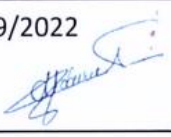

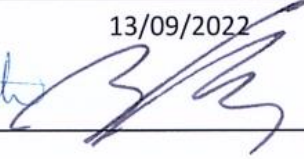
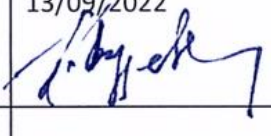


## Clarification Note

### *on the acceptance by a NoBo of the results of an independent assessment carried out by an AsBo*

	Written by	Verified by	Approved by
Name	Dragan JOVICIC	Anna GIGANTINO Bart ACCOU	Josef DOPPELBAUER
Position	Project officer	Head of Analysis and Monitoring Unit Head of Safety and Operation Unit	Executive Director
Date	12/09/2022 	12/09/2022  13/09/2022 	13/09/2022 
Signature			

#### Document History

Version	Date	Comments
1.0	13/09/2022	First version of the document following the internal review process

*The purpose of this document is to provide the European railway stakeholders with information regarding the application of the Commission Implementing Regulation (EU) No 402/2013 on the common safety method for risk evaluation and assessment in the context of TSIs, and other European legal acts, that reference to it. The clarifications contained in this document may be integrated in the next revision of either the legal text or the associated guidelines without prejudice of the formal process foreseen for updating the guidelines.*

*The present document is a non-legally binding guidance of the European Union Agency for Railways. It represents the views of the European Union Agency for Railways and not those of other EU institutions and bodies. It is without prejudice to the decision-making processes foreseen by the applicable EU legislation. Furthermore, a binding interpretation of EU law is the sole competence of the Court of Justice of the European Union.*

## Table of content

<b>Table of content</b> .....	<b>2</b>
<b>List of Figures</b> .....	<b>2</b>
<b>List of Tables</b> .....	<b>2</b>
<b>1. Purpose of the note</b> .....	<b>3</b>
<b>2. Recurrent problems of acceptance of AsBo reports by NoBos</b> .....	<b>3</b>
<b>3. Mandatory acceptance by a NoBo of assessment results provided by an AsBo</b> .....	<b>4</b>
<b>4. Amendments made to the ERA assessment scheme [Ref. 000MRA1044]</b> .....	<b>4</b>
<b>5. Conclusion</b> .....	<b>6</b>
<b>Annex A : BACKGROUND OF THIS CLARIFICATION NOTE</b> .....	<b>7</b>
A.1 Typical misreading of requirements in European railway legislation .....	7
A.2 Railway conformity assessment bodies (CABs) : NoBos, DeBos, AsBos.....	7
A.3 Acknowledgment of competence of NoBos, DeBos and AsBos.....	9
A.4 Mutual recognition of reports and certificates issued by acknowledged CABs.....	10
A.5 Legal bases in EU laws for the mutual recognition between NoBos and AsBos .....	10
A.5.1 Biased reading of specific requirements outside the overall context of EU legislation .....	10
A.5.2 Integrated set of requirements within the overall context of EU legislation .....	11
A.6 Compliance with other legal acts under the provisions of point 2.1 in Annex IV to the Interoperability Directive 2016/797 .....	11

## List of Figures

<i>Figure 1: Conformity assessment activities carried out by NoBos, DeBos, AsBos.</i> .....	<b>8</b>
<i>Figure 2: Mutual recognition by the NoBo of results from the AsBo report, in the scope of the 'EC' verification of conformity.</i> .....	<b>12</b>

## List of Tables

<i>Table 1: Evaluation tasks performed by the AsBo</i> .....	<b>4</b>
<i>Table 2: Verifications and acceptance by the NoBo of the results of an independent assessment carried out by an AsBo</i> .....	<b>5</b>
<i>Table 3: Provisions in EU legislation for the compliance with other applicable legal acts.</i> .....	<b>11</b>

