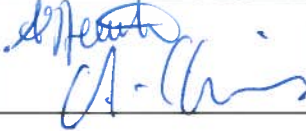



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Technical document

REQUIREMENTS FOR CONFORMITY ASSESSMENT BODIES SEEKING NOTIFICATION

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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 as Agency Regulation 2016/796 Art 34.4.

The 27th of June 2017, the Management Board of the Agency adopted its Decision No. 156 “*Provisions on auditing notified conformity assessment bodies in the framework of Article 34 § 3 of Regulation (EU) 2016/796*”, to which this document refers.

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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PART 1: 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 fulfills 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 continues fulfilling the requirements identified in the Interoperability Directive (EU) 2016/797.

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) – **accreditation** path, or
- › a relevant national authority complying with the legal requirements identified in the Interoperability Directive (EU) 2016/797 – **recognition** (i.e. non accreditation) path.

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

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 pending on the path followed, within:

- › two weeks if **accreditation**, or
- › two months if **recognition**.

NOTE 1: The 'Blue Guide' on the implementation of EU product rules 2016 provides an exhaustive description about the above topics. See <http://ec.europa.eu/DocsRoom/documents/18027>.

About this technical document

This technical document is composed by:

- › **PART 1 INTRODUCTION**
which introduces the topic of assessments and accreditation/recognition for NoBos, including references.
- › **PART 2.A FRAMEWORK**
which provides an overarching framework for the application of the requirements described in PART 2.B.
- › **PART 2.B REQUIREMENTS**
which provides requirements to apply when assessing bodies seeking notification under the IODs.

NOTE 1: In this document the terms conformity assessment bodies (CAB) and "certification body" (in reference to the ISO/IEC 17065) are considered synonyms.

1. Abbreviations and acronyms

Table 1 : Table of abbreviations and acronyms

<i>Abbreviation, acronyms</i>	<i>Meaning</i>
EA	European Co-operation for accreditation as defined by art. 14 of [14]
EC	European Commission
MS	European Union Member State
AT	Assessment team
ERA, Agency	European Union Agency for Railways as defined by [20] in <i>Table 3</i>
NAB	National Accreditation Body as defined by art. 4 of [15] in <i>Table 3</i>
NSA	National safety authority as defined by [19] in <i>Table 3</i>
CAB	Conformity Assessment Body
Decision 713/2010, decision on railway modules,	Document [16] described in <i>Table 3</i>
Decision on generic modules	Documents [14] described in <i>Table 3</i>
TSI	Technical Specification for Interoperability
Regulation on CSM-RA, CSM-RA	Document [17] described in <i>Table 3</i>
IOD 2008	Document [11] described in <i>Table 3</i>
IOD 2016	Document [18] described in <i>Table 3</i>
QMS	Quality Management System
ISO/IEC 17065	Document [1] described in <i>Table 2</i>
ISO/IEC 17021	Document [2] described in <i>Table 2</i>
ISO/IEC 17020	Document [3] described in <i>Table 2</i>
ISO/IEC 17025	Document [4] described in <i>Table 2</i>
ISO/IEC 17011	Document [5] described in <i>Table 2</i>
ISO 9001	Document [8] described in <i>Table 2</i>
ISO 19011	Document [10] described in <i>Table 2</i>
ILAC	International Laboratory Notification Cooperation - The international organisation for notification bodies operating in accordance with ISO/IEC 17011 and involved in the notification of conformity assessment bodies
IAF	International Notification Forum. The IAF is the world association of conformity assessment notification bodies and other bodies interested in conformity

<i>Abbreviation, acronyms</i>	<i>Meaning</i>
	assessment in the fields of management systems, products, services, personnel and other similar programmes of conformity assessment
RSD	Railway safety Directive, Document [19] described in <i>Table 3</i>

2. Reference documents

The knowledge of these standards is a fundamental prerequisite for a correct understanding of this document.

Table 2 : Table of reference documents

<i>Ref</i>	<i>Title</i>	<i>Version</i>
[1]	EN ISO/IEC 17065 - Conformity assessment — Requirements for bodies certifying products, processes and services	2012
[2]	EN ISO/IEC 17021-1 - Conformity assessment - Requirements for bodies providing audit and certification of management systems	2015
[3]	EN ISO/IEC 17020 - Conformity assessment — Requirements for the operation of various types of bodies performing inspection	2012
[4]	EN ISO/IEC 17025 - General requirements for the competence of testing and calibration laboratories	2005
[5]	EN ISO/IEC 17011 - Conformity assessment - General requirements for notification bodies accrediting conformity assessment bodies	2004
[6]	IAF MD 5 - Determination of Audit Time of Quality and Environmental Management Systems - Issue 3, issued on 09 June 2015; Application from 09 June 2016	2015
[6 bis]	EA-2/17 INF - EA Document on Accreditation for Notification Purposes	2014
[7]	ISO 9000 - Quality management systems — Fundamentals and vocabulary	2015
[8]	ISO 9001 - Quality management systems — Requirements	2008
[9]	ISO 9001 - Quality management systems — Requirements	2015
[10]	ISO 19011 - Guidelines for auditing management system	2011

3. Reference legislation

The knowledge of this legislation is a fundamental prerequisite for a correct understanding of this document.

Table 3 : Table of reference legislation

<i>Ref</i>	<i>Title</i>	<i>Reference</i>
[11]	Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community	OJ L 191, 18.07.2008
[12]	Directive 2004/49/EC of the European Parliament and of the Council of 29 April 2004 on safety on the Community's railways and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on	OJ L 164, 30.04.2004, p. 44,

<i>Ref</i>	<i>Title</i>	<i>Reference</i>
	the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification (Railway Safety Directive)	
[13]	Regulation (EC) N°1335/2008 of the European Parliament and of the Council of 16 December 2008 amending Regulation (EC) No 881/2004 establishing a European Railway Agency (Agency Regulation)	OJ L 354, 31.12.2008
[14]	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
[15]	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
[16]	Commission Decision 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 (2010/713/EU)	OJ L 319, 04.12.2010
[17]	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
[18]	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 138/44, 26.5.2016
[19]	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
[20]	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
[21]	REGULATION (EC) No 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
[22]	REGULATION (EC) No 45/2001 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2000 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

NOTE 1: the above legislation is in each case meant to include all the applicable amendments.

