR MEMBER STATES' NOTIFYING AUTHORITIES

1. Objectives of the ERA Assessment Scheme

The application of this assessment scheme is intended to provide confidence to Member States' notifying authorities that CABs have the correct procedures and competence to perform notified conformity assessment bodies' activities as described in the EU railway legal framework.

Information on the application of the ERA Assessment Scheme shall be provided in the:

- notification output;
- technical annex associated to the notification output, and
- NANDO database.

2. Application of the ERA Assessment Scheme

This assessment scheme is addressed to notifying authorities appointed by Member States to carry out CAB assessment, notification and monitoring activities (cf. Article 27(1) of IOD 2016).

The ERA Assessment Scheme applies also to the bodies delegated by the notifying authorities to carry out CAB assessment, notification and monitoring activities (cf. Article 27(4) of IOD 2016).

The notifying authorities, or delegated bodies, should apply ERA Assessment Scheme in the framework of necessary procedures set up and carried out concerning the assessment and monitoring of conformity assessment bodies for the IOD 2016.

Following EA's endorsement, and the transition period referred therein, the ERA Assessment Scheme shall be mandatory for the notification of a CAB under the accreditation regime.

MSs may decide that the ERA Assessment Scheme is to be used for:

- the notification of a CAB which is not accredited in accordance with Article 27 of IOD 2016 (recognition regime);
- CABs designated under Article 15(8) of IOD 2016, to meet the requirements set out in Articles 30 to 34 and 45 of IOD 2016.

3. Scheme owner

The European Union Agency for Railways is the owner of this harmonized assessment scheme.

4. Baseline standard for the ERA Assessment Scheme

A common reference standard is needed for the ERA Assessment Scheme.

The following principles have been considered in identifying the baseline standard:

- One international standard shall be considered sufficient to ensure the competence of the CAB to perform NoBo activities.
- The suitable standard shall cover all the activities which a notified CAB may be demanded to perform in relation to the assigned modules described in the relevant TSI(s).
- The ERA Assessment Scheme shall define as few additional requirements as possible in comparison to the chosen baseline standard.

For these reasons, the baseline standard is the EN ISO/IEC 17065:2012 "Conformity assessment – requirements for bodies certifying products, processes and services".

5. Legal requirements

According to Article 33 of the IOD 2016, compliance with a harmonised standard gives presumption of conformity with the requirements set out in the same Directive, in so far as the applicable harmonised standards cover those requirements.

The applicable harmonised standard for the ERA Assessment Scheme is EN ISO/IEC 17065:2012 "Conformity assessment – requirements for bodies certifying products, processes and services".

Compliance with the requirements identified in the ERA Assessment Scheme gives presumption of conformity with the relevant requirements of IOD 2016 and EA-2/17 M: 2020.

The relevant requirements for notified conformity assessment bodies in IOD 2016 are provided in Articles 30 to 32, 34 and 41 of IOD 2016.

Table 4 correlates the requirements of the IOD 2016 with the relevant clauses of EN ISO/IEC 17065 and the additional clauses of the ERA Assessment Scheme.

NOTE 1: The following table is based on EA-2/17 M: 2020 – Annex D. See document [9] in Table 2.

Table 4 : NoBo requirements comparison: Directive EU 2016/797, EN ISO/IEC 17065 and ERA Assessment Scheme

Directive 2016/797	*Clause in EN ISO/IEC 17065*	*Additional clause/s in Part 2 of the ERA Assessment Scheme*
Art 30(1)	See relevant references below	See relevant references below
Art 30(2)	4.1.1	4.1.1
Art 30(3)	6.1, 6.2, 7.1.1, 7.3.2, 7.4.3, 7.4.4	6.1, 6.2, 7.1.1, 7.4.3, 7.4.4
Art 30(3a, b, c)	4.4, 6.1.1.1, 6.1.1.2, 6.1.2, 6.2.1, 7.1.1, 7.1.2, 7.3, 7.4.4, 7.10.1, 7.10.2	6.1.1.1, 6.1.1.2, 6.1.2.1, 6.1.2.2, 6.2, 6.2.1, 7.1.2, 7.4.4
Art 30 (3. last sentence)	4.3.2, 6.2, 7.3.1	6.2
Art 30(4)	4.3.1	-
Art 30(5)	4.5, 6.1.1.3	-
Art 30(6)	-	4.0
Art 30(7)	-	4.0
Art 31(1)	4.2	4.1, 4.2, Annex J

Directive 2016/797	*Clause in EN ISO/IEC 17065*	*Additional clause/s in Part 2 of the ERA Assessment Scheme*
Art 31(2)	4.2.3, 4.2.4, 4.2.5, 5.2	4.2 (introduction), 4.2.3, 4.2.4, 5.2.5, 5.2.1, 5.2.3
Art 31(3, 4)	4.2.6, 4.2.10	4.2 (introduction), 4.2.6, 4.2.10, Annex J
Art 31(5)	4.2.3, 4.2.7, 4.2.10, 6.2.2	4.2.3, 6.2.2.1, 6.2.2.2
Art 31(6)	4.2.2, 4.2.3, 4.2.5, 4.2.12, 6.1.1.2, 6.1.2, 6.1.3	4.2 (introduction), 4.2.3, 4.2.5, 6.1.1.2, 6.1.2.1,6.1.2.2, 6.1.3
Art 32(1 a, b, c, d)	6.1.1.2, 6.1.2.1, 6.1.2.2, 6.2.1	6.1.1.2, 6.1.2.1, 6.1.2.2, 6.2.1
Art 32(2)	4.2.3, 4.2.4, 5.2	4.2.3, 4.2.4, 5.2
Art 34(1, 2, 3, 4)	6.2.2	6.2.2.1, 6.2.2.2
Art 41(1)	4.1.2.2	Annex F, Annex G, Annex H
Art 41(2)	-	5.1, 6.2, Annex F, section H.4 of Annex H
Art 41(3)	7.6.6	-
Art 41(4)	7.10, 7.11	section H.12 and section H.13 of Annex H
Art 41(5)	7.10, 7.11	-

6. Cycle for the ERA Assessment Scheme

The cycle shall conform to the provisions in point 7.9 of EN ISO/IEC 17011.

7. Cooperation between notifying authorities and other entities

Notifying authorities or their delegated bodies are encouraged to cooperate with other entities for the application of the ERA Assessment Scheme.

NOTE 1: The suggested cooperation is between notifying authorities (or their delegated bodies) and organisations belonging to the same MS or to another MS such as (e.g. non exhaustive):

- *National Accreditation Bodies (within EA coordination) for accreditation regime*
- *Relevant national authorities for recognition regime*
- *National Safety Authorities*
- *Suitable independent competent bodies.*

8. Notifying authorities' assessment team

Notifying authorities (or their delegates) should apply the provisions in this clause.

This clause details the requirements provided in Article 28 of IOD 2016.

8.0. Principles

Members of the notifying authorities assessment team (AT) shall be selected based on the following criteria:

- Independence,
- competence, and
- efficiency.

NOTE 1: Clause 7.4 of EN ISO/IEC 17011 provides additional provisions and clarifications regarding the assessment team.

The objective is to appoint an assessment team based on the minimum number of staff having the complete competence required to evaluate the CAB under assessment, including:

- the design and implementation of CAB's management system;
- the competence of the CAB's staff;
- the CAB's ability to perform evaluation and certification activities;
- the organisational structure of the CAB, including ownership and related bodies and its arrangements for managing independence and impartiality.

The assessment of the CAB shall be performed:

- according to the required details provided by EN ISO/IEC 17065 and by PART 2 of this document, and
- in the shortest time and with the lowest cost for the CAB.

8.1. Composition

The number of persons composing the assessment team and their qualification may vary according to the scope or scopes of assessment.

As general guideline, an assessment team should include the following roles.

- AT Lead Assessor (LA);
- AT Assessor (AS);
- AT Technical expert (TE).

NOTE 1: Roles defined above should not be confused with the boards, group of persons or person described in PART 2 of this document point 5.1.3: the first set of roles refers to the notifying authority assessment team, the second to the CAB.

NOTE 2: The AT may include more than one Technical Expert (TE) to evaluate staff competence as appropriate and in accordance to the CAB's scope of notification (e.g. rolling stock, infrastructure, energy).

It is common assessment practice that a single person may perform several roles within the team for which he/she has the necessary competence. The title provided for those roles may vary in each notifying authority assessment team, however the competence should remain the same as listed.

8.1.1. AT Lead Assessor (LA)

The person ultimately responsible for the assessment. The Lead Assessor's main responsibilities are to:

- organise the assessment;
- coordinate the assessment team;
- conduct the assessment of the CAB's:
  - management system;
  - staff competence;
- decide on non-conformities and their classification;
- conduct the follow up to close the non-conformities.

8.1.2. AT Assessor (AS)

The person responsible for:

- conducting the assessment of the CAB's:
  - management system;
  - staff competence;
- evaluation and certification activities performed;
- deciding on non-conformities and their classification.

8.1.3. AT Technical expert (TE)

The person responsible in the assessment team for examining the specific technical aspects and competence, during document checks and on-site assessment and, whenever needed, during witnessing visits in support of the LA or AS.

8.2. Independence and impartiality

Members of the assessment team shall not have any professional, financial, family or friendship links or links of any other kind with the organisation to be assessed, which could compromise their impartiality.

The notifying authority or the delegated body shall ensure that the highest level of independence is maintained in the assessment team.

If a person has previously worked for a CAB to be assessed, this person cannot be part of the assessment team until a minimum period of two years has elapsed since the end of the work relation with the CAB.

The notifying authority or the delegated body can be consulted in the event of queries concerning the independence of a team member.

NOTE 1: To ensure impartiality of the assessment team towards CAB under assessment, it is considered a good practice to change the AT Lead Assessor and the AT Technical experts in each cycle of assessment. In those cases where it is not possible to change the assessment team, actions shall be taken to eliminate any possible risk of impartiality.

8.3. Competence

The competence required in the assessment team will depend on the scope of the assessment.

The following table provides the qualification selection criteria for the assessment team.

Table 5 : Criteria of competence for assessment team

Role	*Competence*
AT Lead Assessor	Qualified as lead assessor in EN ISO/IEC 17065. Knowledge and understanding of the ERA Assessment Scheme.
AT Assessor	Qualified as assessor in EN ISO/IEC 17065. Knowledge and understanding of the ERA Assessment Scheme.
AT Technical expert	Qualified as technical expert in at least part of scope of assessment described in this scheme. Knowledge and understanding of the ERA Assessment Scheme.

8.4. Principles of efficiency

The assessment team shall cover the assessment scope or scopes with the minimum number of members possible.

9. Notifying authority's assessment

CABs can be assessed for one or more products defined in section 0 of PART 2.

The scope of the notifying authority's assessment shall cover all the applicable TSIs and railway modules as required therein.

The CAB shall provide adequate information to the notifying authority or, where appropriate, to the delegated body responsible for the assessment.

The output of the notifying authority, or its delegated body, assessment of a CAB shall comprise of at least an:

- Assessment report, and
- Assessment certificate when the CAB meets the applicable requirements.

The assessment report shall contain at least the following information:

- Legal basis;
- Assessment standard: the ERA technical document "Requirements for conformity assessment bodies seeking notification - 000MRA1044 v2.0" together with EN ISO/IEC 17065:2012;
- Scope of assessment as defined by the ERA Assessment Scheme (see Annex D);
- Signature of the responsible person of the notifying authority, or its delegated body, performing the assessment of the CAB.

The assessment certificate or its annex/es (enclosure, appendix, etc.) shall contain at least the following information:

- Unique identification reference;
- Legal basis (IOD 2016);
- Scope of assessment: the ERA technical document “Requirements for conformity assessment bodies seeking notification - 000MRA1044 v2.0” together with EN ISO/IEC 17065:2012;
- Subsystems;
- Reference to the annexes of the certificate;
- Validity date of the certificate.

Information on the assessment certificate and related scope definition shall be publicly available (e.g. on the internet website of the notifying authority or of its delegated body).

NOTE 1: For accredited CABs, the assessment certificate is the accreditation certificate. For recognised CABs, the assessment certificate is equivalent to the document issued by the relevant recognition body to attest CAB compliance with the requirements in Article 30, Article 31, Article 32, Article 34 and Article 41 of IOD 2016.

PART 2. REQUIREMENTS FOR CONFORMITY ASSESSMENT BODIES

Reading instructions and numbering

Conformity assessment bodies (hereafter "CABs") seeking notification by Member States to the European Commission, within the scope of the IOD 2016 have to fulfil the requirements described hereunder.

The ERA Assessment Scheme uses as baseline the standard EN ISO/IEC 17065:2012 "Conformity assessment — Requirements for bodies certifying products, processes and services". Therefore:

- All the requirements included in the standard EN ISO/IEC 17065:2012 apply.
- The ERA Assessment Scheme does not contradict nor exclude any of the requirements of the EN ISO/IEC 17065:2012.
- The ERA Assessment Scheme provides amplified criteria for the IOD 2016 (ref. page v of the EN ISO/IEC 17065:2012).

PART 2:

- shall be read together with EN ISO/IEC 17065, and
- follows the same numbering structure of the EN ISO/IEC 17065 up to the second level (e.g. 4.2).

The text contained in this PART 2 shall be added to the text of the EN ISO/IEC 17065 where indicated.

An introductory sentence *in italic* provides information on how and where to include the text in the EN ISO/IEC 17065.

In case no additions to the EN ISO/IEC 17065 are needed, the sentence "Text in EN ISO/IEC 17065 applies" is included.

Several informative *NOTES* in *italic* can be found throughout the document.

****

Foreword

Text in EN ISO/IEC 17065 applies.

Introduction

The following text shall be added at the end of the introduction.

This document describes amplified criteria for the IOD 2016 to be applied in addition to the general criteria described in the EN ISO/IEC 17065:2012.

The amplified criteria to the general requirements detail the specific aspects of the railway interoperability and safety domain.

The amplified criteria set out in this document do not contradict nor exclude any of the requirements set out in the baseline standard.

1. Scope

NOTE 1: The ERA Assessment Scheme relates to product assessment. In this clause remove the terms "process" and "service".

The following text shall be added at the end of the clause.

The scope of CAB assessment activities includes one or more of the products below:

- Infrastructure;
- Energy;
- Trackside Control-command and signalling;
- On-board Control-command and signalling;
- Rolling stock.

Each scope of assessment refers to a structural subsystem and all interoperability constituents related to it as defined by the IOD 2016 and the relevant TSIs.

NOTE 2: In the railway sector, products include subsystems and interoperability constituents.

Fixed installations, parts of the 'network', as defined in Article 2(4) of IOD 2016, are a specific form of product.

2. Normative references

Text in EN ISO/IEC 17065 applies.

