Report

Sectorial scheme for accreditation of notified bodies under Directive 2008/57/EC

HARMONISED REQUIREMENTS

ERA/ADV/2014-15/REP-002 V 6.1

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Document History

Version	*Date*	*Comments*
6.0	17/12/2015	For ADVICE
6.1	12/01/2016	Footnote on 6.2.2.1;

Foreword

This report has been drafted by the European Railway Agency (ERA) following consultations with an ad-hoc task force composed by representatives of the following entities:

- EA: European co-operation for accreditation;
- NB-Rail: the association of the European notified bodies under the IOD;
- ANSF: the Italian national safety authority for railways;
- EBA: the German national safety authority for railways;
- EPSF: the French national safety authority for railways;
- EIM: The European association of the railway infrastructure managers;
- CER: The European association of railways;
- UNIFE: the association of the European railway industry;
- OTIF: the Intergovernmental organisation for international carriage by rail.

This publication may be translated into other languages as required. The English language version remains the definitive version; it is available on the ERA website www.era.europa.eu

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.

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

This document has been drafted using a set of colours according to ERA templates policy. This document can be photocopied with black/white machines without any loss of information.

ERA designed this document to be printed on A4 format paper, two side.

Introduction

This document details the harmonised accreditation scheme for Conformity Assessment Bodies (CABs) seeking accreditation as basis for notification by Member States to European Commission, within the scope of the EU Railway Interoperability Directive 2008/57/EC.

This document is composed by:

- an introductory section, and
- the accreditation scheme text.

The introductory section describes the overarching framework in which the harmonised accreditation scheme is included.

The accreditation scheme is divided into:

- PART I: which provides general references and information, and
- PART II: which provides harmonised requirements to apply when accrediting CABs for the purpose of notification under the IOD.

The harmonised accreditation scheme uses as baseline standard EN ISO/IEC 17065:2012 "Conformity assessment — Requirements for bodies certifying products, processes and services"; therefore:

- The baseline standard EN ISO/IEC 17065:2012 applies in all its clauses;
- The harmonised accreditation scheme does not contradict or exclude any of the requirements of the EN ISO/IEC 17065:2012, and
- The harmonised accreditation scheme provides railway interoperability specific amplified criteria to the baseline standard, as required by the EN ISO/IEC 17065:2012 standard in its introduction (ref. page v).

REMARKS

- For the sake of improving readability and application of the scheme during the accreditation process, PART II of this document follows same section numbering as the standard ISO/IEC 17065:2012 up to the second level (e.g. clause 4.2). Therefore the PART II of this document shall be read together with the ISO/IEC 17065:2012.
- The term "CAB" and "certification body" (in reference to the ISO/IEC 17065) are considered synonyms throughout the text of PART II.

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European Railway Agency

INTRODUCTORY SECTION

ON THE FRAMEWORK OF THIS ACCREDITATION SCHEME

1. Introduction

Conformity assessment means the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled. The process of conformity assessment is performed by Conformity Assessment Bodies (CABs).

Once the **notifying authority** of a Member State (MS) identifies the CABs and notify them to the European Commission, the CABs can be called notified bodies (NoBos). Being notified by MSs implies that notified bodies take responsibilities in areas of public interest. NoBos remain accountable to the competent national authorities.

Within the framework of the railway Interoperability Directive (IOD), notified bodies are the bodies responsible for:

- assessing the conformity of the interoperability constituents;
- assessing the suitability for use of the interoperability constituents;
- verifying railway subsystems.

Unless stated otherwise, in this text the term "conformity assessment**"** indicates the above three procedures.

The legal minimum requirements for being a Notified Body are defined in Annex VIII of the IOD. Additional requirements, set by international standards or specific accreditation scheme, shall be considered best practice.

Member States can choose between two paths to identify CABs to be notified: accreditation and recognition.

Accreditation means an attestation provided by the national accreditation body (NAB) that a conformity assessment body meets all the requirements to carry out a specific conformity assessment activity. Those requirements are set by EU legislation, harmonised standards and in addition - where applicable – by relevant sectorial schemes. (ref. art 2(10) of Regulation (EC) 765/2008).

When a Member State decides not to use accreditation, it shall provide the EC and the other EU Member States with all the documentary evidence necessary for the verification of the competence of the conformity assessment bodies it selects for the implementation of the Community harmonisation legislation in question. This process is known as recognition. (ref. art 5(2) of Regulation (EC) 765/2008).

Finally, notification is the act of the EU Member State's competent authority informing the European Commission and the other EU Member States that a conformity assessment body (CAB) meets all requirements and has been designated to carry out conformity assessment according to the Directive. With the notification, Member States declare that the CABs fulfil all the requirements relating to notified bodies as set out in the Directive 2008/57/EC. (ref. point 5.3.2 Blue Guide Version 1.1 – 15/07/2015).