PART 2.A: FRAMEWORK

1. Objectives of the 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 this assessment scheme shall be provided in the:

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

NOTE 1: This assessment scheme is not modifying the legal framework in which it is established.

2. Application of this assessment scheme

This assessment scheme is addressed to appointed Member States notifying authorities as

- › IOD 2016 art.27.1, and
- › IOD 2008 art. 28.1.

The appointed Member States notifying authorities should apply this scheme in the framework of the necessary procedures set up and carried out concerning the assessment of the conformity assessment bodies for the interoperability Directives.

3. Scheme owner

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

4. Baseline standard for the assessment scheme

A common reference standard is needed for the 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 conformity assessment body may be demanded to perform in relation to the assigned modules described in the relevant TSI(s).
- › The 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".

NOTE 1: An installation is a specific form of product.

5. Legal requirements

This scheme is based on the harmonised standard EN ISO/IEC 17065:2012 "Conformity assessment – requirements for bodies certifying products, processes and services".

According to art. 33 of the interoperability Directive EU 2016/797, conformity with a harmonised standard presumes compliance with the requirements set out in the same directive EU 2016/797.

5.1. Comparison between legal requirements and this scheme

IOD 2016 and IOD 2008 provide legal requirements for notified conformity assessment bodies:

- › IOD 2016 art. 30, 31, 32 and 34
- › IOD 2008 ANNEX VIII.

Compliance to the requirements identified in this assessment scheme ensures compliance with the requirements of both directives.

The following table links the legal requirements of these directives and those of this assessment scheme.

NOTE 1: The following table is based on EA-2/17 INF: 2014 - ANNEX B. See document [6bis] in table 2 of this document.

Table 4 : requirements comparison: directives and assessment scheme

<i>2008/57/EC ANNEX VIII</i>	<i>Clause in text</i>	<i>EU 2016/797</i>	<i>Clause in text</i>
1	4.2	Art 30(1)	Not applicable
2	4.2	Art 30(2)	4.1.1
2-second sentence	4.1	Art 30(3)	6.1, 6.2, 7.1, 7.4, 7.6
3	4.3	Art 30(3a, b, c)	4.4, 7.1, 7.3, 7.4, 7.10
4	6.1	Art 30(3-last sentence)	4.3, 6.2, 7.3
5	4.2	Art 30(4)	4.3
6	4.3	Art 30(5)	4.5
7	4.5	Art 30(6)	4
		Art 30(7)	4
		Art 31(1)	4.2
		Art 31(2)	4.2, 5.2
		Art 31(3, 4)	4.2
		Art 31(5)	4.2, 6.2
		Art 32(1 a, b, c, d)	6.1, 6.2
		Art 32(2)	4.2, 5.2
		Art 33	Not applicable
		Art 34(1, 2, 3, 4)	6.2

6. Cycle for this assessment scheme

The cycle shall conform to the provisions in point 7.11 of ISO/IEC 17011.

7. Cooperation between notifying authorities and other entities

Notifying authorities are encouraged to cooperate with/delegate other entities for the application of this assessment scheme.

NOTE 1: the suggested cooperation is between notifying authorities (or their delegates) 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 path*
- › *Relevant national authorities for recognition path*
- › *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 art. 28 of IOD 2016
- › may be used as the procedure for assessment referred to in art. 29 of IOD 2008.

8.1. Principles

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

- › Independence,
- › competence, and
- › efficiency.

NOTE 1: the ISO/IEC 17011 clause 7.5.2 provides clarification 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 ISO/IEC 17065 and by Part 2.B of this document, and
- › in the shortest time and with the lowest cost for the CAB.

8.2. 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: do not confuse the roles defined above with the boards, group of persons or person described in Part 2.B of this document point 5.1.3: the first set of roles refers to the notifying authority assessment team, the second to the CAB.

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 name, title provided for those roles may vary in each notifying authority assessment team, however the competence should remain the same as listed.

8.2.1. 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.

8.2.2. AT Assessor (AS)

This person is 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.

For complex projects, the LA and AS may need the support of Technical Experts (TEs).

8.2.3. AT Technical expert (TE)

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

8.3. 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 assessment entity shall ensure that the highest level of independence is maintained in the assessment team.

Where a member of the assessment team has previously worked for the CAB being assessed, he/she cannot be part of the assessment team until a minimum period of two years has elapsed since he/she last worked for the CAB.

The person of the assessment entity who is responsible for independence of staff can be consulted in the event of any queries regarding the compliance 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.

8.4. 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

<i>Function</i>	<i>Competence</i>
AT Lead Assessor	Qualified as lead assessor in ISO/IEC 17065. Knowledge of assessment scheme for notified bodies for railways.
AT Assessor	Qualified as assessor in ISO/IEC 17065. Knowledge of assessment scheme for notified bodies for railways.
AT Technical expert	Qualified as technical expert in at least part of scope of assessment described in this scheme. Knowledge of assessment scheme for notified bodies for railways.

8.5. Principles of efficiency

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

9. Information to provide

At least the following information shall be included as output of the notifying authority assessment.

- › Assessment standard: EN ISO/IEC 17065:2012 together with the SCHEME FOR ASSESSMENT FOR THE PURPOSE OF NOTIFICATION UNDER THE DIRECTIVE (EU) 2016/797 or 2008/57/EC. Scheme version 2016.
- › Scope of assessment as defined by the assessment scheme.
- › Signature of the responsible person of the body performing the assessment of the CAB
- › Legal basis
- › Reference to annexes of the certificate
- › Output unique identification number
- › Validity date

Assessment certification and related scope definition shall be publicly available (e.g. on the internet web site of the related notifying authority).

NOTE 1: Usually the output of an assessment is a document stating the positive result of the assessment (e.g.) a certificate.

PART 2.B: REQUIREMENTS

Reading instructions

Conformity assessment bodies (hereafter “CABs”) seeking notification by Member States to the European Commission, within the scope of the EU Railway Interoperability Directives 2016/797/EC (IOD 2016) or 2008/57/EC (IOD 2008) have to fulfill the requirements hereunder described.