3. Terms and definitions

The following text shall be added at the end of the clause.

3.14 Competence

Ability to apply knowledge and skills to achieve intended results (Ref. to 3.10.4 of ISO 9000:2015).

3.15 QMS approval

QMS approval means the complete conformity assessment activity performed by the CAB in relation to the applicant's ability to establish and apply a product related Quality Management System. The assessment activity could lead to a positive or negative result.

3.16 Accredited test

Accredited test means:

- a test performed by a test laboratory accredited under the EN ISO/IEC 17025 within the limits of its accreditation certificate and associated annex, and
- performed under the conditions and rules of assessment.

3.17 Designated bodies (DeBo)

Bodies designated by Member States responsible for carrying out the conformity assessment activities regarding notified national technical rules for implementing the essential requirements for the cases listed in Article 13(2) of IOD 2016.

3.18 CSM-RA assessment bodies (AsBo)

Bodies as defined by Article 3(14) of Regulation on CSM-RA.

4. General requirements

The following text shall be added as a new clause 4.0, immediately before clause 4.1.

4.0. Coordination of CABs notified under IOD 2016

The CAB shall commit itself in writing to:

- follow the activities and apply the documents of the coordination group of notified CABs referred to in Article 30 (6) of IOD 2016,
- participate to all its coordination group plenary meetings or shall demonstrate that they are informed about the meetings and findings, and
- for CABs assessed for the control-command and signalling scope, participate to the activities of the ERTMS group referred in Article 29 of the Agency Regulation (EU) 2016/796.

4.1. Legal and contractual matters

Point 4.1.1: The following text shall be added at the end of the clause.

The CAB shall:

- be legally independent from the following entities:
  - manufacturer;
  - a rail transport undertaking;
  - an infrastructure manager;
  - a keeper;
  - an entity in charge of maintenance (ECM);
  - entity performing consultancy services (see 3.2 EN ISO/IEC 17065).

4.2. Management of impartiality

Point 4.2: the following text shall be added as an introduction to this point.

The requirements for management of impartiality which are stipulated in the relevant standards (i.e. EN ISO/IEC 17065, ISO/IEC 17020, ISO/IEC 17021-1 and ISO/IEC 17025) apply, as appropriate, to the:

- CAB as legal entity;
- Management, certification decision and review staff of the CAB;
- personnel of the CAB carrying out conformity assessment activities.

For CABs notified under the IOD 2016, the impartiality and independence requirements for the CAB and its personnel in relation to their role and consultancy activities, are provided in Annex J.

NOTE: For the purposes of the ERA Assessment Scheme, the following definitions for impartiality and independence from points 5.3 and 5.4 of EN ISO/IEC 17000:2020, apply:

Impartiality - objectivity with regard to the outcome of a conformity assessment activity.

Note 1 to entry: Objectivity can be understood as freedom from bias or freedom from conflicts of interest.

Independence - freedom of a person or organization from the control or authority of another person or organization.

Point 4.2.3: the following text shall be added at the end of the point.

The risk identification shall include the risks arising from the following elements:

- ownership of the CAB, including the list of the major share owners;
- shared resources, including personnel, facilities and finance, and branding;
- other resources under the CAB's direct control (e.g. hired-in personnel, experts carrying out conformity assessment activities).

Sharing resources with authorities designated to issue:

- authorisation for the placing into service of fixed installations;
- vehicle authorisation for placing on the market;
- safety certificates;
- licenses.

shall be considered as a relationship presenting the CAB with a risk to impartiality which shall be identified and managed.

Risk management shall include at least contractual provisions for staff to promptly inform its CAB about existing or new risks to its impartiality.

Point 4.2.4: the following text shall be added at the end of the point.

The management of the risk shall be documented and include at least the following information:

- description of the risk;
- type of activities to which the risk assessment relates;
- CAB and its staff relationships relevant for the identified risk(s);
- mitigating measures (e.g. contractual arrangements) to eliminate or minimise the risk, including related monitoring measures.

Such risk assessment shall consider consequences (see 3.6 ISO/IEC 31000:2018) which may escalate through cascading and cumulative effects.

It shall also specify and describe which risk(s) cannot be minimized to an acceptable level or cannot be eliminated. This may result in a CAB staff member not being allowed to participate in a certain conformity assessment activity(ies).

Point 4.2.5: the following text shall be added at the end of the point.

The top management commitment shall be documented.

Point 4.2.6: the following text shall be added at the end of the bullet points indicated.

d) The CAB shall not offer consultancy (see 3.2 EN ISO/IEC 17065) towards its client within the scope of the CAB notification;
e) The CAB shall not offer QMS consultancy or internal audit to its client within the scope of the CAB notification.

Point 4.2.10: the following text shall be added at the end of the point.

The specified period shall be not less than 2 years. This period may be reduced on a case-by-case basis depending on an appropriate documented risk-based evaluation.

Point 4.2.11: the following text shall be added at the end of the point.

The CAB shall create and update an appropriate impartiality analysis which records identified risks and actions.

4.3. Liability and financing

Text in EN ISO/IEC 17065 applies.

4.4. Non-discriminatory conditions

Text in EN ISO/IEC 17065 applies.

4.5. Confidentiality

Text in EN ISO/IEC 17065 applies.

4.6. Publicly available information

Text in EN ISO/IEC 17065 applies.

5. Structural requirements

5.1. Organizational structure and top management

Point 5.1.3: the following text shall be added at the end of the point.

The following table illustrates the correspondence between the elements of the bullet point listed in 5.1.3 and the names provided in the ERA Assessment Scheme.

NOTE 1: The name provided in this document to those boards, groups of persons or persons can be different in each CAB, nevertheless the competence shall remain the same.

Table 6 : Correspondence table between items listed in 5.1.3, identified person or group of person and competence description.

Point in 5.1.3	*Board, group of persons or persons identified in this document*
f) evaluation	technical lead evaluator, (lead) inspector, (lead) auditor as applicable
g) review	technical reviewer
h) decisions on certification	decision maker

NOTE 2: All the boards, persons or groups of persons as described in point 5.1.3 of EN ISO/IEC 17065 shall be identified for the purposes of assessment; however only the boards, persons or groups of persons as described in Table 6 (i.e. decision maker, technical reviewer, technical lead evaluator, (lead) inspector and (lead) auditor) have been detailed for the specific purpose and scope of this document.

One person can be appointed to more than one of the roles described in Annex C:

- within the CAB, e.g. role of decision-maker in one project and role of technical reviewer in another project;
- within one project.

In both cases the following conditions shall be met:

- the required roles for the individual project are formally appointed;
- the relevant requirements defined in EN ISO/IEC 17065 and the ERA Assessment Scheme for the required roles are respected (cf. section 7.5.1 for the technical reviewer and section 7.6.2 for the decision maker);
- the competences for the roles concerned are met by this person.

Provided the conditions above are met, the following roles may be accomplished by the same person in each individual project:

- decision maker + technical reviewer;
- technical lead evaluator + (lead) inspector + (lead) auditor;
- technical lead evaluator + (lead) inspector;
- technical lead evaluator + (lead) auditor;
- (lead) inspector + (lead) auditor.

5.2. Mechanism for safeguarding impartiality

Point 5.2.1: the following text shall be added at the end of the bullet points indicated.

b) including those that may be caused by:

- sharing resources with any of the entities listed in section 4.2.3 of the ERA Assessment Scheme;
- other activities of shared resources of the CAB.

c) including employing other resources under the CAB's direct control (hired-in personnel, experts carrying out conformity assessment activities).

Point 5.2.2: the following text shall be added at the end of the point.

c) regular meetings, at least once per year, are held and documented.

Point 5.2.3: the following text shall be added at the end of the point.

ERA shall be included in the list of bodies to which the mechanism to safeguard impartially shall address communication of independent actions undertaken.

6. Resource requirements

6.1. Certification body personnel

Point 6.1.1.1: the following text shall be added at the end of the point.

The evaluation of the sufficient number of personnel shall be produced in writing.

The CAB shall keep a record of its internal resources and of "other resources under its direct control" (e.g. hired-in personnel, experts carrying out conformity assessment activities).

At all times and for each conformity assessment procedure and each kind or category of product in relation to which it has been notified, a CAB shall have at its disposal the necessary personnel with

technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks (cf. Article 30 (3) of IOD).

While a CAB may have recourse to subsidiaries and other resources under its direct control, it shall not rely for all project's evaluations on subsidiaries and other resources under its direct control.

Point 6.1.1.2: the following text shall be added at the end of the point.

The board, group of persons or person identified in *Table 6* of section 5.1.3 shall fulfil the competence profiles described in this document.

Per each scope of assessment, at least one of the above boards, groups of persons or person identified in section 5.1.3, bullet points f), g) and h) shall be able to participate and contribute actively to coordination group of notified CAB referred to in Article 30 (6) of Regulation (EU) 2016/796 meetings held in English (e.g. NB-Rail).

The competence of the board, group of persons or person identified in section 5.1.3 bullet points f), g) and h) is described as:

Table 7 : Competence composition description

Item	*Sub-item*	*Notes*
Description		*Activity to perform*
Training and Experience	› General › Specific in addition to general	*Achieved academic grade and recorded professional experience*
Knowledge	› Legal framework › Technical topics › Non-technical skills	*Details on needed theoretical knowledge related to the job assigned*

The assessment of the competence shall be performed by the assessment team of the notifying authority or of the NAB (Article 27(1) and Article 27(3) of IOD 2016) by means of interviews and review of evidences. The notifying authority may delegate this assessment to another body (Article 27(4) of IOD 2016).

Annex C provides the detailed competence description on the above-mentioned board, group of persons or person identified in *Table 6* of section 5.1.3 bullet points f), g) and h).

Point 6.1.2.1: the following text shall be added at the end of the point.

The procedure for management of competencies of the personnel shall ensure the continuity of the necessary competence.

NOTE 1: The competence management should also include the following elements: initial competency assessment, ongoing training, competency re-assessment and monitoring.

NOTE 2: A person can be appointed to different roles for different projects, e.g. a person assigned as a technical reviewer in one project can be appointed as inspector/auditor in another project (on the condition that the person fulfils all the required competences). Independency and impartiality as defined in EN ISO 17065 for all these roles shall be respected per project.

NOTE 3: The appointment of more than one role to the same person of the same body and for the same project can be done, on the condition that:

a) the person fulfils all the required competences;
b) all requirements related to independence and impartiality for the respective roles are fulfilled on project level (e.g. EN ISO/IEC 17065 section 7.5.1 for the technical reviewer and section 7.6.2 for the decision maker).

Point 6.1.2.1: the following text shall be added at the end of the bullet point a).

The criteria for the competence of the board, group of persons or person identified in *Table 6* of section 5.1.3 bullet points f), g) and h) are provided in this document in Annex C.

Point 6.1.2.1: the following text shall be added at the end of the bullet point e).

For the surveillance of the personnel involved in evaluation activities and for monitoring of competences, the following requirements shall apply:

- for staff performing testing: points 6.2.3 and 6.2.5 of EN ISO/IEC 17025
- for inspectors: points 6.1.8 and 6.1.9 of ISO/IEC 17020, and
- for QMS Assessors: points from 7.2.9 to 7.2.11 of EN ISO/IEC 17021-1.

Point 6.1.2.2: the following text shall be added at the end of the point.

Modifications to the records do not trigger an additional assessment by the notifying authority.

Point 6.1.3: the following text shall be added in bullet point b), following sub-bullet point 3) (copied here just for better understanding).

3) an operator or developer of processes, or

4) an entity engaged in activities for the authorisation of (railway) products certified by a CAB

6.2. Resources for evaluation

Point 6.2: the following text shall be added as an introduction of point 6.2 immediately before 6.2.1.

Depending on the scope of the evaluation activities there may be inspection, audit and testing within a project.

The test reports shall document the test results. These test reports shall be an input to the inspection activities.

If a project includes inspection and audit activities, a technical lead evaluator, lead inspector and a lead auditor shall be appointed.

If a project includes only inspection a lead inspector shall be appointed.

If a project includes only auditing, a lead auditor shall be appointed.

Point 6.2.1: the following text shall be added at the end of the point.

NOTE 1: For internal resources and other resources under the CAB's direct control (see 6.1.1.1 of EN ISO/IEC 17065) only impartiality requirements of the referenced standards apply. The independence requirements that apply to internal resources of a CAB are defined in section 4.2.6 of the ERA Assessment Scheme.

NOTE 2: Hired-in personnel are considered as resources for evaluation working under the direct control and quality management system of the CAB.

Point 6.2.2.1: the following text shall be added at the end of the point.

The CAB shall keep records to demonstrate that the outsourced bodies fulfil the requirements as described in point 7.4 of Part 2 of this document for respectively testing, inspection and QMS audit.

In case the CAB outsources inspection activities and QMS approval under its responsibility as NoBo, according to the module or modules chosen by the client, the outsourced bodies shall be accredited according to:

- EN ISO/IEC 17020 type A as described in section A.1 of Annex A, if providing inspections,
- EN ISO/IEC 17021-1 if providing QMS approval.

The CAB may also outsource evaluation activities to a CAB notified under the IOD 2016 having the same notification scope.

NOTE 1: The CAB shall itself normally perform the inspections that it contracts to undertake (see 6.3.1 of EN ISO/IEC 17020). Reasons to subcontract can include the following (see NOTE 1 to point 6.3.1 of the EN ISO/IEC 17020):

- *An unforeseen or abnormal overload;*
- *Key inspection staff members being incapacitated;*
- *Key facilities or items of equipment being temporarily unfit for use;*
- *Part of the contract from the client involving inspection not covered by the CAB's scope or being beyond the capability or resource of the CAB.*

NOTE 2: Use of external personnel under contract is not outsourcing (see NOTE 2 to point 6.2.2.1 of EN ISO/IEC 17065). Such hired personnel shall carry out its activities under the responsibility and quality system of the CAB. Hiring a body or bodies is outsourcing.

NOTE 3: The concerned activities (i.e. inspection and QMS approval) are the ones under the responsibility of the CAB as part of its evaluation activities, and those ones only. The activities described in this point do not include the testing and inspection activities that are under the responsibility of the client of the CAB as part of the client evidence production activities. Some flexibility is allowed as regards to testing activities, as described in point 6.2.2.2.

NOTE 4: The limits of responsibilities between the client and the NoBo depend on the modules that have been chosen by the client in line with the prescription of the chapter 6 of the relevant TSI(s). These limits are defined by the respective modules and chapter 6 of the relevant TSI(s).

NOTE 5: The categorization as Types A, B and C is applicable to inspection bodies only.

Without prejudice to the NoBo conformity assessment, where the applicant contracts an AsBo for the specific conformity assessment described in point 7.4.3, the requirements in this clause of the EN ISO/IEC 17065 standard shall not apply to the AsBo, as there is no legally binding contract between the NoBo and the AsBo.