NOTE: the EC Blue Guide Blue Guide Version 1.1 – 15/07/2015 provides an exhaustive description about the above topics. The Blue Guide is available at this link: http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=7326&lang=en&title=%E2%80%98Blue-Guide%E2%80%99-on-the-implementation-of-EU-product-rules

2. Objectives of this harmonised accreditation scheme

The use of this harmonised accreditation scheme is expected to increase the mutual trust amongst the relevant stakeholders in the EC certification process, such as (non exhaustive):

- NSAs, in granting authorisation for placing in service of subsystems, network projects or vehicles;
- manufacturers or applicants intending to prepare EC declarations based on EC certificates;
- RUs and/or IMs intending to operate the certified products;
- ECMs intending to maintain the certified products; and
- owners and keepers of the certified products.

This trust is considered to bring several measurable and non-measureable benefits; for example the reduction of the timeline for granting authorizations for subsystems, vehicles and network projects.

The application of this harmonised accreditation scheme is intended to provide confidence to Member State's notifying authorities that CABs have the correct procedures and competence to perform NoBo activities as described in the EU railway legal framework.

Information on the application of this accreditation scheme shall be provided:

- On the NAB's accreditation certificate for a CAB;
- in the technical annex associated to the NAB's accreditation certificate, and
- in the NANDO database.

The responsibility of the notification and following activities remains within the Member States.

3. Field of application of this harmonised accreditation scheme

This harmonised accreditation scheme shall be applied in the framework of accreditation of CABs of the purpose of notification under the IOD.

The CABs selected by Member States for the purpose of notification as described by art. 5(2) of the Reg. 765/2008 are out of the field of application of this document.

NOTE: CABs selected by Member States are usually known as recognised notified bodies.

4. Baseline standard for this harmonised accreditation scheme

ERA has applied the following principles in identifying the baseline standard:

- The accreditation to 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 NoBo may be demanded to perform in relation to the assigned modules described in the relevant TSI(s).
- In addition to the suitable baseline standard, the accreditation scheme shall define as few additional requirements as possible.
- The analysis regarding the international standards and modules provided in the EA guide EA-2/17 INF: 2014 has been taken into account by ERA.

NOTE: Although EA-2/17 is an informative document, it is considered as good industry practice for defining requirements for NAB accreditation of CABs for notification purposes. In this context, the EA-2/17 provide comparative analysis of the choice of international standard and the defined modules.

ERA indicates the EN ISO/IEC 17065:2012 "Conformity assessment – requirements for bodies certifying products, processes and services" as baseline standard.

4.1. International standards quoted in this harmonised accreditation scheme

In this harmonised scheme, elements have been taken from the following standards:

- EN ISO/IEC 17021-1:2015 - Conformity assessment - Requirements for bodies providing audit and certification of management systems;

- EN ISO/IEC 17020:2012 - Conformity assessment — Requirements for the operation of various types of bodies performing inspection;
- EN ISO/IEC 17025:2005 - General requirements for the competence of testing and calibration laboratories;
- EN ISO/IEC 17065:2012 - Conformity assessment — Requirements for bodies certifying products, processes and services;
- EN ISO/IEC 17011:2004 - Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies.

An appropriate knowledge of the above mentioned International standards is considered a fundamental prerequisite for a correct understanding of the accreditation scheme text.

5. Accreditation cycle for this harmonised accreditation scheme

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

6. Collaboration between NABs and other entities

The NABs are encouraged to develop collaborations with other entities to identify and hire Technical Experts for the purpose of assessment.

NOTE: the collaborations suggested are between NABs and (e.g. non exhaustive):

- *NSAs (belonging to the same MS or to other MS);*
- *suitable independent competent bodies (belonging to the same MS or to other MS);*

7. Maintenance of this harmonised accreditation scheme

The following e-mail address shall be used for any feedback about the implementation and the daily application of this harmonised accreditation scheme:

- accreditation.scheme.nobo@era.europa.eu

Anyone can send communications to this e-mail address. ERA will store all communications and treat them transparently and will use them for statistical purposes.

ERA will consider the communications received for future revisions of the accreditation scheme.

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ACCREDITATION SCHEME TEXT

PART I: REFERENCES AND INFORMATION

1. Definitions

Notified Body

Notified bodies are conformity assessment bodies which have been officially designated by a national authority to carry out the procedures for conformity assessment within the meaning of applicable Union harmonisation legislation when a third party is required. They are called 'notified bodies' under EU legislation. (Generic definition - ref. point 5.2.1 Blue Guide Version 1.1 – 15/07/2015).