## 1. Purpose of the note

- 1.1. The purpose of this note is to outline the legal bases that make compulsory the mutual recognition by the NoBo of independent assessment results carried out by an AsBo for the same scope of work.
- 1.2. Some TSIs, or other European legal acts, explicitly request the applicant:
  - (a) to use Regulation 402/2013 on the CSM for risk assessment for demonstrating the compliance with specific safety requirements defined in the TSIs, and
  - (b) to designate a body for the independent assessment of that demonstration.  
Depending on the TSI, the applicant has the freedom<sup>(1)</sup> to designate either the NoBo, or the AsBo, for carrying out that independent assessment.
- 1.3. Thereby, when the applicant appoints the AsBo for those independent assessments, the provisions of point 2.1 in Annex IV to the Interoperability Directive, and Articles 6(3)(b) and 15(4) of Regulation 402/2013, shall apply. This means that the NoBo 'EC' verification of conformity shall not prejudice to the obligations of the applicant to comply with those other legal acts. The NoBo shall mutually recognise the results of the independent assessments carried out by the AsBo on those specific safety requirements, without any restrictions, in particular not with respect to type A, B or C of independence of the AsBo.

## 2. Recurrent problems of acceptance of AsBo reports by NoBos

- 2.1. When the applicant/proposer appoints an AsBo for the independent assessment of the demonstration of compliance with those explicit safety requirements defined in a TSI :
  - (a) the applicant/proposer legitimately requests the NoBo to mutually recognise the results from the AsBo report, within the NoBo procedure for 'EC' verification of conformity with the applicable TSIs;
  - (b) some NoBos limit the reading of the EU railway legislation to Articles 30 to 34 of the Interoperability Directive 2016/797, the ERA assessment scheme [Ref. 000MRA1044], and Clauses 6.2 and 7.4 of the ISO/IEC 17065:2015 standard referenced therein, outside the overall context of the EU railway legislation;
  - (c) although NoBos do not have a legally binding contract with AsBos, they mistakenly consider AsBos as their own sub-contractors. They require AsBos to comply with Clauses 6.2.2. and 7.4.5 of the ISO/IEC 17065:2015, i.e. to fulfil the Type A AsBo requirements;
  - (d) such NoBos disregard the requirements for mutual recognition in Articles 6(3)(b) and 15(4) of Regulation 402/2013; they require the AsBo to be a third-party body. By doing so, they breach their obligation to mutually recognise reports of Type -B and -C AsBos, although these AsBos are accredited, or recognised, in accordance with Regulation 402/2013. Such NoBos unnecessarily duplicate assessments carried out by the body that accredited, or recognised, the AsBo.  
The argument they put forward is that Types -B and -C AsBos do not meet the same independence requirements as third-party bodies.

Such interpretation<sup>(2)</sup> is inconsistent with EU railway legislation, as NoBos consider requirements in isolation and outside the overall context of the whole set of applicable requirements.

---

<sup>(1)</sup> *It is to note that the choice does not exist in every TSI. For example, the LOC&PAS TSI allows the use of two methods for demonstrating compliance with the safety requirements. Only method "1" allows the applicant to designate either the NoBo, or the AsBo. When applying method "2), by default the AsBo shall carry out the independent assessment of the demonstration.*

<sup>(2)</sup> *It is also reminded that a binding interpretation of EU law is the sole competence of the Court of Justice of the European Union.*

### 3. Mandatory acceptance by a NoBo of assessment results provided by an AsBo

- 3.1. The ERA assessment scheme [Ref. 000MRA1044] was reviewed to clearly define the conditions under which a NoBo shall accept the results of an independent assessment carried by an AsBo.
- 3.2. Pending the publication of the revised ERA assessment scheme and its entry into force, the recommendations in section § 4. below shall be applied by the NoBo, when, under the provisions of other EU legal acts, an AsBo is appointed to independently assess the applicant's demonstration of compliance with the applicable requirements.
- 3.3. Section § 4. describes the respective obligations of NoBos and AsBos where, under the provisions of point 2.1 in Annex IV to the Interoperability Directive, a TSI requires the applicant:
- (a) to comply with another legal act, or with specific safety requirements defined in the TSI, and
  - (b) to appoint another body for the independent assessment of the applicant's demonstration of compliance with that other legal act, or with those specific safety requirements.