Point 6.2.2.2: the following text shall be added at the end of the point.

The CAB can outsource to non-independent bodies only specific testing tasks of the evaluation activities, in line with the provisions in Article 34 of IOD 2016, chapter 6 of the relevant TSI(s) and within the limits of responsibilities defined in the chosen module(s).

Conditions for confidence are described in Annex F of this document.

NOTE 1: Different conditions apply for accredited tests and non-accredited tests.

Without prejudice to the NoBo conformity assessment, where the applicant contracts an AsBo for the specific conformity assessment described in point 7.4.3, the requirements in this clause of the EN ISO/IEC 17065 standard shall not apply to the AsBo, as there is no legally binding contract between the NoBo and the AsBo.

7. Process requirements

7.1. General

Point 7.1.2: the following text shall be added at the end of the point.

Requirements are defined by (not exhaustive):

- essential requirements as defined in the IOD 2016;
- requirements included in the Decision 2010/713/EU on railway modules;
- basic parameters included in the TSIs;
- standards quoted in the TSIs;

NOTE 2: Those standards are usually called mandatory standards.

- Harmonised European Standards applied in full or in part, as defined by the applicant in order to meet the essential requirements as defined in the TSIs;

NOTE 3: Those standards are usually called industrial standards.

- alternative solutions to Harmonised European Standards, such as other public standards, documentation and company standards applied in full or in part, as defined by the applicant in relation to meet the essential requirements as defined in the TSIs;

NOTE 4: Those standards are usually called industrial standards.

- ERA technical opinions;
- ERA technical documents;
- acceptable means of compliance.

NOTE 5: The ERA Assessment Scheme includes implicitly an "evidence phase" which is not defined in the EN ISO/IEC 17065, because it is not performed by the CAB seeking notification.

The "evidence phase" includes products, installations and associated documentation; it produces fundamental inputs for the evaluation, review and certification decision performed by the CAB seeking notification.

Figure 1 in Annex E provides a graphical representation:

- *Evidence phase (not included in the EN ISO/IEC 17065), performed by other organisations than the CAB seeking notification;*
- *Evaluation (included in the EN ISO/IEC 17065 - see point 7.4), performed by the CAB seeking notification;*
- *Review (included in the EN ISO/IEC 17065 – see point 7.5), performed by the CAB seeking notification;*
- *Certification decision (included in the EN ISO/IEC 17065 – see point 7.6), performed by the CAB seeking notification.*

NOTE 6: The client of the CAB may have produced the evidences by any organisation the client deems appropriate (in-house bodies, testing laboratories, in-house inspection bodies, outsourcing to external bodies, where according to applicable TSIs, and to point 2.1 in Annex IV to IOD 2016, the applicant designates an AsBo for specific assessment, etc.). Restrictions may apply on conditions for producing evidences (e.g. possible needs for accredited lab).

7.2. Application

The following text shall be added at the end of the section.

The certification body shall have a written procedure to manage applications.

The necessary information to be contained within the application shall include at least the following:

a) name and address of the applicant and, if the application is lodged by the authorised representative, the name and address of the authorised representative;
b) contact details (e.g. office phone, mobile phone, e-mail, etc.) of the physical person acting as contact point for the applicant or for the authorised representative;
c) all relevant information for the product including type (i.e. product ID, product definition), and product (i.e. configuration, version, interfaces);
d) all the applicable TSIs, including any available or expected derogations;
e) the choice of the module or modules for assessment;
f) the scope of ISV (if the application refers to an ISV);
g) where the applicant designates an AsBo for the cases described in point 7.4.3, the applicant's Declaration, as per Article 16 of Regulation on CSM-RA, and the AsBo safety assessment report;

   NOTE 4: The client of the CAB has to describe the organisation in place (e.g. Project Plan) for the management of the product under assessment, and the sharing of conformity assessment activities between the relevant bodies, i.e. NoBo(s), DeBo(s), AsBo(s) – if applicable, any applicant's in-house assessment , etc.).

h) declaration in writing containing the statement "that the same Application has not been lodged with any other notified body";
i) any relevant EC Certificate, technical file, technical documentation;
j) in case of use of ISV(s), also ISV Certificate(s), ISV Technical File(s), ISV Declaration(s) of any preceding modules and ISV(s). If these are not available at time of application, the intended ISV scope and interfaces shall be precisely defined.

7.3. Application review

Text in EN ISO/IEC 17065 applies.

7.4. Evaluation

Point 7.4.1: The following text shall be added at the end of the point.

The plan for evaluation shall be documented and it shall be the first document of the evaluation phase. The plan shall be updated if and as required during the project progress.

Point 7.4.2: The following text shall be added at the end of the point.

The assignment of the personnel to perform each evaluation task shall be in writing.

Point 7.4.3: The following text shall be added at the end of the point.

7.4.3.1 Evaluation tasks performed by the NoBo

Depending on the appropriate module or modules chosen, the evaluation tasks shall contain at least one of the following conformity assessment activities:

- Testing fulfilling the requirements in Annex F
- Inspection fulfilling the requirements in Annex G, and
- Quality Management System Approval fulfilling the requirements in Annex H.

The evaluation task shall follow the document flow as described in Figure 1 in Annex E.

With reference to the section 7.4.3.2 below, where a TSI, or another applicable legal act of the Union, requires a risk assessment to be carried out according to Annex I of the Regulation on CSM-RA, for the independent assessment of that, the applicant is allowed to designate the NoBo selected for the conformity assessment of the relevant structural sub-system if the following conditions are met:

- the NoBo shall also be accredited, or recognised, as specified in Article 7 of the Regulation on CSM-RA;
- the NoBo shall deliver a safety assessment report compliant with the requirements of the Regulation on CSM-RA.

NOTE 1: This option is possible in Regulation (EU) No 1302/2014 [26] (TSI Locomotives and passenger rolling stock), Regulation (EU) No 1303/2014 [29] (TSI Safety in railway tunnels), or new cases covered by NOTE 2 in section 7.4.3.2.

7.4.3.2 Evaluation tasks performed by the AsBo

By virtue of point 2.1 in Annex IV to the IOD 2016, the 'EC' verification procedure, whereby a NoBo checks and certifies that a subsystem complies with the relevant TSI(s), shall not prejudice to the obligations of the applicant to comply with:

- the other applicable legal acts of the Union, and with;
- any verifications by the assessment bodies required by the rules defined in those other legal acts.

NOTE 1: Some TSIs (TSI Locomotives and passenger rolling stock, TSI Control-command and signalling, TSI Freight wagons and TSI Safety in railway tunnels for items related to rolling stock), the CSM-RA and the PA VA are examples of other applicable legal acts of the Union that require a risk assessment according to Annex I of the CSM-RA and verifications by other assessment bodies (in practice by an AsBo).

The compliance with the EN ISO/IEC 17065 standard and the other requirements of this ERA Assessment Scheme shall not conflict with the requirements and obligations concerning the specific scopes for the conformity assessment of the safety requirements defined in:

- Clause 6.2.3.5 (itself referring to clauses in 4.2. e.g. 4.2.3.4.2, 4.2.4.2.2, 4.2.5.3.5, 4.2.5.5.8 and 4.2.5.5.9) of the Regulation (EU) No 1302/2014 [26] (TSI Locomotives and passenger rolling stock), which requires the applicant to designate for that assessment either the NoBo selected for the rolling stock subsystem or an AsBo as defined in the Regulation on CSM-RA.
- Clause 3.2.1 of the Regulation (EU) 2016/919 [28] (TSI Control-command and signalling), which requires the assessment of compliance with those safety requirements of the TSI Control-command and signalling to be performed by an AsBo.
- Clause 7.2.2.4 of the Regulation (EU) No 321/2013 [27] (TSI Freight wagons), which requires the applicant to provide a positive assessment by an AsBo.
- Clause 6.2.6(c) of the Regulation (EU) No 1303/2014 [29] (TSI Safety in railway tunnels), when applied, requires a safety assessment report in compliance with the Regulation on CSM-RA.
- Article 13(3) and point 18.1 in Annex I of the Implementing Regulation (EU) 2018/545 [21] on practical arrangements for vehicle authorisations (PA VA) which require a safety assessment report referred to in Article 15 of the Regulation on CSM-RA.

NOTE 2: The references above are to be updated with relevant future TSI amendments and versions and with other future applicable legal acts of the Union which could require a risk assessment according to Annex I of the Regulation on CSM-RA and an independent assessment by an AsBo.

Those clauses require the application of the risk management process in Annex I of the Regulation on CSM-RA, and an independent assessment of the demonstration of compliance with that process. When the independent assessment for those specific scopes is carried out by an AsBo, this shall be without restrictions with respect to the type A, B or C of independence of the AsBo, all permitted by the Regulation on CSM-RA.

In accordance with the principles stated in Article 6(3) and Article 15(4) of the Regulation on CSM-RA, and where relevant for the evaluation activities, the NoBo shall accept the applicant's declaration and the results from the AsBo independent assessment. The results for those specific scopes shall be completed by the AsBo prior to the NoBo evaluation activities.

Point 7.4.4: The following text shall be added at the end of the point for complementing the last sentence.

Without prejudice to the NoBo conformity assessment, where the applicant contracts an AsBo for the specific conformity assessment described in point 7.4.3, the requirements in this clause of the EN ISO/IEC 17065 shall not apply to the AsBo, as there is no legally binding contract between the NoBo and the AsBo.

Where the evidence of independent assessment of the specific safety requirements listed in point 7.4.3 is produced by an AsBo, according to the Regulation on CSM-RA, the NoBo shall:

a) obtain beforehand from the applicant a documented description of the specific scope of the conformity assessments for which the applicant contracted an AsBo;
b) verify whether the applicant provides, as documented evidence, a safety assessment report from the AsBo, that covers the complete scope of the conformity assessment in bullet a) above;

c) verify the following information concerning the AsBo which performs the conformity assessment in bullet a):
   1) the AsBo is accredited, or recognised, for at least the relevant scope in compliance with the requirements and criteria defined in Annex II of the Regulation on CSM-RA, including the EN ISO/IEC 17020:2012 standard referenced therein;
   2) the AsBo accreditation/recognition is still valid;
   3) the AsBo is registered in the ERADIS database, or if not yet registered there, published on the website of the associated national accreditation or recognition body;
   4) the scope of the AsBo safety assessment report covers the same object of assessment as the one in the scope of the NoBo assessment;
   5) the AsBo safety assessment report clearly makes reference to the safety related application conditions (SRACs) the applicant exports with respect to specific safety requirements within the scope of point 7.4.3.2;

d) verify, in compliance with Article 16 of Regulation on CSM-RA, whether the applicant provides a declaration that covers fully the conformity assessment within the scope of point 7.4.3;
e) verify whether the applicant's declaration covers the same object of assessment as the one in the scope of the NoBo assessment;
f) derive from the AsBo safety assessment report, and the applicant's declaration, all conditions and limits of use relevant for the object of assessment. The NoBo shall:
   1) take them into account during the evaluation activities, and
   2) report them in the NoBo certification level documents, the accompanying conformity assessment reports and NoBo file.

   These conditions and limits of use include, but not limited to, the safety related application conditions (SRACs).

g) verify whether the applicant's declaration explicitly states that, according to Article 16 of Regulation on CSM-RA, "*all identified hazards and associated risks are controlled to an acceptable level*";
h) evaluate the absence of justified doubts concerning the assumptions made or the appropriateness of the results contained in the applicant's declaration.

Point 7.4.5: The following text shall be added at the end of the point.

Without prejudice to the NoBo conformity assessment, where the applicant contracts an AsBo for the specific conformity assessment described in point 7.4.3, the requirements in this clause of the EN ISO/IEC 17065 shall not apply to the AsBo, as there is no legally binding contract between the NoBo and the AsBo.

Point 7.4.6: The following text shall be added at the end of the point.

NOTE: Where the NoBo is not provided with the information and the results concerning the independent assessment of the specific safety requirements listed in Point 7.4.4, or the NoBo has justified and documented doubts concerning the assumptions made or the appropriateness of the results, the NoBo shall inform the applicant about it.

Point 7.4.9: The following text shall be added at the end of the point.

Per each product under evaluation, the results of the evaluation phase shall be recorded by an inspection report and/or a QMS audit report depending on the module chosen by the client of the CAB.

7.5. Review

Point 7.5.1: The following text shall be added at the end of the point.

The assignment of the personnel to perform revision task shall be in writing.

The board, group of persons or person assigned to have the overall authority and responsibility of reviewing as point 5.1.3 bullet point g) is called “technical reviewer”.

The technical reviewer shall have the competence as described in section C.2 of Annex C.

7.6. Certification decision

Point 7.6.2 The following text shall be added at the end of the point.

The assignment of the personnel to perform certification decision tasks shall be in writing.

The board, group of persons or person assigned to make decisions on certification as point 5.1.3 bullet point h) decision is called “decision maker”.

The decision maker shall have the competence as described in section C.1 of Annex C.

NOTE 1: It is a good practice to have in a single document the matrix of assignments for evaluation, revision and certification decision tasks. This document may have several names in the CAB (e.g. project plan, project quality plan, project assignments, etc.)

*NOTE 2: As provided by point 7.6.2, the decision maker **shall never be involved in any phase of the evaluation** of the product under certification. This implies that the decision maker, if having the adequate competence, can act also as technical reviewer.*

7.7. Certification documentation

Text in EN ISO/IEC 17065 applies.

Point 7.7.1 The following text shall be added as a new bullet point (g) after bullet point (f):

g) where relevant, the results taken into account from the conformity assessment activities described in point 7.4.3 and Point 7.4.4 that the applicant contracted to an AsBo.

NOTE 2: The information in bullet point g) is necessary for transparency reasons with respect to stakeholders other than the applicant.

7.8. Directory of certified products

Text in EN ISO/IEC 17065 applies.

7.9. Surveillance

Text in EN ISO/IEC 17065 applies.

7.10. Changes affecting certification

Text in EN ISO/IEC 17065 applies.

7.11. Termination, reduction, suspension or withdrawal of certification

Text in EN ISO/IEC 17065 applies.

7.12. Records

Text in EN ISO/IEC 17065 applies.

7.13. Complaints and appeals

Text in EN ISO/IEC 17065 applies.

8. Management system requirements

8.1. Options

Text in EN ISO/IEC 17065 applies.

8.2. General management system documentation (Option A)

Text in EN ISO/IEC 17065 applies.

8.3. Control of documents (Option A)

Text in EN ISO/IEC 17065 applies.

8.4. Control of records (Option A)

Text in EN ISO/IEC 17065 applies.

8.5. Management review (Option A)

Text in EN ISO/IEC 17065 applies.