Notifying authority

A notifying authority is the governmental or public body with the task to designate and notify conformity assessment bodies under Union harmonisation legislation.

National accreditation body (NAB)

The sole body in a Member State that performs accreditation with authority derived from the State (ref. 765/2008 art. 2(11)).

European co-operation for accreditation (EA)

The body recognised by European Commission as the European accreditation infrastructure as defined in art 14 of 265/2008.

Conformity assessment body (CAB)

Shall mean a body that performs conformity assessment activities including calibration, testing, certification and inspection (ref. art 2(13) of Reg 765/2008).

Module

Module means conformity assessment procedures to be used in the European railway legislation as set out in the Decision 713/2010 or in the Annex of a TSI.

European railway agency (ERA)

The agency established by the Reg 881/2004.

National safety authority (NSA)

National railway safety authority as defined by art 16 of directive 49/2004/EC.

2. Abbreviations and acronyms

Table 1 - Table of abbreviations and acronyms

Abbreviation, acronyms	Meaning
EA	European Co-operation for accreditation
EC	European Commission
MS	European Union Member State
ERA, Agency	European Railway Agency

Abbreviation, acronyms	Meaning
PO	ERA Project Officer
IOD, Interoperability Directive	Document 12 described in table 3
NAB	National accreditation body
CAB	Conformity Assessment Body
NSA	National Safety Authority
Decision 713/2010, Decision on railway modules	Document 17 described in table 3
TSI	Technical Specification for Interoperability
Regulation on CSM-RA, CSM-RA	Document 18 described in table 3
QMS	Quality Management System
ISO/IEC 17065	Document 1 described in table 2
ISO/IEC 17021	Document 2 described in table 2
ISO/IEC 17020	Document 3 described in table 2
ISO/IEC 17025	Document 4 described in table 2
ISO/IEC 17011	Document 5 described in table 2
ISO 9001	Document 10 described in table 2
ILAC	International Laboratory Accreditation Cooperation - The international organisation for accreditation bodies operating in accordance with ISO/IEC 17011 and involved in the accreditation of conformity assessment bodies
IAF	International Accreditation Forum. The IAF is the world association of conformity assessment accreditation bodies and other bodies interested in conformity assessment in the fields of management systems, products, services, personnel and other similar programmes of conformity assessment
APS	Authorisation for placing in service

3. Reference documents

Table 2 - Table of reference documents

Ref. N°	Title	Version
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

Ref. N°	Title	Version
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 accreditation bodies accrediting conformity assessment bodies	2004
6	EA-2/17 EA Document on Accreditation for Notification Purposes	2014
7	EA-2/13 EA Cross Border Accreditation Policy And Procedure for Cross Border Cooperation between EA Members	2012
8	IAF MD 5:2015 Determination of Audit Time of Quality and Environmental Management Systems - Issue 3, issued on 09 June 2015; Application from 09 June 2016	2015
9	ISO 9000 Quality management systems — Fundamentals and vocabulary	2015
10	ISO 9001 Quality management systems — Requirements	2008
11	ISO 9001 Quality management systems — Requirements	2015

4. Reference legislation

Table 3 - Table of reference legislation

Ref. N°	Title	Reference
12	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
13	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 the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification (Railway Safety Directive)	OJ L 164, 30.04.2004, p. 44,
14	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
15	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
16	Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93	OJ L 218, 13.08.2008
17	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

Ref. N°	Title	Reference
18	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

NOTE: the above legislation is meant including all the applicable amendments.

5. Legal requirements for Notified Bodies

Annex VIII of IOD sets out the minimum requirements which shall be taken into account by each Member State when notifying CABs to the EC.

The fulfilment of the requirements of this harmonised scheme provides compliance with the minimum criteria set out in Annex VIII of IOD.

Any NAB accreditation certificate for a CAB based on this harmonised scheme, according to art 11(2) of Reg. 765/2008 and to art 28(2) of the IOD, provides presumption of compliance for the notification purposes.

Member States' notifying authority shall take into account the withdrawal of an accreditation certificate based on this harmonised scheme when assessing the notification status of a CAB.

The table below provides the reference between the IOD Minimum criteria set out in Annex VIII of IOD and the clauses in the ISO/IEC 17065 plus amplified criteria set out in this document.

NOTE: the following table is in line with EA 2/17- INF 2014.