This 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.
- › This assessment scheme does not contradict nor exclude any of the requirements of the EN ISO/IEC 17065:2012.
- › This assessment scheme provides amplified criteria for the railway interoperability directives (ref. page v of the EN ISO/IEC 17065:2012).

This PART 2.B:

- › shall be read together with ISO/IEC 17065, and
- › follows the same numbering structure of the 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 ISO/IEC 17065 where indicated.

An introductory sentence *in italic* provides information on how and where to include the text in the ISO/IEC 17065. These sentences in italic shall be considered as metadata (aid in structuring the text).

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

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

Foreword

Text in ISO/IEC 17065 applies.

Introduction

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

This document describes amplified criteria for the railway interoperability directives 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 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: this 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.

There are four possible scopes, as listed below:

- › Infrastructure;

- › Energy;
- › Control, Command and Signalling;
- › Rolling stock

NOTE 2: the four scopes above represent four products. Other possible scopes, as substructure of the above scopes, are possible if they lead to a certification decision which may grant certificates of verification for railway subsystems. A possible substructure may be (e.g.) for freight wagons.

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

CABs can be assessed for one or several of these scopes.

NOTE 4: the assessment scope “control command and signalling” covers both subsystems, including interoperability constituents, of:

- › *trackside control-command and signalling, and*
- › *on-board control-command and signalling.*

Each scope of assessment:

- › contains all the applicable railway modules as described in the relevant TSI or TSIs; and
- › is underpinned by one or more relevant TSI.

In case the CAB has a documented procedure covering:

- › the analysis of changes from a TSI caused by a TSI amendment;
- › the resulting competence requirements triggered by such changes and implemented solutions, and
- › any necessary upgrade of internal CAB documents and templates,

then the CAB shall be permitted to claim that the assessment scope includes also such TSI amendment.

The CAB shall provide adequate information to the notifying authority responsible for assessment and to the notifying authority.

NOTE 5: This information can be provided during the annual supervision performed by notifying authority.

2. Normative references

Text in 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 skill 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 activity could lead to a positive or negative result.

3.16 Accredited test

Accredited test means:

- › a test performed by an test laboratory accredited under the 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 verification procedure regarding notified national technical rules for implementing the essential requirements when:

- › no relevant TSI exists, or
- › a derogation has been notified, or
- › a specific case requires the application of technical rules not included in the relevant TSI.

3.18 CSM-RA assessment Bodies (AsBo)

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

4. General requirements

The following text shall be added immediately after the clause 4 and immediately before clause 4.1

The CAB shall commit itself in writing to:

- › follow the activities and apply the documents of the coordination group of notified bodies NB Rail,
- › participate to all the coordination group plenary meetings or shall demonstrate that they are informed about the meetings and about the findings, and
- › For CABs assessed for the Control, Command and Signalling scope, participate to the activities of the ERTMS group referred in art. 29 of the 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);
- › be functionally independent from any of the following entities:
 - authorities designated to issue:
 - authorisations for placing in service structural subsystems and railway vehicles,
 - licences,
 - safety certificates,
 - bodies in charge of investigations in the event of accidents.

4.2. Management of Impartiality

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

The risk identification shall include the following elements:

- › Ownership of the CAB, including the list of the major share owners;

- › Description of shared resources, including personnel, facilities and finance, and branding.

Sharing resources with any of the entities listed in ANNEX VIII of the IOD, point 2 (ref. to point 4.1 of this document) is considered as unacceptable risk of impartiality for the CAB.

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.

- a) CAB shall not be also the supplier, purchaser, owner, user of the products which they assess, or the authorised representative of any of those parties.

The CAB, its top-level management and the personnel responsible for carrying out the activities for evaluation (ref. point 7.4 of the ISO/IEC 17065), review (ref. point 7.5 of the ISO/IEC 17065) and certification decision ((ref. point 7.6 of the ISO/IEC 17065) shall not be directly involved in the design, manufacture or construction, marketing, installation, use or maintenance of those products, or represent the parties engaged in those activities.

NOTE 1: the text above implement the provisions of art 31.3 and 31.4 of the IOD 2016

- d) CAB shall not offer any consultancy, as defined in 3.2.a of ISO/IEC 17065, towards any client within the scope of the CAB notification;

- e) CAB shall not offer any QMS consultancy or internal audit to any 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 ISO/IEC 17065 applies.

4.4. Non-discriminatory conditions

Text in ISO/IEC 17065 applies.

4.5. Confidentiality

Text in ISO/IEC 17065 applies.

4.6. Publicly available information

Text in 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 this 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
h)	Decision maker
g)	Technical reviewer
f)	Technical manager (per scope of assessment)

NOTE 2: all the boards, persons or groups of persons as described in 5.1.3 of ISO/IEC 17065 shall be identified for the purposes of assessment; however only the boards, persons or groups of persons as described in the previous table (i.e. Decision maker, Technical reviewer and Technical manager) have been detailed for the specific purpose and scope of this document.

5.2. Mechanism for safeguarding Impartiality

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.

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 the table of 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 5.1.3 bullet points h), g) and f) shall be able to participate and contribute actively to notified bodies coordination group meetings held in English (e.g. NB-Rail).

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

Table 7 : Competence composition description

ITEM	SUB ITEM	NOTES
Description		<i>Activity to perform</i>
Training and Experience	<ul style="list-style-type: none"> › General › Specific in addition to general 	<i>Achieved academic grade and recorded professional experience</i>
Knowledge	<ul style="list-style-type: none"> › Legal framework › Technical topics › Non-technical skills 	<i>Details on needed theoretical knowledge related to the job assigned</i>

The assessment of the competence shall be performed by the notifying authority assessment team by means of interviews and review of evidences.

ANNEX C provides the detailed competence description on the above mentioned board, group of persons or person identified in the table of 5.1.3 bullet points h), g) and f)

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 include also the following elements: initial competency assessment, ongoing training, competency re-assessment and monitoring.

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

The criteria for the competence the board, group of persons or person identified in table of 5.1.3 bullet point h), g) and f) 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 skills monitoring, the following requirements shall apply:

- › for inspectors: points 6.1.8 and 6.1.9 of ISO/IEC 17020, and
- › QMS Assessors: points from 7.2.9 to 7.2.11 of ISO/IEC 17021-1.

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

The modifications of the records do not trigger an additional assessment from notifying authority.