8.6. Internal audits (Option A)

Text in EN ISO/IEC 17065 applies.

8.7. Corrective actions (Option A)

Text in EN ISO/IEC 17065 applies.

8.8. Preventive actions (Option A)

Text in EN ISO/IEC 17065 applies.

Annex A. (informative) Principles for product certification bodies and their certification activities

Text in EN ISO/IEC 17065 applies.

Annex B. (Informative) Application of this international standard for processes and services

Text in EN ISO/IEC 17065 applies.

Annex C. (Normative) Competence descriptions

C.0. General

This Annex does not exist in the EN ISO/IEC 17065.

This normative annex describes the competence of the boards, groups of persons or persons as identified in point 5.1.3:

- decision maker;
- technical reviewer;

The titles provided to these boards, groups of persons or persons can be different in each organisation, nevertheless the competence shall remain the same.

For the purpose of the evaluation activities, this normative annex also describes the competence of the following roles:

- technical lead evaluator;
- lead inspector;
- inspector;
- QMS lead auditor;
- QMS auditor.

To facilitate users of this scheme, a comparative table of the competences required for the different roles described in sections C.1 to C.7, is provided in Appendix A to this scheme. Appendix A is published as a separate document on the Agency's website.

C.1. Decision maker

C.1.1. Description

The person(s) assigned to make certification decision as described in 7.6.2.

C.1.2. Training and experience

C.1.2.1 General

One or more of the following possibilities shall apply:

- MASTER university degree (or equivalent) in a relevant subject + 6 years of proven professional experience preferably relevant for the railways;
- BACHELOR university degree (or equivalent) + 8 years of proven professional experience preferably relevant for the railways;
- Relevant technical vocational trainings in the field of the scope of the assessment of at least 2 years + 11 years of proven professional experience preferably relevant for the railways.

C.1.2.2 Specific in addition to General

Sound knowledge and understanding of the relevant requirements for the CAB certification processes based on EN ISO/IEC 17065 and the testing, inspection and auditing processes based respectively on EN ISO/IEC 17025, EN ISO/IEC 17020 and EN ISO/IEC 17021-1.

C.1.3. Knowledge

C.1.3.1 Legal framework

Sound knowledge and understanding on the following topics:

- **IOD 2016**: EC conformity assessment, EC suitability of use, EC verification, Article 15 and Annex IV on the role of NoBo in the process of verification; authorisation for the placing in service of fixed installations; vehicle authorisation for placing on the market; role of applicant, NoBo, DeBo, Assessment bodies under the CSM-RA, and where relevant, under PA VA; upgrade/renewal of an existing subsystem; European legal framework and National legal framework.
- **Railway modules**: Decision 2010/713/EU on railway modules, difference between module with QMS and without QMS, applicable modules according to TSIs.
- **RSD 2016:** Regulation on CSM-RA, legal text and Annex I.
- **TSIs:** Text structure, affected subsystem per TSI, concepts of mandatory standards, harmonised standards, industrial standards, acceptable means of compliance, alternative solutions.
- **Only for mobile subsystems (rolling stock and on-board control-command and signalling subsystems):** PA VA.
- **Regulation 2019/250**: the templates for 'EC' declarations and certificates for railway interoperability constituents and subsystems, the declaration of conformity to an authorised railway vehicle type and on the 'EC' verification procedures for subsystems.

C.1.3.2 Technical topics

- General knowledge and understanding of all the areas from Annex D. (Normative) List of technical topics per scope of assessment.

C.1.3.3 Non-technical skills

- Ability to understand and evaluate technical documents that are part of the Evaluation file to allow him/her to make a justified certification decision;
- Proven ability to apply sound professional judgement;
- Ability and authority to provide or not provide the certification if the product evaluation project does or does not fulfil the quality requirements.

C.2. Technical reviewer

C.2.1. Description

The person assigned for reviewing all the information and results related to the evaluation as described in point 7.5.1 of EN ISO/IEC 17065.

C.2.2. Training and experience

C.2.2.1 General

One or more of the following possibilities shall apply:

- MASTER university degree (or equivalent) in a relevant subject + 3 years of proven professional experience preferably relevant for the railways;
- BACHELOR university degree (or equivalent) + 5 years of proven professional experience preferably relevant for the railways;
- Relevant technical vocational trainings in the field of the scope of the assessment of at least 2 years + 8 years of proven professional experience preferably relevant for the railways.

C.2.2.2 Specific in addition to General

- Training (internal or external) on the relevant requirements for the CAB inspection processes based on EN ISO/IEC 17020, EN ISO/IEC 17021-1 and EN ISO/IEC 17065;
- Proven experience (e.g. 5 completed projects) in any scope of assessment (cf. Annex D), with at least one in the following roles: lead inspector or QMS lead auditor.

C.2.3. Knowledge

C.2.3.1 Legal framework

Sound knowledge and understanding of the following topics:

- **IOD 2016**: EC conformity assessment, EC suitability of use, EC verification, Article 15 and Annex IV on the role of NoBo in the process of verification; authorisation for the placing in service of fixed installations; vehicle authorisation for placing on the market; role of applicant, NoBo, DeBo, Assessment bodies under the CSM-RA, and where relevant, under PA VA; upgrade/renewal of an existing subsystem; European legal framework and National legal framework.
- **Railway modules**: Decision 2010/713/EU on railway modules, difference between module with QMS and without QMS, Applicable modules according to TSIs.
- **RSD 2016:** CSM-RA, legal text and Annex I.
- Interrelations to the **RSD 2016** and to the **Regulation on CSM-RA:** allocation of roles and responsibilities and risk and safety management.
- **EN ISO/IEC 17065** and the relevant requirements for the CAB evaluation processes based on **EN ISO/IEC 17020, EN ISO/IEC 17021-1** and **EN ISO/IEC 17025** in combination with the **ERA Assessment Scheme**.
- **TSIs:** Text structure, affected subsystem per TSI, concepts of mandatory standards, harmonised standards, industrial standards, mandatory and informative ERTMS specifications, acceptable means of compliance, alternative solutions.
- **ERA documents**: technical opinions, technical advices, technical documents, ERA guidance, lines to take, etc.
- **Only for mobile subsystems (rolling stock and on-board control-command and signalling subsystems):** PA VA.
- **Documents of the Coordination group of the notified bodies** (Article 44 of IOD 2016): RfU and Q/C.

General knowledge and understanding of the following topics:

- **Modules based on quality assurance:** general knowledge and understanding of auditing procedures.
- **Technical standards:** depending on the scope of the assessment:
  - of the content of the standards quoted in the applicable TSIs, and
  - ability to understand and evaluate the content of the industrial standards which can be used at designing or manufacturing phases.

C.2.3.2 Technical topics

- General knowledge and understanding of all the areas from Annex D.

C.2.3.3 Non-technical skills

- Proven ability to apply sound professional judgement;
- Knowledge and understanding of the interfaces with other technical scope related to interoperability and safe integration;

- Ability to analyse and verify that the technical documents that are part of the Evaluation file cover all relevant requirements;
- Ability to recommend or not recommend the certification if the product evaluation project does or does not fulfil the quality requirements;
- Good quality of work;
- Impartial and non-discriminatory behaviour.

C.3. Technical lead evaluator

C.3.1. Description

For each individual project, where inspection and auditing activities are required, a technical lead evaluator shall be appointed. This technical lead evaluator has the overall authority and responsibility to ensure that all project activities of the evaluation phase are correctly prepared, executed and documented in reports and other records as described in point 7.4 of the EN ISO/IEC 17065. Therefore, the technical lead evaluator shall set up a project team according to the requirements of the ERA Assessment Scheme to cover all the evaluation activities.

C.3.2. Training and experience

C.3.2.1 General

One or more of the following possibilities shall apply:

- MASTER university degree (or equivalent) in a relevant subject + 3 years of proven professional experience relevant for the technical scope in which the person is intended to work;
- BACHELOR university degree (or equivalent) + 5 years of proven professional experience relevant for the technical scope in which the person is intended to work;
- Relevant technical vocational trainings in the field of the scope of the assessment of at least 2 years + 8 years of proven professional experience relevant for the technical scope in which the person is intended to work.

C.3.2.2 Specific in addition to General

- Training (internal or external) on the relevant requirements for the CAB evaluation processes based on EN ISO/IEC 17020, EN ISO/IEC 17021-1 and EN ISO/IEC 17065;
- Proven experience (e.g. more than one completed evaluation project) in any scope of assessment (cf. Annex D) as at least one of the following: lead inspector and/or QMS lead auditor.

C.3.3. Knowledge

C.3.3.1 Legal framework

Sound knowledge and understanding of the following topics:

- **IOD 2016**: EC conformity assessment, EC suitability of use, EC verification, Article 15 and Annex IV on the role of NoBo in the process of verification; authorisation for the placing in service of fixed installations; vehicle authorisation for placing on the market; role of applicant, NoBo, DeBo, Assessment bodies under the CSM-RA, and where relevant, under PA VA; upgrade/renewal of an existing subsystem; European legal framework and National legal framework.
- **Railway modules**: Decision 2010/713/EU on railway modules, difference between module with QMS and without QMS, Applicable modules according to TSIs.
- Interrelations to the **RSD 2016** and to the **Regulation on CSM-RA:** allocation of roles and responsibilities and risk and safety management.
- **EN ISO/IEC 17065** and the relevant requirements for the CAB evaluation processes based on **EN ISO/IEC 17020, EN ISO/IEC 17021-1** and **EN ISO/IEC 17025** in combination with the **ERA Assessment Scheme**.
- **TSIs:** Text structure, affected subsystem per TSI, concepts of mandatory standards, harmonised standards, industrial standards, mandatory and informative ERTMS specifications, acceptable means of compliance, alternative solutions.
- **ERA documents**: technical opinions, technical advices, technical documents, ERA guidance, lines to take, etc.
- **Only for mobile subsystems (rolling stock and on-board control-command and signalling subsystems):** PA VA.
- **Documents of the Coordination group of the notified bodies** (Article 44 of IOD 2016): RfU and Q/C.
- **Health and safety requirements**: competence of general procedures to manage staff safety for performing on site activities (e.g. tests under energised equipment, with rolling stock in motion, in factories, etc.).

C.3.3.2 Technical topics

- General knowledge and understanding as applicable from Annex D. (Normative) List of technical topics per scope of assessment.

C.3.3.3 Non-technical skills

- Ability to manage on on-going basis the project activities for evaluation;
- Ability to form and coordinate a project evaluation team;
- Ability to manage subcontracted project evaluation activities;
- General knowledge of manufacturer's quality management system methodology i.e. ISO 9001.

The technical lead evaluator may be supported by:

- (lead) inspectors for inspection activities (ref. Annex G of this document), and;
- (lead) auditors for the quality management system approval (ref. Annex H of this document).

C.4. Inspector (per scope of assessment)

C.4.1. Description

The inspector supports the technical lead evaluator in performing the activities related to inspections within the scope of assessment. Where appropriate, the inspector may support the auditor or the lead auditor acting as technical expert. The inspector may also act as mentor to other inspectors.

C.4.2. Training and Experience

C.4.2.1 General

One or more of the following possibilities shall apply:

- MASTER university degree (or equivalent) in a relevant subject + 3 years of proven professional experience relevant for the technical scope in which the person is intended to work;
- BACHELOR university degree (or equivalent) + 5 years of proven professional experience relevant for the technical scope in which the person is intended to work;
- Relevant technical vocational trainings in the field of the scope of the assessment of at least 2 years + 8 years of proven professional experience relevant for the technical scope in which the person is intended to work.

C.4.2.2 Specific in addition to General

- Training (internal or external) on the relevant requirements for the CAB inspection processes based on EN ISO/IEC 17020 and EN ISO/IEC 17065;
- Proven experience of at least 1 year as mentoring period according to EN ISO/IEC 17020 point 6.1.6 including minimum participation in more than one project and documented final positive assessment of the competences in the relevant technical scope in which the person is intended to work as inspector.

C.4.3. Knowledge

C.4.3.1 Legal framework

- General knowledge and understanding of railway related European legal framework, including vocabulary (e.g. IOD 2016, TSIs and modules).
- **ERA documents**: technical opinions, technical advices, technical documents, ERA guidance, lines to take, etc.
- **Documents of the Coordination group of the notified bodies** (Article 44 of IOD 2016): RfU and Q/C.

C.4.3.2 Technical topics

- Sound knowledge and understanding of relevant parts of Annex D. (Normative) List of technical topics per scope of assessment.
- Sound knowledge and understanding of the interfaces with other technical scope related to interoperability and safe integration;
- **Technical standards:** depending on the relevant parts of Annex D:
  - General broad overview of the content of the standards quoted in the applicable TSIs, and
  - Ability to understand and evaluate the content of the industrial standards which can be used in the designing or manufacturing phases.

C.4.3.3 Non-technical skills

- Ability to prepare and update assessment plans for the projects, including the assessment requirements;
- Ability to supervise inspectors under supervision works;
- Ability to analyse, judge and make decisions;
- Ability for appropriate project and self-organisation;
- Effective communication skills;
- Writing and editing skills for preparing technical reports;
- Good quality of work;
- Impartial and non-discriminatory behaviour.

C.5. Lead inspector

The lead inspector has the overall authority and responsibility to ensure that all project inspection activities of the evaluation phase are correctly prepared, executed and documented in reports and other records as described in point 7.4 of the EN ISO/IEC 17065.

If a project involves several inspectors or subcontracted activities, one inspector shall be nominated as “lead inspector” with the following additional non-technical skills:

- proven competence in project management and in the most spread project management IT tools;
- ability to prepare assessment plan, including assessment requirements;
- ability to form and direct project teams;
- ability to coordinate inspectors’ works;
- ability to supervise subcontracted activities.

C.6. QMS lead auditor

C.6.1. Description

The QMS lead auditor has the overall authority and responsibility to ensure that all project auditing activities of the evaluation phase are correctly prepared, executed and documented in reports and other records as described in point 7.4 of the EN ISO/IEC 17065.

QMS lead auditor supports the technical lead evaluator in the QMS audit activities.

C.6.2. Training and experience

C.6.2.1 General

One or more of the following possibilities shall apply:

- MASTER university degree (or equivalent) in a relevant subject + 3 years of proven professional experience relevant to quality management systems relating to a technical area, preferably in railways;
- BACHELOR university degree (or equivalent) + 5 years of proven professional experience relevant to quality management systems relating to a technical area, preferably in railways;
- Relevant technical vocational trainings in technical area, preferably in railways of at least 2 years + 8 years of proven professional experience relevant to quality management systems relating to a technical area, preferably in railways.