### 4. Amendments made to the ERA assessment scheme [Ref. 000MRA1044]

- 4.1. The following text is added for Clause 7.4.3 of the ISO/IEC 17065/2012 standard.

**Table 1: Evaluation tasks performed by the AsBo**

<p>[L 1] <i>By virtue of point 2.1 in Annex IV to the Interoperability Directive 2016/797, the 'EC' verification procedure, whereby a NoBo checks and certifies that a sub-system complies with the relevant TSI(s), shall not prejudice to the obligations of the applicant to comply with:</i></p> <ul style="list-style-type: none"> <li><i>(a) the other applicable legal acts of the Union, and with;</i></li> <li><i>(b) any verifications by the assessment bodies required by the rules defined in those other legal acts.</i></li> </ul> <p><i>NOTE 1: Some TSIs (TSI locomotives and passenger rolling stock, TSI control-command and signalling, TSI Freight wagons and TSI safety in railway tunnels for items related to rolling stock ), the CSM-RA and the PA VA<sup>(3)</sup> are examples of other applicable legal acts of the Union that require a risk assessment according to Annex I of the CSM-RA and verifications by other assessment bodies (in practice by an AsBo).</i></p> <p>[L 2] <i>The compliance with the EN ISO/IEC 17065:2012 standard and the other requirements of the ERA Assessment Scheme shall not conflict with the requirements and obligations concerning the specific scopes for the conformity assessment of the safety requirements defined in:</i></p> <ul style="list-style-type: none"> <li><i>(a) Section § 6.2.3.5 of the LOC &amp; PAS TSI<sup>(4)</sup> (itself referring to sections § 4.2.3.4.2, § 4.2.4.2.2, § 4.2.5.3.5, § 4.2.5.5.8 and § 4.2.5.5.9) requires the applicant to designate for that assessment either the NoBo selected for the rolling stock subsystem or an AsBo as defined in the CSM-RA.</i></li> <li><i>(b) Clause 3.2.1 of the CCS TSI<sup>(5)</sup> requires the assessment of compliance with those safety requirements of the CCS TSI to be performed by an AsBo.</i></li> </ul>
---

- (3) *Commission Implementing Regulation (EU) 2018/545 of 4 April 2018 establishing practical arrangements for the railway vehicle authorisation and railway vehicle type authorisation process pursuant to Directive (EU) 2016/797 of the European Parliament and of the Council. (OJ L 90, 6.4.2018).*
- (4) *Commission Regulation (EU) No 1302/2014 of 18 November 2014 concerning a technical specification for interoperability relating to the 'rolling stock — locomotives and passenger rolling stock' subsystem of the rail system in the European Union (OJ L 356/228, 12.12.2014).*
- (5) *Commission Regulation (EU) 2016/919 of 27 May 2016 on the technical specification for interoperability relating to the 'control-command and signalling' subsystems of the rail system in the European Union, amended by Commission Implementing Regulation (EU) 2019/776 of 16 May 2019. (OJ L 158/1, 15.6.2016).*