6.2. Resources for evaluation

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 fulfill the requirements as described in point 7.4 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:

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

The CAB may also outsource evaluation activities to a CAB notified under the IOD 2016 or IOD 2008 (as applicable) 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 ISO/IEC 17020). Reasons to subcontract can include the following (see NOTE 1 on point 6.3.1 of the 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 on point 6.2.2.1 of ISO/IEC 17065). Such hired personnel shall carry out its activities under the responsibility and quality system of the NoBo. 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 NoBo 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 NoBo as part of the client evidence production activities. Some flexibility is allowed as regards 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.

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 prescription of the chapter 6 of the relevant TSI(s) and with the limits of responsibilities defined in the chosen module(s).

Conditions for confidence are described in section 7.4.TEST of this document.

NOTE 1: different conditions apply for accredited test and not-accredited test.

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 2008 and IOD 2016
- › requirements included in the decision for railway modules;
- › basic parameters included in the text of the TSIs;
- › standards quoted in the text of 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 order to meet the essential requirements as defined in the TSIs

NOTE 2: those standards are usually called voluntary 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 3: those standards are usually called voluntary standards.

- › ERA technical opinions;
- › ERA technical documents.

NOTE 1: this assessment scheme includes implicitly an “evidence phase” which is not defined in the 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.

Fig 3 on this PART 2 “Annex E” provides a graphical representation:

- › *Evidence phase (not included in the ISO/IEC 17065); it is performed by other organisation than the CAB seeking notification;*

- › *Evaluation (included in the ISO/IEC 17065 - see point 7.4); it is performed by the CAB seeking notification;*
- › *Review (included in the ISO/IEC 17065 – see point 7.5); it is performed by the CAB seeking notification;*
- › *Certification decision (included in the ISO/IEC 17065 – see point 7.6); it is performed by the CAB seeking notification.*

NOTE 2: 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, 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:

- › name and address of the applicant and, if the application is lodged by the authorised representative, the name and address of the authorised representative;
- › 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;
- › all relevant information for the product including Type (i.e. product ID, product definition), and product (i.e. configuration, version, interfaces);
- › all the applicable TSIs, including any available or expected derogations;
- › the choice of the module or modules for assessment;
- › the scope of ISV (if the application refers to an ISV);
- › the declaration in writing containing the statement “that the same Application has not been lodged with any other Notified Body”;
- › any useful EC Certificate, Technical File, Technical Documentation;
- › in case of use of ISVs also ISV Certificates, ISV Technical Files, ISV Declarations of any preceding Modules or ISVs. 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 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 7.4.9: The following text shall be added at the end of the point.

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

NOTE 1: according to the reading instructions, this point 7.4.9 is here misplaced. It is placed in this part of the document, after point 7.4.1, only to improve the readability of this document.

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

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

- › Testing,
- › Inspection, and
- › Quality Management System Approval.

TESTING

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

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

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

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

- › accredited test;
- › non-accredited test.

NOTE 1: It is common practice that tests are not performed directly by the CAB but by other bodies with the details provided in “7.4.TEST.A – Accredited test” and/or “7.4.TEST.A – 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”.

7.4.TEST.A – 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 both acceptance criteria.

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 assessment mark and/or the assessment ID-number, and
- › if the CAB has received a copy of assessment 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 assessment.

NOTE 3: the assessment certificate and its annex can be also provided electronically via website.

7.4.TEST.B – 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 ISO/IEC 17025 as below:
 - Point 4.1 Organisation
 - Point 4.5 Subcontracting of tests and calibrations
 - Point 4.9 Control of nonconforming testing and/or calibration work
 - Point 5.2 Personnel

- Point 5.3 Accommodation and environmental conditions
 - Point 5.4 Test and calibration methods and method validation
 - Point 5.5 Equipment
 - Point 5.6 Measurement traceability
 - Point 5.7 Sampling
 - Point 5.8 Handling of test and calibration items
 - Point 5.9 Assuring the quality of test and calibration results
 - Point 5.10 Reporting the results
- › 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);
 - › CAB assesses periodically, at least every 24 months, the laboratory to demonstrate that its competence is maintained, as far as required for the purpose of the certification.

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

INSPECTIONS

The evaluation activities related to inspections shall follow the applicable requirements of 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.

7.4.ISP.A Inspection methods, procedures and requirements

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

Point 7.1.1 of 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. Dec 713/2010, Annexes in TSIs, etc.);
- › the text of the TSIs;
- › standards quoted in the text of 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 voluntary standards.

- › ERA technical opinions;
- › ERA technical documents;
- › NB-Rail coordination group documents (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, procedure 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 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, voluntary 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 point 7.4.ISP.B;
- › 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 categorised by 3 kinds of results: Compliant, Non-compliant, 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 point 7.4.ISP.D of this document.

Table 8 : 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 L&P TSI Clause 4.2.3.4.2 (3) Running dynamic behaviour	> 6.2.3.4 >Appendix J-1 >EN14363:2005 (relevant clauses) >Appendix J-2(2) >ERA/TD/2012-17/INT rev 3.0	assessment to be based on EN14363:2005 Lambda-evaluation to reference vehicle	>Test Report to EN14363:2005 for reference vehicle – document ID code “XYZ” >manufacturers description and calculation for Lambda-evaluation - document ID code “ABC”	Compliant, Mrs.Smith, 02.03.2016	>Max. speed =160km/h >Max axle load =14,3t
i+1

7.4. ISP.B Inspection items and samples

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

Point 7.2.1 of 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, isvs 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, nvr, etc.).

The above items and samples for inspection shall:

- › be inspected using the methods and procedures described in point 7.4.ISP.A 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.

7.4.ISP.C Inspection Records

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

7.4. ISP.D 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 recommendation 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 typically should be included in the technical file supporting the EC certificate at the end of the certification phase.

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

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

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

Point 7.4.2 of ISO/IEC 17020 applies with the following elements:

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

Points from a) to e) apply without modifications.

Point f) 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 7.4.ISP.A of this document.

Point g) 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 this document.

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

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

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

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

NOTE 2: Point 7.4.3 of ISO/IEC 17020 shall not apply.