C.6.2.2 Specific in addition to General

- Specific training as auditor (internal or external) based on the EN ISO/IEC 17021-1 lasting at least 5 working days or 40 hours of classroom style training for lead auditing;
- Training (internal or external) on the relevant requirements for the CAB inspection processes based on EN ISO/IEC 17020 and EN ISO/IEC 17065;
- Participation in QMS audits in the railway domain as follows:
  a) For initial nomination as Lead Auditor
  Participation in at least 3 QMS audits:
  - with one of them related to the IOD;
  - in a team of at least 2 persons;
  - with a duration of at least one day;
  - at least at the level of "auditor in training" (reference to 9.2.2.1.4 of EN ISO/IEC 17021-1)
  - during the last 24 months before nomination as QMS lead auditor.

  b) For maintaining the status as Lead Auditor
  Participation in at least 1 QMS audit:
  - related to the IOD;
  - in a team of at least 1 person;
  - with a duration of at least one day;
  - at the level of "lead auditor";
  - during the last 36 months.

  c) For re-nomination as Lead Auditor (where requirement b) has not been met)
  Participation in at least 1 QMS audit:
  - related to the IOD;
  - in a team of at least 2 persons;
  - with a duration of at least one day;
  - at least at the level of "auditor in training" (reference to 9.2.2.1.4 of EN ISO/IEC 17021-1) during the last 6 months.

C.6.3. Knowledge

C.6.3.1 Legal framework

- General knowledge and understanding of railway related European legal framework, including vocabulary (e.g. IOD 2016, TSIs and modules);
- General application of an QMS and relevant aspects of safety related aspects of a project when applied to the railway technology production process;
- Typical operation and maintenance of the product;
- Typical design/production defects of this or similar products/ technology and on previous defects of which have materialised in previous applications of this or similar products/ technology – limited to those defects which could interfere with safety, health, the environment or any other essential requirement as defined by IOD 2016.

C.6.3.2 Technical topics

- General knowledge and understanding of relevant parts of *Annex D. (Normative) List of technical topics per scope of assessment* necessary to achieve the intended results of the audit they are expected to perform.
- The QMS lead auditor can be accompanied by technical experts as point 9.2.2.2.2 of EN ISO/IEC 17021-1 to fulfil these requirements.

C.6.3.3 Non-technical skills

- Auditing skills and knowledge: general and appropriate for specific scope of assessment;
- Desired personal behaviour as described in Annex D of EN ISO/IEC 17021-1;
- Complete list of audit criteria of the complete project;
- Form and direct an audit team;
- Quality management requirements of relevant railway standards;
- Relevant TSIs aspects;
- Relevant modules;
- Understand interface with common manufacturer certification (e.g. ISO 9001).

If needed, the QMS lead auditor can be supported by QMS auditors.

C.7. QMS auditor

C.7.1. Description

The QMS auditor supports the QMS lead auditor.

C.7.2. Training and experience

C.7.2.1 General

One or more of the following possibilities shall apply:

- MASTER university degree (or equivalent) in a relevant subject + 1 year of proven professional experience relevant to quality management systems relating to a technical area, preferably in railways;
- BACHELOR university degree (or equivalent) + 3 years of proven professional experience relevant to quality management systems relating to a technical area, preferably in railways;
- Relevant technical vocational trainings in technical area, preferably in railways of at least 2 years + 6 years of proven professional experience relevant to quality management systems relating to a technical area, preferably in railways.

C.7.2.2 Specific in addition to General

- Specific training as auditor (internal or external) based on the EN ISO/IEC 17021-1 lasting at least 5 working days or 40 hours of classroom style training for auditing;
- Training (internal or external) on the relevant requirements for the CAB inspection processes based on EN ISO/IEC 17020 and EN ISO/IEC 17065;
- Participation in QMS audits in the railway domain as follows:
  a) For initial nomination as QMS auditor
  Participation in at least 2 QMS audits:
  - with one of them related to the IOD;
  - in a team of at least 2 persons;
  - with a duration of at least one day;
  - at least at the level of “auditor in training” (reference to 9.2.2.1.4 of EN ISO/IEC 17021-1)
  - during the last 24 months before nomination as QMS lead auditor.

  b) For maintaining the status as QMS auditor
  Participation in at least 1 QMS audit:
  - related to the IOD;
  - in a team of at least 1 person;
  - with a duration of at least one day;
  - at the level of “auditor”;
  - during the last 36 months.

c) For re-nomination as QMS auditor (where requirement b) has not been met)
Participation in at least 1 QMS audit:

- related to the IOD;
- in a team of at least 2 persons;
- with a duration of at least one day;
- at least at the level of “auditor in training” (reference to 9.2.2.1.4 of EN ISO/IEC 17021-1) during the last 6 months.

C.7.3. Knowledge

C.7.3.1 Legal framework:

› General knowledge and understanding of railway related European legal framework, including vocabulary (e.g. IOD 2016, TSIs and modules).

C.7.3.2 Technical topics

› General knowledge and understanding of relevant parts of Annex D necessary to achieve the intended results of the audit they are expected to perform.
› The QMS auditor can be accompanied by technical experts as point 9.2.2.2.2 of EN ISO/IEC 17021-1 to fulfil these requirements.

C.7.3.3 Non-technical skills

› Auditing skills and knowledge: general and appropriate for specific scope of assessment;
› Desired personal behaviour as described in Annex D of EN ISO/IEC 17021-1.

Annex D. (Normative) List of technical topics per scope of assessment

Introduction

This Annex does not exist in the EN ISO/IEC 17065.

The following lists of items apply in relation to the scope of assessment as explained by the following table.

Table 8 : Applicable specific knowledge per scope of assessment

Scope of assessment	*Applicable list of specific knowledge*
Infrastructure	D.0 + D.1
Energy	D.0 + D.2
Control-command and signalling	D.0 + D.3
Rolling stock	D.0 + D.4

The content of the following lists is entirely applicable; only for readability sake, the content of the list has been grouped into several macro items.

D.0. General

A breadth of knowledge of following general and specific railway matters:

- understanding of the processes and potential defects related to the lifecycle of the railway products, such as – non exhaustive – design, development, manufacturing, construction, assembly, testing, repairing and maintenance;
- understanding of any new technologies related to railways;
- understanding of integration of the product within the subsystem;
- understanding of the risk derived or likely to be derived from the integration of the product into the railway system;
- understanding of safety analysis and functional analysis for items required by TSIs;
- ability to perform sound robust judgement on any deviation of the product under assessment from the complete set of requirements provided by the applicable legislation including, non-exhaustive, TSIs, harmonised standards, European and international standards, industrial standards.

D.1. Infrastructure

D.1.1. General

- Assessment or design or construction or supervision of works and technical expertise in the field of EU railway infrastructure;
- Infrastructure scope of assessment covers the TSI Infrastructure and, when applicable, the TSI Persons reduced mobility and the TSI Safety in railway tunnels;

D.1.2. Civil works and installations

- Bridges, retaining walls, noise barriers and other structures withstanding traffic loads or aerodynamic effects;
- Earthworks withstanding traffic loads;
- Structure gauge;
- Tunnels including basics of tunnel construction, fire behaviour of tunnel elements and equipment, evacuation facilities in tunnel including emergency lighting, communication and procedures, including safety analysis (e.g. risk assessment);
- Passengers' stations building and installations, including visual, tactile and spoken information relevant parameters and tests;
- Platforms;
- Level track crossings for passengers;

D.1.3. Permanent way

- Track components (e.g. rails, sleepers, fastening systems, etc.) including manufacturing processes, and concepts of track resistance to traffic loads;
- Track alignment and layout;
- Switches and crossings;

D.1.4. Documents (including referenced standards, annexes and referenced documents)

- TSI Infrastructure;
- TSI Persons reduced mobility for items related to infrastructure;
- TSI Safety in railway tunnels for items related to infrastructure.

D.2. Energy

D.2.1. General

- Assessment or design or construction or supervision of works and technical expertise in the field of EU railway traction electrification;
- Energy scope of assessment covers the TSI Energy and, when applicable, the TSI Safety in railway tunnels;

D.2.2. Pantograph

- Contact strips, horns, arms including manufacturing processes;
- Kinematic pantograph gauge calculation;

D.2.3. Overhead contact lines

- Contact wire materials including manufacturing processes;
- Geometry of the overhead contact line including mechanical design and behaviour;
- Dynamic behaviour of the overhead contact line and its interaction with the pantograph;
- Execution of site dynamic measurements and interpretation of the results from the tests of the contact forces exerted by the pantograph to the overhead contact line;
- Interpretation of data and use of the simulation tools applied for assessment of dynamic behaviour and quality of current collection;
- Methodology and execution of current measurement tests;

D.2.4. Power supply

- Energy power supply for railways: voltage, frequency, sizing power supply subsystem;
- Knowledge on the power supply domain, and in particular of the EU railway traction electrification;
- Performance of the power supply subsystem and interface with rolling stock;
- Electrical protection coordination arrangements including interface with rolling stock protections and earthing and grounding system for electrical substations;
- Harmonics and dynamic effects for AC traction power supply systems;
- Knowledge of low voltage, medium voltage and high voltage distribution systems; equipment and connection of the neutral wire;
- Knowledge on rolling stock's interaction with power supply system both in sizing/dimensioning and harmonics and dynamic effects;

D.2.5. Electrical safety rules

- General knowledge and understanding of safety rules and protective provisions against electric shock;

D.2.6. Documents (including referenced standards, annexes and referenced documents)

- TSI Energy;
- TSI Safety in railway tunnels for items related to energy.

D.3. Control-command and signalling

D.3.1. General

- Railway signalling principles;
- Railway communication principles;

D.3.2. Train protection system

- Class A system;
- Class B system (including principles and functionalities);
- Interfaces and safe integration with other subsystems on-board and trackside and class A train protection system;

D.3.3. Radio communication

- GSM-R;
- Interfaces with other communication systems (including public and railway specific);

D.3.4. Balise/EUROLOOP

- Installation arrangements (including mechanical and information connections);
- Correctness of the telegrams sent in relation with the track layout;
- Communication via balise and EUROLOOP;

D.3.5. Train detection system

- Compatibility with vehicles;
- Electromagnetic compatibility;

D.3.6. Documents (including referenced standards, annexes and referenced documents)

- TSI Control-command and signalling;
- Mandatory (ERA CCS subset requirements, etc.) and informative ERTMS specifications.

D.4. Rolling stock

D.4.1. General

- Assessment or design or manufacturing and technical expertise in the field of railway rolling stock;
- Rolling stock scope of assessment covers the TSI Locomotives and passenger rolling stock, the TSI Noise, the TSI Freight wagons, and the relevant requirements of the TSI Energy, TSI Safety in railway tunnels and TSI Persons reduced mobility for items related to rolling stock.

D.4.2. Structure and mechanical parts

- Mechanical assemblies, such as (non-exhaustive) loads, stresses, fatigue, calculation, simulations and tests;

D.4.3. Track interaction and gauging

- Dynamic behaviour of railway vehicles such as (non-exhaustive) loads, parameters, infringement with infrastructure gauge.
- Electromagnetic compatibility (including. compatibility with train detection system).

D.4.4. Braking

- Braking system usually fitted on railway vehicles example pneumatic breaking;
- Braking performance, such as (non-exhaustive) calculation, tests;
- Functional safety analysis;

D.4.5. Passenger related items

- Functional analysis on functions such as (non-exhaustive) passenger doors, information system, including safety;

D.4.6. Environmental conditions

- No specific technology;

D.4.7. Aerodynamic effects

- Fluid mechanics such as (non-exhaustive) relevant parameters, calculations, simulations and tests;

D.4.8. Lights, and acoustics

- Light technology such as (non-exhaustive) colour and luminous intensity;
- Acoustics such as (non-exhaustive) relevant parameters, simulation, noise level measurement;

D.4.9. Traction and electric equipment

- Power supply systems used in railways;
- Current collection via a pantograph such as (non-exhaustive) relevant parameters, dynamic behaviour, simulations and tests;
- Safety of electric installations; protective measures;

D.4.10. Driver's cab

- Driver's machine interface such as (non-exhaustive) design, ergonomic aspects;

D.4.11. Fire safety

- Fire behaviour of materials;

D.4.12. Servicing

- No specific technology;

D.4.13. Energy supply system to trains

- Design of overhead contact line and power supply;
- Fire behaviour of cables and reliability of electrical installations;
- Pantograph, contact strips, materials and materials' behaviours of the pantograph in all its components.

D.4.14. Documents (including referenced standards, annexes and referenced documents)

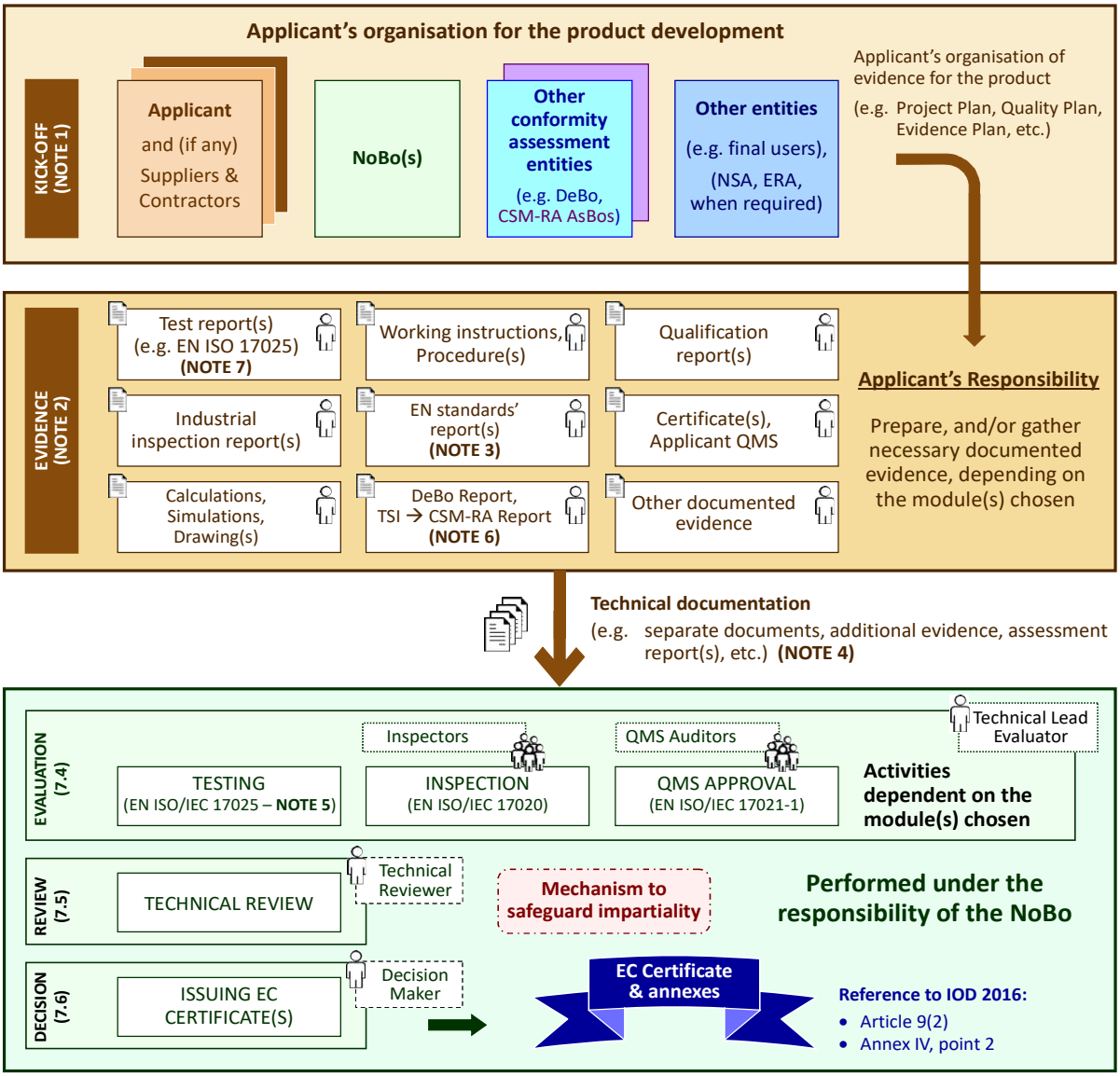
- TSI Locomotives and passenger rolling stock;
- TSI Noise;
- TSI Freight wagons;
- TSI Persons reduced mobility for items related to rolling stock;
- TSI Safety in railway tunnels for items related to rolling stock.