Table 4 Comparison table between requirements of ANNEX VIII of IOD and clauses of this document

Requirements of ANNEX VIII of the IOD	Clause of EN ISO/IEC 17065:2012 + amplified requirements of this harmonised scheme, part II where specified
1. The body, its Director and the staff responsible for carrying out the checking operations may not become involved either directly or as authorised representatives in the design, manufacture, construction, marketing or maintenance of the interoperability constituents or subsystems or in their use. This does not exclude the possibility of an exchange of technical information between the manufacturer and that body.	4.2.1 of EN ISO/IEC 17065:2012 4.2.2 of EN ISO/IEC 17065:2012 4.2.5 of EN ISO/IEC 17065:2012 + amplified requirements in this Harmonised Scheme, Part II 4.2.6 of EN ISO/IEC 17065:2012 + amplified requirements in this Harmonised Scheme, Part II 4.2.7 of EN ISO/IEC 17065:2012 4.2.8 of EN ISO/IEC 17065:2012 4.2.9 of EN ISO/IEC 17065:2012 4.2.10 of EN ISO/IEC 17065:2012 + amplified requirements in this Harmonised Scheme, Part II 4.2.11 of EN ISO/IEC 17065:2012 + amplified requirements in this Harmonised Scheme, Part II 4.2.12 of EN ISO/IEC 17065:2012
2. The body and the staff responsible for the checks must carry out the checks with the	4.2.2 of EN ISO/IEC 17065:2012

Requirements of ANNEX VIII of the IOD	Clause of EN ISO/IEC 17065:2012 + amplified requirements of this harmonised scheme, part II where specified
greatest possible professional integrity and the greatest possible technical competence and must be free of any pressure and incentive, in particular of a financial type, which could affect their judgement or the results of their inspection, in particular from persons or groups of persons affected by the results of the checks.	4.2.3 of EN ISO/IEC 17065:2012 4.2.5 of EN ISO/IEC 17065:2012 + amplified requirements in this Harmonised Scheme, Part II 4.2.12 of EN ISO/IEC 17065:2012 6.1.1.2 of EN ISO/IEC 17065:2012 + amplified requirements in this Harmonised Scheme, Part II 6.1.2 of EN ISO/IEC 17065:2012 + amplified requirements in this Harmonised Scheme, Part II 6.1.3 of EN ISO/IEC 17065:2012
In particular, the body and the staff responsible for the checks must be functionally independent of the authorities designated to issue authorisations for placing in service in the framework of this Directive, licences in the framework of Directive 95/18/EC and safety certificates in the framework of Directive 2004/49/EC, and of the bodies in charge of investigations in the event of accidents.	4.1.1 of EN ISO/IEC 17065:2012 + amplified requirements in this Harmonised Scheme, Part II 4.2.3 of EN ISO/IEC 17065:2012 + amplified requirements in this Harmonised Scheme, Part II
3. The body must employ staff and possess the means required to perform adequately the technical and administrative tasks linked with the checks; it should also have access to the equipment needed for exceptional checks.	4.3.2 of EN ISO/IEC 17065:2012 6.2 of EN ISO/IEC 17065:2012 + amplified requirements in this Harmonised Scheme, Part II 7.3.1 of EN ISO/IEC 17065:2012
4. The staff responsible for the checks must possess: — proper technical and vocational training, — a satisfactory knowledge of the requirements relating to the checks that they carry out and sufficient practice in those checks, — the ability to draw up the certificates, records and reports which constitute the formal record of the inspections conducted.	6.1.1.2 of EN ISO/IEC 17065:2012 + amplified requirements in this Harmonised Scheme, Part II 6.1.2 of EN ISO/IEC 17065:2012 + amplified requirements in this Harmonised Scheme, Part II 6.2.1 of EN ISO/IEC 17065:2012 + amplified requirements in this Harmonised Scheme, Part II
5. The independence of the staff responsible for inspections must be guaranteed. No official must be remunerated either on the basis of the number of inspections performed or of the results of those inspections.	4.2.3 of EN ISO/IEC 17065:2012 4.2.4 of EN ISO/IEC 17065:2012 4.4.4 of EN ISO/IEC 17065:2012 5.2 of EN ISO/IEC 17065:2012 + amplified requirements in this Harmonised Scheme, Part II

Requirements of ANNEX VIII of the IOD	Clause of EN ISO/IEC 17065:2012 + amplified requirements of this harmonised scheme, part II where specified
6. The body must take out civil liability insurance unless that liability is covered by the State under national law or unless the checks are carried out directly by that Member State.	4.3 of EN ISO/IEC 17065:2012
7. The staff of the body are bound by professional secrecy with regard to everything they learn in the performance of their duties (with the exception of the competent administrative authorities and accident investigation bodies in the State where they perform those activities as well as accident investigation bodies responsible for the investigation of accidents caused by the failure of the interoperability constituents or subsystems checked) in pursuance of this Directive or any provision of national law implementing the Directive.	4.5 of EN ISO/IEC 17065:2012 6.1.1.3 of EN ISO/IEC 17065:2012

6. Scheme owner

According to the article 13(2a) of Regulation n° 765/2008, the European Commission is the scheme owner.