**Table 1: Evaluation tasks performed by the AsBo**

<p>(c) Clause 7.2.2.4 of the Freight Wagon TSI<sup>(6)</sup> requires the applicant to provide a positive assessment by an AsBo.</p> <p>(d) Clause 6.2.6(c) of the SRT TSI<sup>(7)</sup>, when applied, requires a safety assessment report in compliance with the CSM-RA.</p> <p>(e) Article 13(3) and point 18.1 in Annex I of the PA VA<sup>(3)</sup> require a safety assessment report referred to in Article 15 of the CSM-RA.</p> <p>NOTE 2: The references above are to be updated with relevant future TSI amendments and versions, or with other future applicable legal acts of the Union which could require a risk assessment according to Annex I of the CSM-RA and an independent assessment by an AsBo.</p> <p>[L 3] Those clauses require the application of the risk management process in Annex I of the CSM-RA, and an independent assessment of the demonstration of compliance with that process. When the independent assessment for those specific scopes is carried out by an AsBo, this shall be without restrictions with respect to the type A, B or C of independence of the AsBo, all permitted by the CSM-RA.</p> <p>[L 4] In accordance with the principles stated in Article 6(3) and Article 15(4) of the CSM-RA, and where relevant for the evaluation activities, the NoBo shall accept the applicant's declaration and the results from the AsBo independent assessment. The results for those specific scopes shall be completed by the AsBo prior to the NoBo evaluation activities.</p>
---

#### 4.2. The following text is added for Clause 7.4.4 of the ISO/IEC 17065/2012 standard.

**Table 2: Verifications and acceptance by the NoBo of the results of an independent assessment carried out by an AsBo.**

<p>[L 1] Without prejudice to the NoBo conformity assessment, where the applicant contracts an AsBo for the specific conformity assessment described in section § 4.1. above, the requirements in this clause [i.e. Clause 7.4.4] of the EN ISO/IEC 17065 shall not apply to the AsBo, as there is no legally binding contract between the NoBo and the AsBo.</p> <p>[L 2] Where the evidence of independent assessment of the specific safety requirements listed in section § 4.1. above is produced by an AsBo, according to the CSM-RA, the NoBo shall:</p> <p>(a) obtain beforehand from the applicant a documented description of the specific scope of the conformity assessments for which the applicant contracted an AsBo;</p> <p>(b) verify whether the applicant provides, as documented evidence, a safety assessment report from the AsBo, that covers the complete scope of the conformity assessment in bullet (a) above;</p> <p>(c) verify the following information concerning the AsBo which performs the conformity assessment in bullet (a) above :</p> <p>(1) the AsBo is accredited, or recognised, for at least the relevant scope in compliance with the requirements and criteria defined in Annex II of the CSM-RA, including the EN ISO/IEC 17020:2012 standard referenced therein;</p> <p>(2) the AsBo accreditation/recognition is still valid;</p>
---

(6) Commission Regulation (EU) No 1303/2014 of 18 November 2014 concerning the technical specification for interoperability relating to 'safety in railway tunnels' of the rail system of the European Union. (OJ L 356, 12.12.2014).

(7) Commission Regulation (EU) 2016/919 of 27 May 2016 on the technical specification for interoperability relating to the 'control-command and signalling' subsystems of the rail system in the European Union, amended by Commission Implementing Regulation (EU) 2019/776 of 16 May 2019. (OJ L 158/1, 15.6.2016).

**Table 2: Verifications and acceptance by the NoBo of the results of an independent assessment carried out by an AsBo.**

<p>(3) <i>the AsBo is registered in the ERADIS database, or if not yet registered there, published on the website of the associated national accreditation or recognition body;</i></p> <p>(4) <i>the scope of the AsBo safety assessment report covers the same object of assessment as the one in the scope of the NoBo assessment;</i></p> <p>(5) <i>the AsBo safety assessment report clearly makes reference to the safety related application conditions (SRACs) the applicant exports with respect to specific safety requirements within the scope of § 4.1. above;</i></p> <p>(d) <i>verify, in compliance with Article 16 of CSM-RA, whether the applicant provides a Declaration that covers fully the conformity assessment within the scope of section § 4.1. above;</i></p> <p>(e) <i>verify whether the applicant's Declaration covers the same object of assessment as the one in the scope of the NoBo assessment;</i></p> <p>(f) <i>derive from the AsBo safety assessment report, and the applicant's Declaration, all conditions and limits of use relevant for the object of assessment. The NoBo shall :</i></p> <p style="padding-left: 20px;">(1) <i>take them into account during the evaluation activities, and;</i></p> <p style="padding-left: 20px;">(2) <i>report them in the NoBo certification level documents, the accompanying conformity assessment reports and NoBo file.</i></p> <p><i>These conditions and limits of use include, but are not limited to, the safety related application conditions (SRACs).</i></p> <p>(g) <i>verify whether the applicant's Declaration explicitly states that, according to Article 16 of CSM-RA, "all identified hazards and associated risks are controlled to an acceptable level";</i></p> <p>(h) <i>evaluate the absence of justified doubts concerning the assumptions made or the appropriateness of the results contained in the applicant's Declaration.</i></p>
--