QUALITY MANAGEMENT SYSTEM APPROVAL

The evaluation activities related to quality management system shall follow the applicable requirements of ISO/IEC 17021 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 and in this Scheme, the term “Management System Certification” of the ISO/IEC 17021 shall be read as “Quality Management System Approval in the framework of the IOD for a precisely defined product”.

7.4.QMS.A – Application

Points from 9.1.1.a to 9.1.1d of ISO/IEC 17021 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 shall be aligned with language of the Technical File.

- › any other information as required by the module description in decision 2010/713/EU.

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

7.4.QMS.B – Application review

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

7.4.QMS.C - Audit Programme

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

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

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 ISO/IEC 17021 shall apply with amplified requirements described below.

The audit programme shall explain the full certification cycle. For 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 ISO/IEC 17021 (nominally three years) and the QMS approval provided by the Decision on Railway modules.

Point 9.1.3.4 of ISO/IEC 17021 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 point 7.4.QMS.G of this document.

7.4.QMS.D – Determining audit time

Point 9.1.4 including all the subsections of ISO/IEC 17021 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 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.

7.4.QMS.E – Multi site sampling

Point 9.1.5 ISO/IEC 17021 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.

7.4.QMS.F – Multiple management systems

Point 9.1.6 ISO/IEC 17021 applies.

7.4.QMS.G – Determining audit objectives, scope, criteria and topics

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

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

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

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.

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.

AUDIT CRITERIA

The audit criteria are specific to this 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. Dec 713/2010, 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 voluntary standards.

- AC source 6: ERA technical opinions.
- AC source 7: ERA technical documents.
- AC source 8: NB-Rail coordination group documents (e.g. RFUs, Q/Cs, FAQs).

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 developed 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)

NOTE 3: for information and further guidance, in Annex F of this document are provided references from these audit topics to 2010/713/EU, to ISO 9001:2008 and ISO 9001:2015.

As long as all Audit Criteria are satisfied, this scheme is not mandating the auditee to operate a QMS based on ISO 9001.

If the QMS is evaluated according to

- › such H-type Modules where the product must be based on an “existing design” or
- › any D-type Module,

the CAB may have a documented procedure to exclude the audit criteria related as following:

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 F 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 9001:2008 or ISO 9001:2015.

7.4.QMS.H - Audit team selection and assignments

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

The competence criteria of the audit team leader shall be as described in point 6.2 of ISO/IEC 17065 as “QMS LEAD AUDITOR”.

7.4.QMS.I - Audit plan

Point 9.2.3 including all the subsections of ISO/IEC 17021 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.

7.4.QMS.L - Initial certification audit

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

7.4.QMS.M - Conducting audits

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

The findings referred to in ISO/IEC 17021 9.4.8.2.k shall be reported separately for each audit criterion listed in point 7.4.QMS.G of this document.

NOTE 1: It is good practice, to perform audit stage1 as remote audit.

7.4.QMS.N - Approval decision

Point 9.5 including all the subsections of ISO/IEC 17021 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.

7.4.QMS.O - Maintaining approval

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

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

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 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 Annex C.

NOTE 1: it is a good practice to have in 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...)

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;*
- › *other board, group of persons or person described in this document, such as (e.g.) technical manager, etc.*

7.7. Certification documentation

Text in ISO/IEC 17065 applies.

7.8. Directory of certified products

Text in ISO/IEC 17065 applies.

7.9. Surveillance

Text in ISO/IEC 17065 applies.

7.10. Changes affecting certification

Text in ISO/IEC 17065 applies.

7.11. Termination, reduction, suspension or withdrawal of certification

Text in ISO/IEC 17065 applies.

7.12. Records

Text in ISO/IEC 17065 applies.

7.13. Complaints and appeals

Text in ISO/IEC 17065 applies.

8. Management system requirements

8.1. Options

Text in ISO/IEC 17065 applies.

8.2. General management system documentation (Option A)

Text in ISO/IEC 17065 applies.

8.3. Control of documents (Option A)

Text in ISO/IEC 17065 applies.

8.4. Control of records (Option A)

Text in ISO/IEC 17065 applies.

8.5. Management review (Option A)

Text in ISO/IEC 17065 applies.

8.6. Internal audits (Option A)

Text in ISO/IEC 17065 applies.

8.7. Corrective actions (Option A)

Text in ISO/IEC 17065 applies.

8.8. Preventive actions (Option A)

Text in ISO/IEC 17065 applies.

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

Text in ISO/IEC 17065 applies.

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

Text in ISO/IEC 17065 applies.

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Annex C (Normative) Competence descriptions

This Annex does not exist in the 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;
- › technical manager (per scope of assessment).

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

DECISION MAKER

Description: he/she is the person(s) assigned to make certification decision as described in 7.6.2.

Training and experience

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.

Specific in addition to General:

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

Knowledge

Legal framework:

Basic understanding on the following topics:

- › **Interoperability Directives 2008/57/EC and 2016/797:** role of NoBo, EC conformity assessment, EC suitability of use, EC verification, art. 18 on the role of NoBo in the process of verification, authorization place in service for structural subsystems and for vehicles, role

- of: applicant, NoBo, DeBo, Assessment bodies under the CSM-RA; upgrade/renewal of an existing subsystem; European legal framework and National legal framework.
- › **Railway modules:** decision on modules 713/2010, difference between module with QMS and without QMS, Applicable modules according to TSIs.
 - › **Railway Safety directive:** CSM-RA, legal text and Annex I.
 - › **Technical Specifications for Interoperability:** Text structure, affected subsystem per TSI, concepts of mandatory standards, voluntary standards, European standard, harmonised standard, alternative solutions.
 - › **Technical standards:** depending on the scope of the assessment:
 - knowledge of the content of the standards quoted in the TSIs which are underpinning the assessment scope, and
 - Ability to understand and evaluate the content of the industrial standards which can be used at designing or manufacturing phases.
 - › **Commission recommendation 2014/897/EU** on matters related to the placing in service and use of structural subsystems and vehicles under Directives 2008/57/EC and 2004/49/EC of the European Parliament and of the Council (also known as DV29bis).

Technical topics:

- › General understanding of all the areas from “ANNEX D: TECHNICAL TOPICS PER SCOPE OF ASSESSMENT”.

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.