Annex E. (Informative) Documents flow chart

This Annex:

- does not have a direct reference in EN ISO/IEC 17065;
- has an informative value, not a normative value;
- is primarily referring to the notified bodies internal activities: "Evaluation" "Review" and "Decision". Other sections of the figure are provided as general framework.

Figure 1 : Documents flow chart



NOTES of Figure 1:

NOTE 1: KICK-OFF phase has no direct reference in EN ISO/IEC 17065; one of the possible outputs of the "Kick off" phase is the evidence plan, which defines which kind of evidences - including tests - are needed, when they are to be done, by whom and whether NoBo presence is required (e.g. if testing is carried out by the applicant without accreditation). One of the main aims of this evidence plan is avoiding double work and thus reducing costs.

NOTE 2: EVIDENCE phase has no direct reference in EN ISO/IEC 17065; the main output is the preparation of all the evidences which will be later assessed by the NoBo in the processes for evaluation, review and certification decision.

NOTE 3: It may include reports according to EN 50126, 50128, 50129 (e.g. Verification & Validation, etc.).

NOTE 4: The output of the EVIDENCE phase, i.e. the technical documentation, can be organised by the applicant in different ways, respecting the requirements defined by the chosen module(s), e.g.:

- *Separate/individual documents (drawings, calculations, testing reports...);*
- *The above-mentioned separate/individual documents accompanied by "evidence assessment report(s)" issued by an internal team of the applicant or by an in-house/internal or external conformity assessment body which is not accredited under EN ISO/IEC 17020;*
- *The above-mentioned separate/individual documents accompanied by "evidence assessment report(s)" issued by an in-house/internal or external conformity assessment body accredited under EN ISO/IEC 17020.*

The above-mentioned "evidence assessment report(s)" consists in a voluntary pre-assessment of the technical documentation; it may support the following work performed by the NoBo (thus reducing the needed resources and costs), especially if the body issuing the evidence assessment report(s) is accredited according to the EN ISO/IEC 17020.

The evaluation of the technical documentation (and of any accompanying evidence assessment report(s)) delivered by the applicant is the role and the responsibility of the NoBo, as described in the "EVALUATION phase".

Without prejudice to other EU legislation, which define roles and responsibilities for other actors (e.g. Regulation on CSM-RA that defines the requirements, roles and responsibilities of an AsBo), the NoBo is the sole decision maker for any issues of relevance whether a product/system complies with the applicable requirements defined in the relevant TSIs.

NOTE 5: This testing is associated with the CAB`s evaluation activities (see Annex F).

Accredited tests, which have been performed by an accredited test laboratory according to EN ISO/IEC 17025, are usually cross-accepted (thus do not need to be repeated).

NOTE 6: The safety assessment report of the AsBo, where the applicant contracts an AsBo for the specific conformity assessment described in point 7.4.3.

NOTE 7: This testing is not associated with the CAB evaluation activities.

These testing activities are performed by the manufacturer and in some cases under the control of the applicant and are not in the scope of the testing in Annex F, e.g.:

- *production related (serial) tests under the control of the manufacturer;*
- *final (commissioning) testing at the end of production under the control of the manufacturer or applicant;*
- *type testing which as part of an H-type module performed under the control of the applicant.*

Information coming from this activity may be used by applicants as evidence input to the CAB evaluation activities. Predominantly this information is input to inspection and may also be input to auditing.

Annex F. (Normative) Testing

F.0. General

The evaluation activities related to testing shall follow the applicable requirements of EN ISO/IEC 17025 described in this point.

The CAB shall ensure that tests used in its evaluation activities have been carried out according to the following acceptance criteria:

- In competent, independent and reproducible manner according to the requirements of EN ISO/IEC 17025, and
- in accordance with the applicable requirements of normative documents for products and their manufacturing process as defined in the TSIs.

The CAB shall have documented methods to ensure the above criteria according to the following possibilities:

- accredited tests (i.e. within the scope of the laboratory accreditation);
- non-accredited tests performed by accredited laboratories or non-accredited entities.

NOTE 1: It is common practice that tests are not performed directly by the CAB but by other bodies with the details provided in section F.1. Accredited test and/or section F.2. Non-accredited test.

NOTE 2: The test reports shall document the test results. The evaluation of the test results, included in the report, is part of the "evaluation phase – INSPECTION".

Testing activities shall be performed by:

- the CAB;
- a Test Laboratory which is accredited to EN ISO/IEC 17025 in connection with the applicable technical standards;
- a non-accredited Test Laboratory, or a Test Laboratory with a different scope of accreditation, under the supervision of the CAB, once the CAB has confirmed for the relevant testing activities that these are performed in conformity with the requirements of this annex;
- another body, e.g. contracting entity, infrastructure manager, if specified in the TSI (e.g. TSI Infrastructure, section 6.2.4.8).

NOTE 3: A CAB expert may use "measuring aids" to support its judgement during an inspection or auditing activity. Such a measuring aid is not a test equipment and not required to be calibrated if it is not used for testing as defined above and if it does not have a significant influence on the results of the inspection or auditing performed.

The evaluation task shall follow the document flow as described in Figure 1 in Annex E.

F.1. Accredited test

The assessment provides the necessary confidence and trust in the test reports prepared under such assessment. The accredited test is the preferred means by CABs for demonstrating acceptance criteria in section F.0.

NOTE 1: It is common practice that tests are contracted by manufacturers and/or applicants directly to accredited test laboratories.

The assessment of the test body / laboratory shall be provided by a signatory of the multilateral agreement of EA or ILAC.

NOTE 2: In EU these usually are the national accreditation bodies.

An accredited test shall be accepted only if:

› the test report includes a valid accreditation mark and/or the accreditation ID-number, and
› if the CAB has received a copy of the accreditation certificate of the laboratory performing the test, including its annex. The performed test must have been performed within the scope and subject to the rules of this accreditation.

NOTE 3: The accreditation certificate and its annex can be also provided electronically via website.

F.2. Non-accredited test

The CAB shall have a documented process for assessing the technical competence of the non-accredited testing laboratory before the performance of the tests. This CAB documented process shall ensure that:

› CAB staff who assesses the testing laboratories have the adequate competence;
› CAB keeps records to demonstrate the performed assessment towards the laboratory for compliance with requirements of EN ISO/IEC 17025 as below:

- Point 4.1 Impartiality;
- Point 4.2 Confidentiality;
- Points 5.1, 5.4, 5.5, 5.6, 5.7 of point 5 Structural requirements;
- Point 6.2 Personnel;
- Point 6.3 Facilities and environmental conditions;
- Point 6.4 Equipment;
- Point 6.5 Metrological traceability;
- Point 6.6 Externally provided products and services;
- Point 7.1 Review of requests and contracts;
- Point 7.2 Selection, verification and validation of methods;
- Point 7.3 Sampling;
- Point 7.4 Handling of test and calibration items;
- Point 7.6 Evaluation of measurement uncertainty;
- Point 7.7 Ensuring the validity of results;
- Point 7.8 Reporting the results;
- Point 7.10 Nonconforming work
- Point 7.11 Control of data and information management;

› the testing laboratory presents all records of a specific test under request by the CAB;
› competence and independence of the laboratory personnel are evaluated and recorded;
› participation to inter-laboratory comparison or proficiency-testing programmes is recorded (if available);
› as far as required for the purpose of the certification, CABs shall assess the testing entities:

- periodically at least every 24 months, or;
- each time a non-accredited test is performed;

to demonstrate that its competence is maintained.

The above list can be amended by a TSI, if the TSI permits certain testing by non-accredited entities (e.g. infrastructure manager). In this case, the TSI may provide alternative requirements to those mentioned above in this section.

Annex G. (Normative) Inspections

G.0. General

The evaluation activities related to inspections shall follow the applicable requirements of EN ISO/IEC 17020 described in this point. The requirements for the resources for evaluation performing inspections are described in point 6.1 of this document.

The evaluation task shall follow the document flow as described in Figure 1 in Annex E.

G.1. Inspection methods, procedures and requirements

Point 7.1 including all the subsections of EN ISO/IEC 17020 applies together with requirements as described below.

Point 7.1.1 of EN ISO/IEC 17020: the following text shall be added at the end.

The specific methods, procedures and requirements for inspection shall be derived at least from the items of the following list.

- modules descriptions (e.g. Decision 2010/713/EU on railway modules, Annexes in TSIs, etc.);
- the text of the TSIs;
- standards quoted in the TSIs;

  NOTE 1: Those standards are usually called mandatory standards.

- Harmonised European Standards applied in full or in part, as defined by the applicant in relation to meet the essential requirements as defined in the TSIs;
- alternative solutions to Harmonised European Standards, such as other public standards, documentation and company standards applied in full or in part, as defined by the applicant in relation to meet the essential requirements as defined in the TSIs;

  NOTE 2: Those standards mentioned in the two previous bullet points are usually called industrial standards.

- ERA technical opinions;
- ERA technical documents;
- Acceptable Means of Compliance (AMOC);
- documents of the coordination group of notified CAB referred to in Article 30 (6) of Regulation (EU) 2016/796 (e.g. RFUs, Q/Cs and FAQs).

The methods, procedures and requirements for inspection derived from the above listed items shall be applied simultaneously.

The evaluation plan (see point 7.4.1 of this document) shall reference to these methods, procedures and requirements.

NOTE 3: The methods, procedures and requirements are usually of generic nature; however, there could be methods, procedures and requirements for a very specific technical solution. In this case the exact set of methods, procedures and requirements applied in a project can only be determined at the end of that project.

Point 7.1.3 of EN ISO/IEC 17020: the following text shall be added at the end.

The inspection method shall include, for each product under inspection, a specific exhaustive check list.

NOTE 1: The check list can be subdivided into several check lists having a matrix style format.

The check list shall systematically include at least the following information.

- TSI parameters: structured list of all individual TSI parameters to be assessed;

  NOTE 2: It can happen that a TSI parameter needs to be subdivided into several sub-elements to support an efficient performance of the inspection.

- TSI mandatory requirements: references to applicable mandatory standards to the aforementioned TSI parameters, other mandatory references within TSIs (e.g. Chapter 6 of the TSIs, Annexes of TSIs) and where they are defined mandatory references to other TSIs or ERA technical documents;
- Other requirements (used to assess conformity with the essential requirements): exhaustive description of project specific choices of harmonised standards, industrial standards and alternative solutions;
- Inspection items: references for one or several evidences used during the inspection of the aforementioned requirements. The inspection items shall refer to following in section G.2 of Annex G;
- Inspection results: professional judgment by the inspection body staff whether the inspection item complies with the aforementioned requirements, including reference to name of staff and date of statement.

  NOTE 3: It is good practice to have inspection results presented in 3 categories:
  - *compliant,*
  - *non-compliant,*
  - *not relevant, with explanation why the parameter/requirement is considered as not relevant (e.g. requirements for pantographs in a diesel locomotive project).*

- Conditions for use: any conditions for use of the product under inspection as resulting from the assessment (e.g. a speed limit for rolling stock).

NOTE 4: The following example can be considered as complying with the above stated minimum set of information in a matrix format. CABs may however decide to add additional columns to increase readability or may include further information. The completed check list may serve as collection of detailed information to support the report as defined in section G.4 of Annex G of this document.

Table 9 : Example of check list matrix

Num	*TSI PARAMETER*	*TSI MANDATORY REQUIREMENTS*	*OTHER REQUIREMENTS*	*INSPECTION ITEMS or SAMPLE*	*INSPECTION RESULTS*	*CONDITIONS FOR USE*
i-1	*….*	*….*	*….*	*….*	*….*	*….*
i	*1302/2014 LOC&PAS TSI* *Clause 4.2.3.4.2 (3) Running dynamic behaviour*	*> 6.2.3.4* *>Appendix J-1* *>EN 14363:2005 (relevant clauses)* *>Appendix J-2(2)* *>ERA/TD/2012-17/INT rev 3.0*	*assessment to be based on* *EN 14363:2005 Lambda-evaluation to reference vehicle*	*>Test Report to EN 14363:2005 for reference vehicle – document ID code "XYZ"* *>manufacturers description and calculation for Lambda-evaluation - document ID code "ABC"*	*Compliant, Mrs. DAVID, 22.12.2022*	*>Max. speed =160km/h* *>Max axle load =14,3t*
i+1	*….*	*….*	*….*	*….*	*….*	*….*

G.2. Inspection items and samples

Point 7.2 including all the subsections of EN ISO/IEC 17020 applies together with requirements as described below.

Point 7.2.1 of EN ISO/IEC 17020: the following text shall be added at the beginning.

Inspection items and inspection samples are defined as:

- items: are documents which demonstrate certain properties of a product;
- samples: are products, which can be a prototype, a first in series or product taken from a mass production.

NOTE 1: All documents used by the CAB for the conformity assessment activity become items under inspection.

The CAB shall receive from the applicant a set of items for inspection, specific for the product under assessment. The items for inspection shall include at least the following elements.