The EC has provided specific mandate to ERA to develop, in collaboration with EA, this harmonised accreditation scheme[1].

7. NAB assessment team

7.1. Principles

Members of the NAB assessment team shall be selected on the criteria of:

- Independence,
- competence, and
- efficiency.

NOTE: the ISO/IEC 17011 provides a definition of the NAB assessment team.

The ultimate goal is to appoint an assessment team based on the lowest number of staff, which together have the complete competence required to evaluate the CAB under accreditation, 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.

This assessment shall be performed:

[1] *EC letter num. ARES (2014) 977679*

- according the required details provided by ISO/IEC 17065 and by Part II of this document, and
- in the shortest time and with the lowest cost for the applicant body.

7.2. Composition

The number of persons composing the NAB's assessment team and their qualification may vary according to the scope or scopes of accreditation. As general guideline, the assessment team should be composed by the following roles.

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

NOTE: not to be confused with the boards, group of persons or person described in Part II of this document point 5.1.3 which refer to the CAB.

It is common accreditation practice that a single person may perform several roles within the team for which he/she has the necessary competence. The name provided to those roles may vary in each NAB, however the competence shall remain the same as listed.

NAB 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;
- evaluation and certification activities performed. Decide on non-conformities and their classification;
- conduct the follow up to close the non-conformities.

NAB 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 from Technical Experts (TEs).

NAB 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 visit in support of the LA or AS.

7.3. 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 NAB 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 a NAB assessment team until a minimum period of two years since they last worked for the CAB has elapsed.

The NAB responsible for independence of staff can be consulted in the event of any queries regarding the compliance of a team member.

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

7.4. Competence

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

The following table provides the qualification selection criteria for the NAB assessment team when assessing a CAB seeking accreditation for the purpose of notification under the Directive 2008/57/EC.

Table 5 Criteria of competence for NAB assessment team

FUNCTION	COMPETENCE
NAB Lead Assessor	Qualified by the NAB as lead assessor in ISO/IEC 17065. Knowledge of ERA accreditation scheme for notified bodies.
NAB Assessor	Qualified by the NAB as assessor in ISO/IEC 17065. Knowledge of ERA accreditation scheme for notified bodies.
NAB Technical expert	Qualified by NAB as technical expert in one or more scopes of accreditation described in this scheme, which shall correspond to the scope to be assessed. Knowledge of ERA accreditation scheme for notified bodies.

7.5. Principles of efficiency

In addition to all the above requirements for NAB assessment teams regarding the independence, impartiality and competence, the following list identifies the principles to appoint the preferable NAB assessment team:

- the NAB assessment team sufficient to cover the assessment scope or scopes with the lowest number of members;
- the NAB assessment team members requiring less travel. This means (e.g.) NAB assessment team members who live nearest to the assessment place;
- the NAB assessment team which includes the highest number of members able to speak the language in which the assessment shall be conducted.

8. Accreditation information

The following information shall be included in the accreditation certificate.

1) Type of certification: certification of product.
2) Accreditation standard: EN ISO/IEC 17065:2012 together with the HARMONISED SCHEME FOR THE ACCREDITATION OF CONFORMITY ASSESSMENT BODIES FOR THE PURPOSE OF NOTIFICATION UNDER THE INTEROPERABILITY DIRECTIVE 2008/57/EC (version 2016).
3) Industry sector: railways.
4) Scope of accreditation as defined by the accreditation scheme:

(One or more of the following scopes of accreditation, as appropriate)

- Infrastructure
- Energy
- Control, Command and Signalling
- Rolling stock

The accreditation certificate shall include the effective date of granting the accreditation.

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

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European Railway Agency

ACCREDITATION SCHEME TEXT

PART II: HARMONISED REQUIREMENTS FOR ACCREDITATION OF NOTIFIED BODIES

REMINDER: Reading instructions

This PART II:

- 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 II 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.

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 specific to railways 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 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: the IOD 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 scope of accreditation, as listed below:

- Infrastructure;
- Energy;
- Control, Command and Signalling;
- Rolling stock.

There are no other possible scope.

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

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

NOTE: the accreditation 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 accreditation:

- 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 accreditation scope includes also such TSI amendment.

The CAB shall provide adequate information to the NAB responsible for accreditation and to the MS notifying entity.

NOTE: This information can be provided during the annual supervision performed by NAB.

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 accreditation.

3.17 Designated bodies (DeBo)

Bodies designated by Member States according to art 17 of IOD responsible for carrying out the verification procedure regarding technical rules for implementing the essential requirements when:

- no relevant TSI exists, or
- a derogation has been notified under Article 9, 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 to apply the documents of the coordination group of notified bodies to Art 28(5) of IOD , and
- participate in all the coordination group plenary meetings or shall demonstrate that they are informed about the meetings and about the findings.