TECHNICAL REVIEWER

Description: he/she is the person assigned for reviewing all the information and results related to the evaluation as described in 7.5.1 of ISO/IEC 17065.

Training and experience

General

- › 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.

Specific in addition to General

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

Knowledge

Legal framework:

Deep understanding of the following topics:

- › **Interoperability Directives 2008/57/EC and 2016/797:** role of NoBo, EC conformity assessment, EC suitability of use, EC verification, art. 18 on the role of NoBo in the process of verification, authorization place in service for structural subsystems and for vehicles, role of: applicant, NoBo, DeBo, Assessment bodies under the CSM-RA; upgrade/renewal of an existing subsystem; European legal framework and National legal framework.
- › **Railway modules:** decision on modules 713/2010, difference between module with QMS and without QMS, Applicable modules according to TSIs.
- › **Railway Safety directive:** CSM-RA, legal text and Annex I.
- › **Technical Specifications for Interoperability:** Text structure, affected subsystem per TSI, concepts of mandatory standards, voluntary standards, harmonised European standard, alternative solutions.
- › **Technical standards:** depending on the scope of the assessment:
 - knowledge of the content of the standards quoted in the TSIs which are underpinning the assessment scope, and
 - Ability to understand and evaluate the content of the industrial standards which can be used at designing or manufacturing phases.
- › **Commission recommendation 2014/897/EU** on matters related to the placing in service and use of structural subsystems and vehicles under Directives 2008/57/EC and 2004/49/EC of the European Parliament and of the Council (also known as DV29bis).
- › **Coordination group of the Notified bodies NB-Rail:** RfU, Q/C, subgroup meetings, role of ERA.

Technical topics:

- › General understanding of all the areas from “ANNEX D: TECHNICAL TOPICS PER SCOPE OF ASSESSMENT”.

Non-technical skills:

- › Good understanding of relevant documents which are only available in English, such as (for example): ERA CCS subset requirements, NB-Rail RfUs, NB-Rail Q&Cs, ERA guidance, etc.

TECHNICAL MANAGER (PER SCOPE OF ASSESSMENT)

Description: for one or more CAB scope or scopes of assessment, he/she has the overall authority and responsibility to ensure that, for all projects, all the activities of the evaluation phase are correctly prepared, executed and documented in reports and other records as described in point 7.4 of the ISO/IEC 17065. The evaluation phase includes all inspections and all QMS audits.

Training and experience

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.

Specific in addition to General

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

Knowledge

Legal framework:

Deep understanding of the following topics:

- › **Interoperability Directives 2008/57/EC and 2016/797:** role of NoBo, EC conformity assessment, EC suitability for use, EC verification, art. 18 on the role of NoBo in the process of verification, authorization place in service for structural subsystems and for vehicles, role of: applicant, NoBo, DeBo, Assessment bodies under the CSM-RA; upgrade/renewal of an existing subsystem; European legal framework and National legal framework.
- › **Railway modules:** decision on modules 713/2010, difference between module with QMS and without QMS, Applicable modules according to TSIs.
- › **Railway Safety directive 49/2004/EC:** allocation of roles and responsibilities, the management of risk and safety performance, CSM-RA, legal text and Annex I.
- › **Technical Specifications for Interoperability:** Text structure, affected subsystem per TSI, concepts of mandatory standards, voluntary standards, European standard, harmonised standard, alternative solutions.
- › **Technical standards:** depending on the scope of the assessment:
 - General broad overview of the content of the standards quoted in the TSIs which are underpinning the assessment scope, and
 - Ability to understand and evaluate the content of the industrial standards which can be used at designing or manufacturing phases.
- › **Commission recommendation 2014/897/EU** on matters related to the placing in service and use of structural subsystems and vehicles under Directives 2008/57/EC and 2004/49/EC of the European Parliament and of the Council (also known as DV29bis).
- › **Coordination group of the Notified bodies NB-Rail:** RfU, Q/C, subgroup meetings, role of ERA.
- › **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.).

Technical topics:

- › Generic understanding as applicable from “ANNEX D: TECHNICAL TOPICS PER SCOPE OF ASSESSMENT”.

Non-technical skills:

- › ability to manage on on-going basis the CAB activities for ongoing staff training and competency assessment including staff availability for on-going projects;
- › ability to manage on on-going basis the CAB activities for evaluation;
- › competence of portfolio, programme and project management of CAB;
- › ability to form and coordinate CAB evaluation teams;

- › ability to manage subcontracted activities;
- › understanding of the interfaces within the IOD, RSD and legislation in relation to safe integration;
- › knowledge of the contents of the International standards for conformity assessment, such as EN ISO/IEC 17020, EN ISO/IEC 17021, EN ISO/IEC 17025, EN ISO/IEC 17065;
- › knowledge of the assessment scheme for Interoperability directive;
- › general knowledge of manufacturer's quality management system methodology i.e. ISO 9001;
- › interfacing with NB-Rail and knowledge of NB-Rail's RfUs, Q/Cs, FAQs, NB-Rail internal organisation and internal working documents;
- › good understanding of relevant documents which are only available in English, such as (for example): ERA CCS subset requirements, NB-Rail RfUs, NB-Rail Q&Cs, ERA guidance, etc.

The Technical manager may be supported by:

- › inspectors for inspection activities (ref. point 7.4.ISP of this document) and
- › auditors for the quality management system approval (ref. point 7.4.QMS of this document).

The inspectors and auditors shall fulfil the competence description provided in this document.

INSPECTOR (PER SCOPE OF ASSESSMENT)

Description: He/she also supports the technical manager in performing the activities related to inspections within the scope of assessment. He/she may support auditor or lead auditor acting as technical expert. He/she may also act as mentor to other inspectors.

Training and Experience

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.

Specific in addition to General

- › Training (internal or external) on the relevant requirements for the CAB inspection processes based on ISO/IEC 17020 and ISO/IEC 17065;
- › Proven experience of at least 1 year as mentoring period according to ISO/IEC 17020 point 6.1.6 including minimum participation and documented positive assessment of his/her competences in 5 projects in the relevant technical scope in which the person is intended to work as inspector.

Knowledge

Legal Framework:

- › General understanding of railway related European legal framework, including vocabulary (e.g. Interoperability Directive 2008/57/EC and 2016/797, TSIs and modules).