- functional description, including interfaces;
- technical description, including interfaces;
- design drawings;
- manufacturing drawings;
- installation drawings;
- "as-built" drawings;
- simulations and calculations reports;
- verification and validation reports;
- testing programme;
- test reports;
- on-site measurement reports;
- manufacturer's final inspection report;
- previous certificates where existing (e.g. EC certificates, ISV certificates, etc.);
- previous technical file/technical documentation where existing;
- previous declaration by manufacturer where existing;
- condition of the product under assessment for:
  - integration into railway system;
  - use;
  - maintenance;
  - commissioning;
- where applicable:
  - previous authorisation certificates for placing into service;
  - listing of data required for interoperability registers (e.g. RINF, ERATV, EVR, NVR, etc.).

The above items and samples for inspection shall:

- be inspected using the methods and procedures described in section G.1 of Annex G of this document;
- relate to the inspection of the design, manufacture, installation, final testing, operation and maintenance of the product under inspection.

NOTE 2: It is normal industry practice that the client proposes to the CAB a system of product/variant/series identification and marking (including any hardware and software); the CAB shall agree on the suitability of such arrangements.

G.3. Inspection records

Point 7.3.1 of EN ISO/IEC 17020 applies without additional elements.

G.4. Inspection reports

Following the inspection of each product under inspection, the CAB shall produce the following documentation:

- an inspection report in which the main findings are identified and links are provided to the accompanying appropriate collection of detailed information, and
- an accompanying appropriate collection of detailed information to support the report and to improve the understanding of the inspection report.

The report shall make clear recommendations to the CAB to perform the certification phase, including clear statement whether the inspection has provided positive results or not, including proposals for conditions and validity period.

NOTE 1: The accompanying collection of detailed information should be included in the technical file supporting the EC certificate at the end of the certification phase.

Point 7.3.2 of EN ISO/IEC 17020 applies without additional elements.

Point 7.4.1 of EN ISO/IEC 17020 applies with the following element.

The term “inspection certificate” shall be removed from the text.

Point 7.4.2 of EN ISO/IEC 17020 applies with the following element.

The term “inspection certificate” shall be removed from the text.

Points from a) to e) of point 7.4.2 of EN ISO/IEC 17020 apply without modifications.

Point f) of point 7.4.2 of EN ISO/IEC 17020: the following text shall be added at the end.

- The statements of conformity shall be provided individually for each TSI parameter in the check list under the heading inspection results as defined in section G.1 of Annex G of the ERA Assessment Scheme.

Point g) of point 7.4.2 of EN ISO/IEC 17020 shall be replaced by the following text.

- g) the overall inspection findings shall summarise the statements of conformity for the individual TSI parameters. The inspection findings shall be reported within the inspection report as defined in clause 7.4.9. of the ERA Assessment Scheme.

NOTE 1: The following elements should be included in the inspection reports:

- *Annex B of EN ISO/IEC 17020 bullet point from a) to g)*
- *Annex B of EN ISO/IEC 17020 bullet point m)*

Other elements from Annex B of EN ISO/IEC 17020 may be applied as well.

Point 7.4.3 of EN ISO/IEC 17020 shall not apply.

Point 7.4.4 of EN ISO/IEC 17020 applies without additional elements.

Annex H. (Normative) Quality Management System Approval

H.0. General

The evaluation activities related to quality management system shall follow the applicable requirements of EN ISO/IEC 17021-1 described in this point. The requirements for the resources for evaluation performing audits are described in point 6.2 of this document.

In the context of the IOD 2016 and in the ERA Assessment Scheme, the term "Management System Certification" of the EN ISO/IEC 17021-1 shall be read as "Quality Management System Approval in the framework of the IOD 2016 for a precisely defined product".

The evaluation task shall follow the document flow as described in Figure 1 in Annex E.

H.1. QMS – Application

Points from 9.1.1.a to 9.1.1d of EN ISO/IEC 17021-1 shall apply with amplified requirements described below.

The application shall also at least include:

- name and address of the manufacturer(s);
- the project breakdown structure detailing the name and address of each involved entity for production, final inspection and serial testing. This shall include all project related sites, main sub-suppliers, and where this is not otherwise known to the CAB, the number of staff involved in the project at the sites;
- for H-type modules name and address of the designer(s), testing body(ies) and verification and validation body(ies).

  NOTE 1: Several sites processing the identical product are possible; these may apply the same QMS or different QMS.

- QMS related documentation relevant for the product under assessment and as required by the CAB to define the scope of work. In case of several QMS being related to the product, documentation related to all of them;
- language(s) requested for the audit and for the audit report;

  NOTE 2: Language of the Audit Report should be aligned with language of the Technical File.

- any other information as required by the module description in Decision 2010/713/EU on railway modules.

NOTE 3: Point 9.1.1.e shall be considered optional.

H.2. QMS – Application review

The QMS application review shall apply point 7.3 of this document in combination with point 9.1.2 of EN ISO/IEC 17021-1.

H.3. QMS – Audit programme

Point 9.1.3.1 of EN ISO/IEC 17021-1 shall apply with amplified requirements described below.

The audit programme is a part of the "plan for the evaluation activities" as defined in point 7.4.1 of EN ISO/IEC 17065.

If the plan for the evaluation activities addresses all the requirements for the audit programme, it shall not be required to prepare a separate audit programme.

The audit programme shall cover only the aspects of the requirements of the management system related to the product under certification.

Point 9.1.3.2 of EN ISO/IEC 17021-1 shall apply with amplified requirements described below.

The audit programme shall explain the full certification cycle. The initial certification shall include a two-stage initial audit, the initial certification decision and following periodic audits for surveillance and/ or re-certification at intervals as defined in each individual TSI. The possibility for unexpected visits shall be mentioned.

Each periodic time interval begins with the last day of the related preceding audit.

The determination of the audit programme and any subsequent adjustments shall consider the size of the client, the scope and complexity of its management system, products and processes as well as demonstrated level of management system effectiveness and the results of any previous audits.

NOTE 1: Differences in periodic intervals of certification are due to the different durations between the certification of the EN ISO/IEC 17021-1 (nominally three years) and the QMS approval provided by the Decision 2010/713/EU on railway modules.

NOTE 2: EN ISO/IEC 17021-1 section 9.1.3.2 defines for the certification of a management system a frequency of periodic surveillance audits of 1 year and a re-certification cycle of 3 years, except the cases where section 9.1.3.2 - NOTE 3 applies ("If specified by the industry specific certification scheme, the certification cycle can be different from three years").

For conformity assessments in the scope of IOD 2016, the Decision 2010/713/EU on railway modules defines a frequency of 'periodic audits' of at least once every 2 years which has been taken as a requirement in the ERA Assessment Scheme.

Surveillance and re-certification audits are both periodic audits.

NOTE 3: Consequently, a two-year re-certification cycle may be implemented without additional surveillance audits, if there is no necessity identified by the CAB to perform surveillance audits at a higher frequency of one audit every two years.

Point 9.1.3.4 of EN ISO/IEC 17021-1 shall apply with amplified requirements described below.

The CAB shall have a documented procedure on how certification(s) already granted to the applicant for the site(s) and scope of activities and product(s) in question by another CAB, is "taken into account".

The Audit Programme shall determine the 'Audit-Objectives, Scope and Criteria' as defined in section H.7 of Annex H of this document.

H.4. QMS – Determining audit time

Point 9.1.4 including all the subsections of EN ISO/IEC 17021-1 shall apply with amplified requirements described below.

The audit time shall be adjusted to focus on the QMS related to the product to be certified.

NOTE 1: IAF MD 5 shall apply taking into account only the number of staff related to the product to be certified and not the full number of staff of the company.

Point 9.1.4.4 of EN ISO/IEC 17021-1 shall apply with amplified requirements described below.

As defined in Annex C of this document, the QMS lead auditor / QMS auditor can be accompanied by technical experts to fulfil the competency requirements. In this case both the time accounted by the Technical Expert(s) as well as the time accounted by the lead auditor/ auditor(s) supported by them shall be accounted only with 50% of their time of participation in the audit activities.

If overlapping activities for several products are audited at the same time and site, the total duration may be reduced accordingly.

H.5. QMS – Multi-site sampling

Point 9.1.5 of EN ISO/IEC 17021-1 shall apply with amplified requirements described below.

Audits are required to include an assessment visit to the premises of the relevant entities concerned.

NOTE 1: It is good practice to prepare a separate audit plan for each specific site if the audit involves more than one site.

H.6. QMS – Multiple management systems standards

Point 9.1.6 of EN ISO/IEC 17021-1 applies.

H.7. QMS – Determining audit objectives, scope, criteria and topics

Point 9.2.1 including all the subsections of EN ISO/IEC 17021-1 applies with amplified requirements described below.

Point 9.2.1.2b of EN ISO/IEC 17021-1 applies with amplified requirements described below.

The terms ‘statutory and regulatory’ requirements shall be read as “IOD 2016 and applicable TSIs”.

H.7.1. Audit objectives

To verify that the QMS is capable of maintaining the continuous compliance of the product against all the applicable requirements of the applicable TSIs.

The QMS approval shall provide confidence that the manufacturer has demonstrated the ability to re-produce TSI-compliant products which are in all their relevant aspects identical to that TSI compliant design prototype on which they are based.

The QMS approval refers to the precise type of product to be certified and its specific design and/or production processes.

H.7.2. Audit scope

The QMS approval shall have a scope for the product itself (object of the EC certification) and the overall design, manufacturing processes and final inspection as required by the applied module.

If the manufacturing process is located on several sites, the audit scope shall be defined in order to verify all the sites.

H.7.3. Audit criteria

The audit criteria are specific to the ERA Assessment Scheme. Throughout all the process' stages the QMS shall satisfy the combination of all audit criteria requirements for the production process including the final inspection and, for H-type Modules, also for the design and type testing as resulting from the following audit criteria sources:

AC source 1: Modules descriptions (e.g. Decision 2010/713/EU on railway modules, Annexes in TSIs, etc).
AC source 2: The text of the TSIs.
AC source 3: Standards quoted in the text of the TSIs.

NOTE 1: The standards identified in AC source 3 are usually known as mandatory standards.

AC source 4: Harmonised European Standards applied in full or in part, as defined by the applicant in relation to meet the essential requirements as defined in the TSIs.
AC source 5: Alternative Solutions to Harmonised European Standards such as other public standards, documentation and company standards applied in full or in part, as defined by the applicant in relation to meet the essential requirements as defined in the TSIs.

NOTE 2: The standards identified in AC source 4 and AC source 5 are usually known as industrial standards.

AC source 6: ERA technical opinions.
AC source 7: ERA technical documents.
AC source 8: Documents of the coordination group of notified CAB referred to in Article 30 (6) of Directive (EU) 2016/797 (e.g. RFUs, Q/Cs, FAQs).

H.7.4. Audit topics

In order to establish a generic structure for QMS auditing activities, the CAB shall establish a documented approach (e.g. a checklist) identifying the following audit topics for guiding the audit team and for the general information of the auditees.

NOTE 1: These audit topics have been derived from the generic audit criteria included in AC sources from 1 to 4.

The CAB shall develop in more depth and detail the provided headings of the audit topics according to the audit criteria specific to the product to be certified.

NOTE 2: In complex project situations, the application of additional sub-headings is recommended.

Audit topics:

1. General aspects QMS, QMS documentation, document management
2. Management responsibility
3. Human resources
4. Infrastructural resources
5. Design - planning, inputs, outputs
6. Design - evaluation, verification & validation
7. Control of design changes
8. Production/ Service provision - performance, evaluation, verification & validation, release of products, control of non-conforming products
9. Control of monitoring and measurement Equipment
10. Procurement and control of purchased goods/services
11. Continuous monitoring, measurement, analysis
12. Continuous improvement – corrective actions, preventive actions (incl. project SMS), management of complaints (see point 4.1.2.2 j. of EN ISO/IEC 17065)

NOTE 3: For information and further guidance, in Annex I of this document are provided references from these audit topics to Decision 2010/713/EU on railway modules and ISO 9001:2015.

As long as all audit criteria are satisfied, the ERA Assessment Scheme is not mandating the auditee to operate a QMS based on ISO 9001.

If the QMS is evaluated according to:

- H-type modules where the product must be based on an "existing design", or;
- D-type module,

the CAB may have a documented procedure to exclude the following audit topics from the above list:

5. Design - planning, inputs, outputs
6. Design - evaluation, verification & validation.

In addition, for D-type modules, the following audit topic may be excluded:

7. Control of design changes.

If the applicant operates a quality management system which is already certified by an accredited body, the CAB shall limit the detailed QMS assessment to the product to be certified only.

The CAB shall not assess again the entire QMS.

NOTE 4: Annex I of this document provides information about the audit topics which shall not be re-assessed in case of a manufacturer's QMS certified to ISO 9001:2015.

H.8. QMS - Audit team selection and assignments

Point 9.2.2 including all the subsections of EN ISO/IEC 17021-1 applies with amplified requirements described below.

The competence criteria of the audit team leader shall be as described in point 7.2 of ISO 19011:2018 as "QMS lead auditor".

H.9. QMS - Audit plan

Point 9.2.3 including all the subsections of EN ISO/IEC 17021-1 applies with amplified requirements described below.

An audit plan shall define the specific application of the audit programme to each individual audit contained in the overarching audit programme. The audit plan shall refer to the audit programme.

H.10. QMS - Initial certification audit

Point 9.3 including all the subsections of EN ISO/IEC 17021-1 applies.

H.11. QMS - Conducting audits

Point 9.4 including all the subsections of EN ISO/IEC 17021-1 applies with amplified requirements described below.

The findings referred to in point 9.4.8.2.k of EN ISO/IEC 17021- 1 shall be reported separately for each audit criterion listed in section H.7 of Annex H of this document.

NOTE 1: It is good practice, to perform audit stage 1 as remote audit.

H.12. QMS - Approval decision

Point 9.5 including all the subsections of EN ISO/IEC 17021-1 applies with amplified requirements described below.

The CAB shall have a documented procedure for granting QMS approval in case of amendments of the TSIs against which the QMS has been already approved.

H.13. QMS - Maintaining approval

Point 9.6 including all the subsections of EN ISO/IEC 17021-1 applies.

NOTE 1: Points from 9.7 to 9.9 of EN ISO/IEC 17021-1 including all the subsections do not apply.

Annex I. (Informative) Audit topics – correlations with ISO 9001

This Annex does not exist in the EN ISO/IEC 17065. This annex has an informative value, not a normative value.

The Decision 2010/713/EU on railway modules states that the NoBo "*shall presume conformity with those requirements in respect of the elements of the QMS that comply with the corresponding specifications of the […] harmonised standard*". The most relevant generic harmonized standard in this regard is the EN ISO 9001: 2015.

Each element of the following list contains the correlation with Decision 2010/713/EU on railway modules and in brackets the references to the related clauses in ISO 9001:2015.

NOTE 1: The audit topics below follow the list of those in section H.7.4 of Annex H of this document.