4.1. Legal and contractual matters

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

The certification body 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 entities listed in ANNEX VIII of the IOD, point 2, second paragraph (reported here for information):
  - authorities designated to issue:
    - authorisations for placing in service in the framework of the IOD,
    - licences in the framework of Directive 95/18/EC,
    - safety certificates in the framework of Directive 2004/49/EC, and
  - 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 4.1.1 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.

- d) CAB cannot offer any consultancy, as defined in 3.2.a of ISO/IEC 17065, towards any client within the scope of the CAB accreditation;
- e) CAB cannot offer any QMS consultancy or internal audit to any client within the scope of the CAB accreditation.

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 case by case basis based 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 accreditation scheme.

NOTE: 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 accreditation)

NOTE: 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 accreditation; however only the boards, persons or groups of persons as described in the previous table have been detailed for the specific 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 accreditation, 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:

- Description: Activity to perform
- Training and Experience - General - Specific in addition to General: Achieved academic grade and recorded experience, and
- Knowledge - Legal framework - Technical topics - Non technical skills: Details on theoretical knowledge related to the job assigned.

The assessment of the competence shall be performed by the NAB 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: 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 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 NAB.

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 any inspection activities, the outsourced inspection bodies shall meet the requirements as type A described in Point A.1 of Annex A of ISO/IEC 17020 in addition to point 7.4.ISP of this document[2].

7. Process requirements

7.1. General

Text in ISO/IEC 17065 applies.

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

Depending of the appropriate module or modules chosen, per each product under evaluation, the results of the evaluation phase shall be recorded by an inspection report and/or a QMS audit report.

[2] *After the finalization of the project, UNIFE and EBA sent to ERA a complaint regarding the limitation to type A inspection bodies in case of outsourced inspection activities. UNIFE and EBA asked to allow also type B and type C inspection bodies to carry out outsourced inspection activities. ERA confirms the EA position stated in EA 2/17:2014 “EA Document on Accreditation for Notification Purposes” allowing only type A inspection bodies for notified bodies inspection activities. However, ERA is prepared to further examine this topic in the framework of a future revision of this harmonised accreditation scheme.*

NOTE: this point 7.4.9 is placed in this part of the document, after point 7.4.1, 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 reproducable 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.

7.4.TEST.A – Accredited test

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

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

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

NOTE: in EU these usually are the NABs.

An accredited test shall be accepted only if:

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

NOTE: the accreditation certificate and its annex can be also provided electronically via NAB (or similar) 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 5.3 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.

The above list can be amended by 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.

NOTE: NB-Rail RFUs may provide further clarifications and more detailed definitions to ensure a uniform approach in the EU.

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: 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: 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: 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: 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: 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: 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: 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 colums 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 7 - 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: 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: 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: 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 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 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 Harmonised 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: 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: 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: 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 TSIs. 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: 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 accredited 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: 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: 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 continuos 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 desing, manufacturing processes and final inspection as required by the 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 desing 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: 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: 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).

NOTE: Refer to RFU-STR-088 for further information.

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: these Audit Topics have been derived from the generic audit criteria included in AC sources from 1 to 4.

The CAB shall developd 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: 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, Measurment, Analysis
12. Continuous Improvement – Corrective Actions, Preventive Actions (incl. project SMS)

NOTE: 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: 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: 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: 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 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 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: 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 imply 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.

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 accreditation).

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 accreditation 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 Directive 2008/57/EC**: 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 accreditation:
  - knowledge of the content of the standards quoted in the TSIs which are underpinning the accreditation 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: SPECIFIC KNOWLEDGE PER SCOPE OF ACCREDITATION".

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 accreditation 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 accreditation as at least one of the following: lead inspector or QMS lead auditor.

Knowledge

Legal framework:

Deep understanding of the following topics:

- **Interoperability Directive 2008/57/EC**: 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 accreditation:
    - knowledge of the content of the standards quoted in the TSIs which are underpinning the accreditation 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: SPECIFIC KNOWLEDGE PER SCOPE OF ACCREDITATION".

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 ACCREDITATION)

Description: for one or more CAB scope or scopes of accreditation, 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 accreditation 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 accreditation as at least one of the following: lead inspector or QMS lead auditor.

Knowledge

Legal framework:

Deep understanding of the following topics:

- **Interoperability Directive 2008/57/EC**: 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 accreditation:
    - General broad overview of the content of the standards quoted in the TSIs which are underpinning the accreditation 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: SPECIFIC KNOWLEDGE PER SCOPE OF ACCREDITATION”.

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 accreditation 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 ACCREDITATION)

Description: Description: He/she also supports the technical manager in performing the activities related to inspections within the scope of accreditation. 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 accreditation 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, TSIs and modules).