Technical topics:

- › Deep understanding of relevant parts of “ANNEX D: TECHNICAL TOPICS PER SCOPE OF ASSESSMENT”.

Non-technical skills:

- › good understanding of relevant documents which are only available in English, such as (e.g. ERA CCS subset requirements, NB-Rail RfUs, NB-Rail Q&Cs, ERA guidance, etc.);
- › ability to prepare and update assessment plans for the projects, including the assessment requirements;
- › understanding of the interfaces with other technical scope related to interoperability and safe integration;
- › 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 skills for preparing technical reports;
- › good quality of work;
- › impartial and non-discriminatory behaviour.

LEAD INSPECTOR

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 assessors’ works;
- › ability to supervise subcontracted activities.

QMS LEAD AUDITOR

Description: he/she supports the technical manager in the QMS audits activities.

Training and experience*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.

Specific in addition to General

- › Specific training as auditor (internal or external) based on the ISO/IEC 17021 lasting at least 5 working days or 40 hours of class room style training for lead auditing;
- › Training (internal or external) on the relevant requirements for the CAB inspection processes based on ISO/IEC 17020 and ISO/IEC 17065;
- › Participation in at least 3 audits in the railway domain, one of them shall be related to the IOD, of a team of at least 2 persons at least each one day duration at least as level of “auditor in training” (reference to 9.2.2.1.4 of ISO/IEC 17021) during the last 24 months before nomination as Lead Auditor.

Knowledge

Legal framework:

- › general understanding of railway related European legal framework, including vocabulary (e.g. Interoperability Directive 2008/57/EC and 2016/797, 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 2008/57/EC.

Technical topics:

- › Deep understanding of relevant parts of “ANNEX D: TECHNICAL TOPICS PER SCOPE OF ASSESSMENT”.
- › The QMS Lead Auditor can be accompanied by technical experts as point 9.2.2.2.2 of ISO/IEC 17021 to fulfil these requirements.

Non-technical skills:

- › auditing skills and knowledge: generic and appropriate for specific scope of assessment;
- › desirable personal behavior as described in Annex D of ISO/IEC 17021;
- › complete list of audit criteria of the complete project;
- › form and direct 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.

QMS AUDITOR

Description: he/she supports the QMS lead auditor.

Training and experience

General

One or more of the following possibilities shall apply:

- › MASTER university degree (or equivalent) in a relevant subject + 1 years 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.

Specific in addition to General

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

Knowledge

Legal framework:

- › General understanding of railway related European legal framework, including vocabulary (e.g. Interoperability Directive 2008/57/EC and 2016/797, TSIs and modules).

Technical topics:

- › Deep understanding of relevant parts of “ANNEX D: TECHNICAL TOPICS PER SCOPE OF ASSESSMENT”.
- › The QMS Auditor can be accompanied by technical experts as point 9.2.2.2.2 of ISO/IEC 17021-1 to fulfil these requirements.

Non-technical skills:

- › auditing skills and knowledge: generic and appropriate for specific scope of assessment;
- › desirable personal behaviour as described in Annex D of ISO/IEC 17021.

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

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

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

Table 9 : Applicable specific knowledge per scope of assessment

SCOPE OF ASSESSMENT	APPLICABLE LIST OF SPECIFIC KNOWLEDGE
Infrastructure	D0 + D1
Energy	D0 + D2
Command, Control and Signalling	D0 + D3
Rolling stock	D0 + D4

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.

D0 - GENERAL

A breadth of knowledge of general and specific railway

Understanding of the processes and potential defects related to the lifecycle of the railways 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.

D1 – INFRASTRUCTURE (INF, PRM, SRT)**General**

- › Assessment or design or construction or supervision of works and technical expertise in the field of EU railway infrastructure;

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;

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;

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.

D2 - ENERGY

General

- › Assessment or design or construction or supervision of works and technical expertise in the field of EU railway traction electrification;

Pantograph

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

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;

Power supply

- › Energy power supply for railways: voltage, frequency, sizing power supply subsystem;
- › Knowledge on the power supply domain, and in particular of the of 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;

Electrical safety rules

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

Documents (including referenced standards, annexes and referenced documents)

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

D3 – COMMAND, CONTROL AND SIGNALLING**General**

- › Railway signalling principles;
- › Railway communication principles;

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;

Radio communication

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

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;

Train detection system

- › Compatibility with vehicles;
- › Electromagnetic compatibility;

Documents (including referenced standards, annexes and referenced documents)

- › TSI Control Command and Signalling.

D4 - ROLLING STOCK (LOC&PAS, NOI, WAG, SRT, PRM).**Structure and mechanical parts**

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

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).

Braking

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

Passenger related items

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

Environmental conditions

- › No specific technology;

Aerodynamic effects

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

Lights, and acoustics

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

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;

Driver's cab

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

Fire safety

- › Fire behaviour of materials;

Servicing

- › No specific technology;

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.

Documents (including referenced standards, annexes and referenced documents)

- › TSI Locomotives and passenger rolling stock;
- › TSI Noise;
- › TSI Wagon;
- › 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