If the applicant operates a quality management system certified by an accredited body, the audit topic shall include only the reference of the ISO 9001:2015 standard **highlighted in bold and underlined**. The remaining references, not bold and not highlighted, are meant to be already covered during the evaluation for ISO 9001:2015 for certification by the accredited body.

1. General aspects of QMS, QMS documentation, document management

   Decision 2010/713/EU on railway modules: All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality management system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

   (ISO 9001:2015 4.1 to 4.4; 7.4; 7.5)

2. Management responsibility

   Decision 2010/713/EU on railway modules: the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality.

   (ISO 9001:2015 **5.1.2a,b**; 5.1 to 5.3, 6.1; 6.2; 6.3)

3. Human resources

   Decision 2010/713/EU on railway modules: the quality records, such as qualification reports on the personnel concerned, etc.

   (ISO 9001:2015 **7.1.1; 7.1.1; 7.1.4; 7.1.6; 7.2; 7.3**)

4. Infrastructural resources

   Decision 2010/713/EU on railway modules: the corresponding manufacturing, quality control and quality management system techniques, processes and systematic actions that will be used.

   (ISO 9001:2015 **7.1.1; 7.1.3; 7.1.4**)

5. Design - planning, inputs, outputs

   Decision 2010/713/EU on railway modules: the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards and/or technical specifications will not be applied in full, the means that will be used to ensure that the requirements of the TSI that apply to the product will be met.

   (ISO 9001:2015 **8.1; 8.2; 8.3.1 to 8.3.3; 8.3.5**)

6. Design - evaluation, verification& validation

Decision 2010/713/EU on railway modules: the design control and design verification techniques, processes and systematic actions that will be used when designing the product pertaining to the product category covered.

(ISO 9001:2015 **8.3.4**)

7. Control of design changes

   Decision 2010/713/EU on railway modules: the design control and design verification techniques, processes and systematic actions that will be used when designing the product pertaining to the product category covered.

   (ISO 9001:2015 **8.2.4; 8.3.6; 8.5.6**)

8. Production / Service provision - performance, evaluation, verification& validation, release of products, control of non-conforming products

   Decision 2010/713/EU on railway modules: the corresponding manufacturing, quality control and quality management system techniques, processes and systematic actions that will be used, the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out, the means of monitoring the achievement of the required design and product quality and the effective operation of the quality management system.

   (ISO 9001:2015 **8.5.1; 8.5.2**; 8.5.3; **8.5.4**; 8.5.5; **8.6; 8.7; 9.1; 10.2**)

9. Control of monitoring and measurement equipment

   Decision 2010/713/EU on railway modules: the corresponding quality control and quality management system techniques, processes and systematic actions that will be used.

   (ISO 9001:2015 **7.1.5; 8.5.1b**)

10. Procurement and control of purchased goods/ services

    Decision 2010/713/EU on railway modules: the corresponding quality control and quality management system techniques, processes and systematic actions that will be used.

    (ISO 9001:2015 **8.4**)

11. Continuous monitoring, measurement, analysis

    Decision 2010/713/EU on railway modules: the corresponding manufacturing, quality control and quality management system techniques, processes and systematic actions that will be used, the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc., and the means of monitoring the achievement of the required design and product quality and the effective operation of the quality management system.

    (ISO 9001:20155 **9.1**; 9.2; 9.3)

12. Continuous improvement – corrective actions, preventive actions (incl. project SMS)

    Decision 2010/713/EU on railway modules: the corresponding manufacturing, quality control and quality management system techniques, processes and systematic actions that will be used.

    (ISO 9001:2015 **10.1; 10.2**; 10.3)

Annex J. (Normative) Impartiality & independence of a CAB and its personnel in relation to their role and consultancy activities

Table 10 : Impartiality & independence of a CAB and its personnel in relation to their role and consultancy activities

	CAB as legal entity	***CAB Management, Certification decision and Review***		***CAB personnel for evaluation***	
		CAB personnel	*Other resources under the CAB's direct control[1]*	*CAB personnel*	*Other resources under the CAB's direct control[1]*
	cf. EN ISO 17065, p. 4.1	*cf. EN ISO 17065, points 4.2.8, 5.1 and 6.1.1.1*		*cf. EN ISO 17065, points 6.1.1.1 and 6.2.1*	
Consultancy[2] services for products within the CAB's notification scope.	Absolute prohibition	Absolute prohibition, from the date of employment of the personnel by the CAB.	Absolute prohibition, from the date of individual contract or formal agreement with the CAB.	Absolute prohibition, from the date of employment of the personnel by the CAB.	Possible, except for the product[4] under evaluation, provided that related risks are assessed and managed by the CAB.
Consultancy[2] services to designated authorities[3] (NSAs, ERA)	Possible, except for the product[4] that has been under certification or evaluation. The CAB shall support the concerned authorities in the risk assessment and management and mitigation of impartiality and independence of judgement hazards.				

1. By means of individual contract (e.g. definite, part-time, etc.), formal agreement or another document that places the resource within the management control and systems/procedures of the CAB (cf. EN ISO 17065, points 6.1.1.1 and 6.1.3)

2. cf. EN ISO 17065, point 3.2

3. E.g. services for vehicle authorisation, track-side approval to authorities defined in point 4.2.3 of the ERA Assessment Scheme.

4. A 'product' in the railway sector includes interoperability constituents and subsystems (cf. PART 2. REQUIREMENTS FOR CONFORMITY ASSESSMENT BODIES - 1. Scope).

Annex K. (Informative) Table of major amendments in ERA Assessment Scheme version 2.0

Table 11 : Correspondence table of major amendments

TD 000MRA1044		*Modifications*
v 1.1	*v 2.0*	
PART 1: INTRODUCTION	Introduction	PART 1: INTRODUCTION - v 1.1 - moved to section "Introduction" of v 2.0.
Table 2 & 3	Table 2 & 3	Tables for reference documents and legislation
PART 2.A	PART 1	Renumbered and title changed to "PART 1: FRAMEWORK FOR MEMBER STATES' NOTIFYING AUTHORITIES"
1	1	-
2	2	Legal reference changed for the assessment scheme application to the bodies delegated by the notifying authorities. DeBos included in the scope of the AS.
4	4	*NOTE 1* deleted.
5	5	Legal references to IOD 2016 and EA-2/17 M: 2020 added.
5.1	5	Section 5.1 deleted and relevant content moved to section 5. Table 4 updated.
6	6	Reference to standard EN ISO/IEC 17011 updated.
8	8	Reference to Article 29 of IOD 2008 deleted.
8.1	8.1	*NOTE 1*: reference to EN ISO/IEC 17011 updated.
8.2	8.2	*NOTE 2* added.
8.3	8.3	"Assessment entity" changed to "notifying authority or the delegated body"
9	9	Text modified to clarify the content of the assessment report and assessment certificate. *NOTE 1* amended to clarify reference to the assessment certificate for accredited and non-accredited, recognised CABs.
PART 2.B	PART 2.	References to 2008/57/EC (IOD 2008) deleted.
1	1.	*NOTE 2, 4 and 5 deleted* Text of NOTE 4 amended and moved to PART 1. - Section 9.
2	2	-
3	3	-
-	4.0	New section numbering introduced. Reference to "Article 30 (6) of Regulation (EU) 2016/797" added.
4.1	4.1	New requirement added: the CAB shall be legally independent from entities performing consultancy services (see 3.2 ISO 17065). Provisions about functional independence deleted.
4.2	4.2	New requirement and NOTE added.

4.2.3	4.2.3	Requirements for the sharing of resources amended.
-	4.2.4	Point 4.2.4 with new requirements for risk management added.
4.2.6	4.2.6	Text clarified to avoid repeating provisions of IOD 2016.
5.1	5.1	Table 6 updated to take into account the amendments in the roles.
5.1	5.1	Provisions for the appointment of more than one role to one person per project added.
5.2	5.2	Point 5.2.1 with new requirements added.
6.1.1.1	6.1.1.1	New requirements added.
6.1.1.2	6.1.1.2	Minor modification (definition of NB Rail). Text for assessment of the competence amended.
6.1.2.1.	6.1.2.1	*NOTE 2* and *NOTE 3* added. Requirements for staff performing testing added.
-	6.1.3	Point 6.1.3 b) with new requirement for the contract with the personnel added.
6.2	6.2	Introduction to point 6.2 added.
-	6.2.1	Point 6.2.1 with new requirements added.
6.2.2.2	6.2.2.2	Clarification on AsBo role in conformity assessment added.
7.1.2	7.1.2	NOTEs' numbering updated. Voluntary standards changed to industrial standards. Clarification on AsBo role in conformity assessment added in *NOTE 6*.
7.2	7.2	Clarification on AsBo role in conformity assessment added in *g)*.
-	7.4.3	Point 7.4.3 with new requirements and NOTEs for the evaluation tasks performed by NoBos and AsBos added.
-	7.4.4	Point 7.4.4 with new requirements and NOTEs for the evaluation tasks performed by NoBos and AsBos added.
-	7.4.5	Point 7.4.5 with clarifications on AsBo role in conformity assessment added.
-	7.4.6	Point 7.4.6 with clarifications on AsBo role in conformity assessment added.
7.4. TESTING	Annex F	Numbering, reference amended.
[*introduction*]	F.0.	New requirements and *NOTE 3* added.
7.4. TEST. B	F.2.	The list of EN ISO/IEC 17025 requirements updated.
7.4. INSPECTIONS	Annex G	Numbering, reference amended.
7.4. ISP. A	G.0.	Heading 'General' added.
7.4. ISP. A	G.1.	Text added and modified: 1. Acceptable Means of Compliance (AMOC);

		2. documents of the coordination group of notified CAB referred to in Article 30 (6) of Regulation (EU) 2016/796 (e.g. RFUs, Q/Cs and FAQs) Table 8 renumbered as Table 9
7.4. QUALITY MANAGEMENT SYSTEM APPROVAL	Annex H	Numbering, reference amended. Text added: Point H.0. New reference to Annex E for the document flow of the evaluation task.
7.4. QMS.C - Audit programme	H.3. QMS – Audit programme	Added NOTE 2 with clarifications on frequency of periodic surveillance. Added NOTE 3 with clarifications on re-certification cycle.
7.4. QMS.G - Determining audit objectives, scope, criteria and topics	H.7.3. Audit criteria	NOTE 2: "*voluntary standard*" replaced by "*industrial standard*" AC source 8: "*NB-Rail coordination group*" replaced by "*coordination group of notified CAB referred to in Article 30 (6) of* Directive (EU) 2016/797".
	H.7.4. Audit topics	NOTE 3: Reference *to ISO 9001:2008* has been removed NOTE 4: Reference *to ISO 9001:2008* has been removed
7.6	7.6	*NOTE 2* corrected, bullet point *"other board, group of persons or person described in this document, such as (e.g.) technical manager, etc."* deleted.
7.7	7.7	New requirements and *NOTE 2* added.
Annex C	C.0.	Alphanumeric numbering of subsections introduced. Text modified to take into account the role and competences of the "*technical lead evaluator*" as well as lead inspector, inspector, lead auditor and auditor.
DECISION MAKER	C.1.3.1.	TSIs: acceptable means of compliance and "*voluntary standards*" replaced by "i*ndustrial standards*". Added legal references to PA VA and Regulation 2019/250.
TECHNICAL REVIEWER	C.2.3.1.	Legal references updated. Legal references added: EN ISO/IEC 17065 and the relevant requirements for the CAB evaluation processes based on EN ISO/IEC 17020, EN ISO/IEC 17021-1 and EN ISO/IEC 17025 in combination with the ERA Assessment Scheme. Interrelations to the RSD 2016 and to the Regulation on CSM-RA: allocation of roles and responsibilities and risk and safety management. EN ISO/IEC 17065 and the relevant requirements for the CAB evaluation processes based on EN ISO/IEC 17020, EN ISO/IEC 17021-1 and EN ISO/IEC 17025 in combination with the ERA Assessment Scheme, ERA documents. TSIs: acceptable means of compliance, mandatory and informative ERTMS specifications and text modified "*voluntary standards*" to "*industrial standards*".

-	C.2.3.3.	Non-technical skills: new requirements defined.
TECHNICAL MANAGER	C.3. Technical lead evaluator	"*Technical Manager*" renamed "*Technical lead evaluator*". *"Technical lead evaluator has the overall authority and responsibility to ensure that all project activities of the evaluation phase are correctly prepared, executed and documented in reports and other records […]".*
INSPECTOR	C.4.2.2.	Requirements for the minimum participation in projects, and related assessments, modified.
-	C.4.3.1.	Added "*ERA documents*" and "*Documents of the Coordination group of the notified bodies*".
-	C.4.3.2.	Improved consistency, requirements from other sections integrated, e.g.: • "Sound understanding of the interfaces with other technical scope related to interoperability and safe integration"; • **Technical standards:** depending on the relevant parts of Annex D: - General broad overview of the content of the standards quoted in the applicable TSIs, and Ability to understand and evaluate the content of the industrial standards which can be used in the designing or manufacturing phases.
-	C.4.3.3.	Improved consistency to include only non-technical skills.
LEAD INSPECTOR	C.5.	Description of the role improved: "*The lead inspector has the overall authority and responsibility to ensure that all project inspection activities of the evaluation phase are correctly prepared, executed and documented in reports and other records […]*".
QMS LEAD AUDITOR	C.6.1.	Description of the role improved: "*The QMS lead auditor has the overall authority and responsibility to ensure that all project auditing activities of the evaluation phase are correctly prepared, executed and documented in reports and other records […]*".
-	Appendix A	Appendix A "*Comparative table of roles and competences specified in Annex C to ERA Assessment Scheme (Technical Document 000MRA1044 v. 2.0)*" introduced for Annex C. Appendix A is published as a separate document.
D1 - INFRASTRUCTURE General	D.1.1	Scope description improved.
D.2 - ENERGY General	D.2.1	Scope description improved.
D.3 - CONTROL - COMMAND AND SIGNALLING	D.3.6	Requirement added: Mandatory (ERA CCS subset requirements, etc.) and informative ERTMS specifications.

D.4 - ROLLING STOCK	D.4.1	Added "***General***" section to describe the scope.
Annex E	Annex E	Flow chart in figure 1 and the NOTES updated to take into account modifications in the scheme, e.g. clarifications on AsBo role (NOTE 4), added NOTE 6 and NOTE 7.
Annex F	Annex I	References to 2008 versions of EN ISO 9001 removed. NOTE 1 added to link the topics' list with H.7.4.
-	Annex J	New Annex '*Impartiality & independence of a CAB and its personnel in relation to their role and consultancy activities*' added.

Bibliography

Text in EN ISO/IEC 17065 applies.

END OF THE DOCUMENT

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