Technical topics:

- Deep understanding of relevant parts of “ANNEX D: SPECIFIC KNOWLEDGE PER SCOPE OF ACCREDITATION”.

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, 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: SPECIFIC KNOWLEDGE PER SCOPE OF ACCREDITATION”.
  The QMS Lead Auditor can be accompanied by technical experts as point 9.2.2.2.2 of ISO/IEC 17021 to fulfil this requirements.

Non-technical skills:

- auditing skills and knowledge: generic and appropriate for specific scope of accreditation;

- desirable personal behaviour 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, TSIs and modules).

Technical topics:

- Deep understanding of relevant parts of “ANNEX D: SPECIFIC KNOWLEDGE PER SCOPE OF ACCREDITATION”.
  The QMS Auditor can be accompanied by technical experts as point 9.2.2.2.2 of ISO/IEC 17021-1 to fulfil this requirements.

Non-technical skills:

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

Annex D (Normative) List of specific knowledge per scope of accreditation

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

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

Table 8 Applicable specific knowledge per scope of accreditation

SCOPE OF ACCREDITATION	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

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 PRM 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

Structure and mechanical parts

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

Track interaction and gauging

- Dynamic behaviour of railway vehicles such as – not exhaustive list - 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)

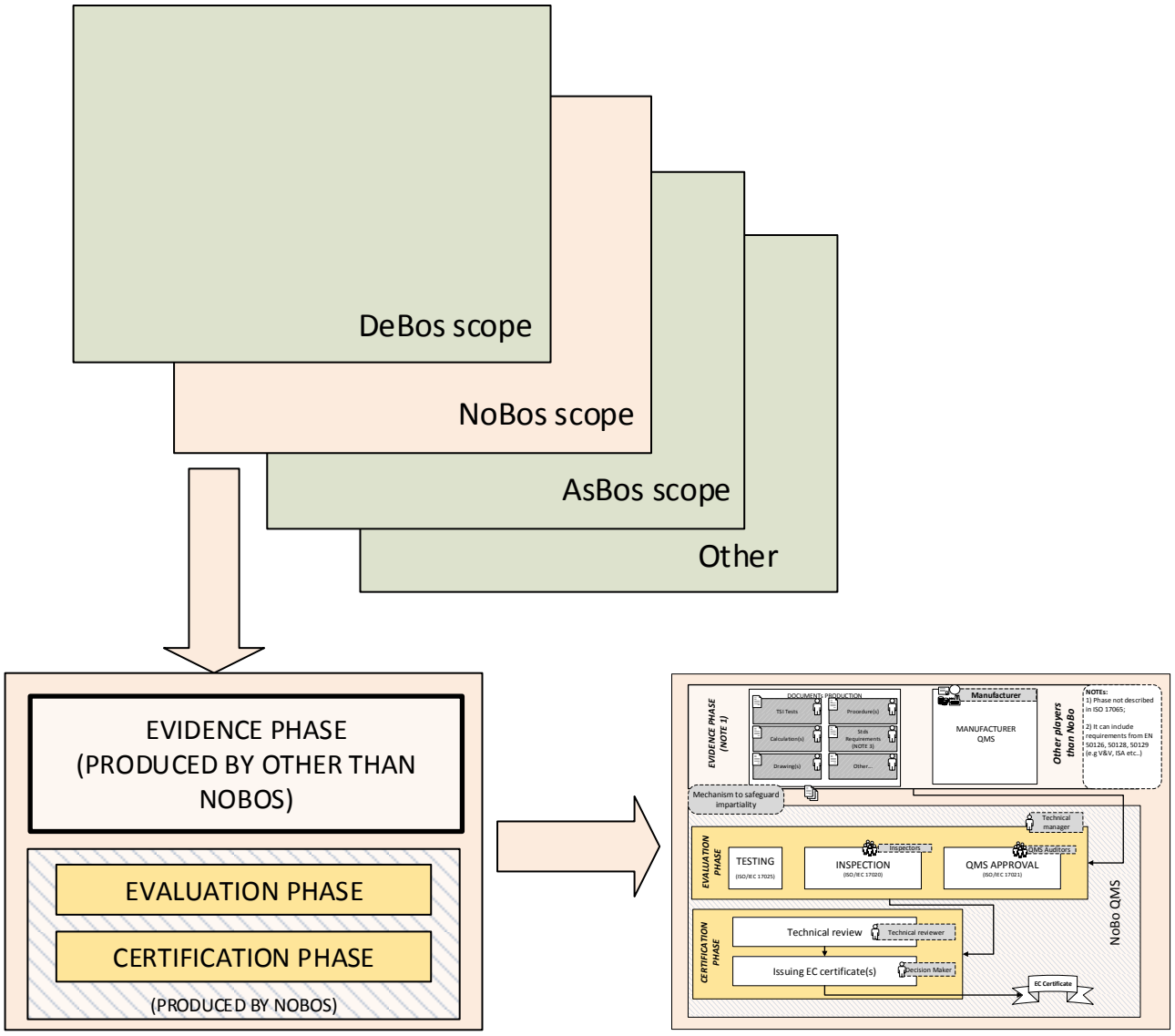
- TSI LOC&PAS;
- TSI NOI;
- TSI WAG;
- TSI SRT for items related to rolling stock;
- TSI PRM for items related to rolling stock.