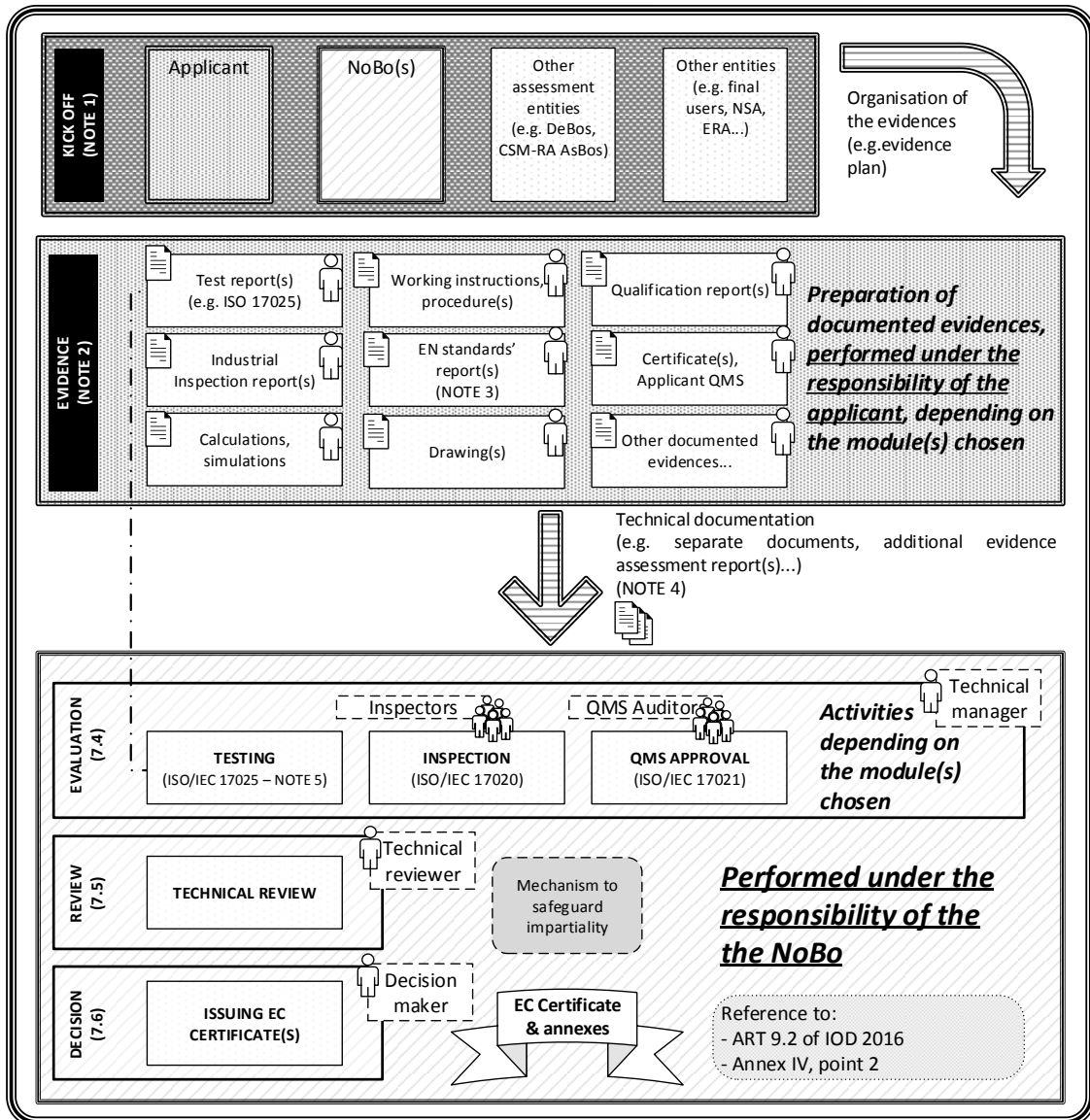
This Annex:

- › does not have a direct reference in 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 - Removed

Figure 2 - Removed

Figure 3 : Documents flow chart



NOTEs of FIG. 3:

- 1) *KICK-OFF phase has no direct reference in 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.*
- 2) *EVIDENCE phase has no direct reference in 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.*
- 3) *It may include reports according to EN 50126, 50128, 50129 (e.g. V&V, ISA etc.).*
- 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 concerned 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 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 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 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".

The NoBo is the sole decision maker for any issues of relevance whether a product/system complies with the applicable requirements.

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

Annex F (Informative) Audit Topics – correlations with ISO 9001

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

The decision 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 in both 2008 and 2015 revision.

Each element of the following list contains the correlation with 2010/713/EU and in brackets the references to the related clauses in ISO 9001:2008 and ISO 9001:2015.

NOTE 1: The following list is co-ordinated with point 7.4.QMS.G of this document.

If the applicant operates a quality management system certified by an accredited body, the audit topic shall include only the reference **highlighted in bold and underlined**. The remaining references, not bold and not highlighted, are meant to be already covered during the evaluation for ISO9001:2008 or 9001:2015 for certification by the accredited body.

1. General Aspects of QMS, QMS Documentation, Document Management

2010/713/EU: 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 9001:2008 4.1; 4.2)

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

2. Management Responsibility

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

(ISO 9001:2008 **5.1a**; 5.1b, c, d; 5.2 to 5.6)

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

3. Human Resources

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

(ISO 9001:2008 **6.1a**; 6.1b; **6.2**)

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

4. Infrastructural Resources

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

(ISO 9001:2008 **6.1; 6.3; 6.4**)

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

5. Design - Planning, Inputs, Outputs

2010/713/EU: 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 9001:2008 **7.1; 7.2; 7.2.3a,b; 7.3.1; 7.3.2; 7.3.3**)

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

6. Design - Evaluation, Verification& Validation

2010/713/EU: 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 9001:2008 **7.3.4; 7.3.5; 7.3.6**)
(ISO 9001:2015 **8.3.4**)

7. Control of Design Changes

2010/713/EU: 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 9001:2008 **7.3.7**)
(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

2010/713/EU: 2011/713/EU: 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 9001:2008 **7.1; 7.2; 7.2.3a,b; 7.5.1 ; 7.5.2; 7.5.3; 7.5.4; 7.5.5; 8.2; 8.3**)
(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

2010/713/EU: the corresponding quality control and quality management system techniques, processes and systematic actions that will be used,
(ISO 9001:2008 **7.6**)
(ISO 9001:2015 **7.1.5; 8.5.1b**)

10. Procurement and Control of purchased goods/ services

2010/713/EU: the corresponding quality control and quality management system techniques, processes and systematic actions that will be used,
(ISO 9001:2008 **7.4**)
(ISO 9001:2015 **8.4**)

11. Continuous Monitoring, Measurement, Analysis

2010/713/EU: 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 9001:2008 **8.1; 8.2.1; 8.2.2; 8.2.3 8.2.4; 8.4**)
(ISO 9001:2015 **9.1; 9.2; 9.3**)

12. Continuous Improvement – Corrective Actions, Preventive Actions (incl. project SMS)

2010/713/EU: the corresponding manufacturing, quality control and quality management system techniques, processes and systematic actions that will be used
(ISO 9001:2008 **8.5**)
(ISO 9001:2015 **10.1; 10.2; 10.3**)

Bibliography

Text in ISO/IEC 17065 applies.

END OF THE DOCUMENT