Annex E (Informative) Graphical representation of notified body's activities

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

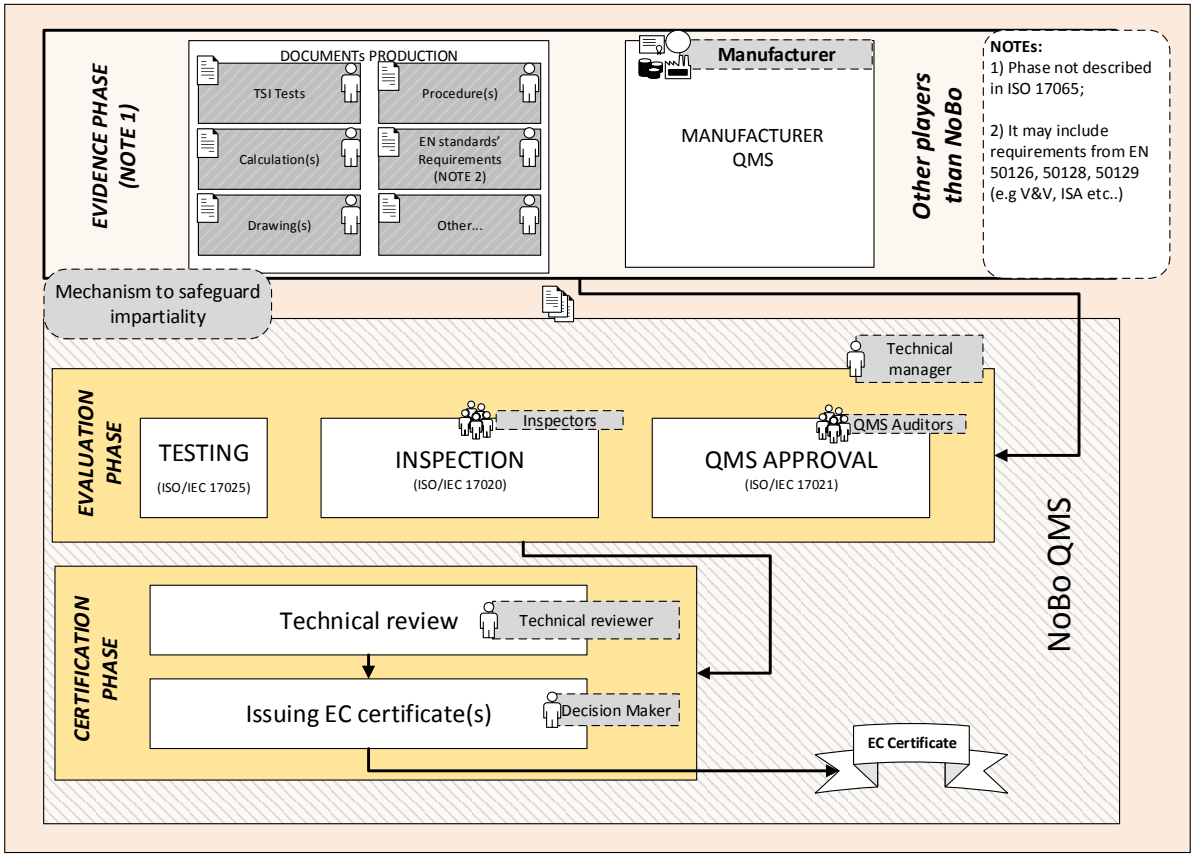
In the framework of the Authorisation for Placing in Service (APIS) checking bodies, the following drawings explain the functional organisation of the certification body and the position in the process of each of the boards, groups of persons or persons as identified in Annex C of this scheme.

Figure 1 - Relation amongst different conformity assessment bodies in railway



Next drawing shows in detail notified body organisation.

Figure 2 Functional organisation of the certification body



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

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

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 are 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: 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 remaning 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
   2011/713/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
   2011/713/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
   2011/713/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
   2011/713/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
   2011/713/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

2011/713/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
   2011/713/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
   2011/713/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, Measurment, 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 9001:20155 **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.

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