## 5. Conclusion

- 5.1. Some TSIs allow the applicant/proposer to appoint an accredited, or a recognised, AsBo for carrying out the independent assessment of the demonstration of compliance with explicit safety requirements defined in those TSIs.
- 5.2. When the applicant/proposer chooses that option, in the scope of the 'EC' verification procedure, the NoBo shall mutually recognise the results of the independent assessments carried out by the AsBo on those specific safety requirements, without any restrictions, in particular not with respect to type A, B or C of independence of the AsBo.
- 5.3. Section § 4. above defines the requirements and conditions that permit the mutual recognition by the NoBo of the independent assessment results carried out by an AsBo.

## ANNEX A : BACKGROUND OF THIS CLARIFICATION NOTE

### A.1 Typical misreading of requirements in European railway legislation

- [L 1.] It is important to bear in mind that the European railway legislation is made of a set of legal texts that complement each other to form a coherent whole.
- [L 2.] Thereby, to avoid a biased or incomplete compliance with the law, the stakeholders shall not read any legal act in isolation from each other, but within the overall context of the EU railway legislation, i.e. in an integrated manner.
- [L 3.] A separate legal act may define more precise requirements on the obligations of the different actors involved in the independent assessment, the safe design, operation and maintenance of railway products, constituents and sub-systems.

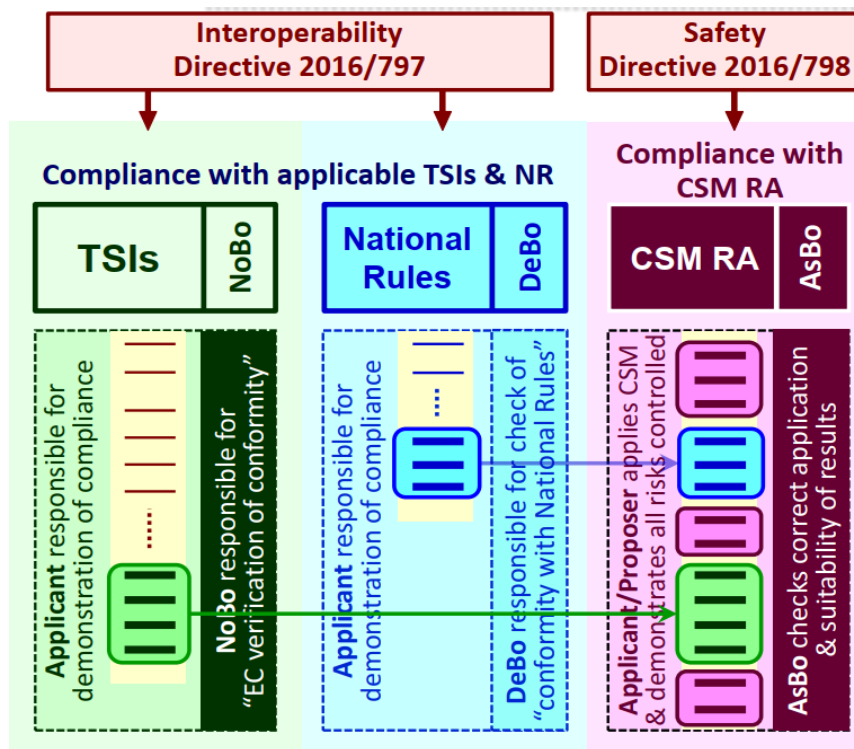
### A.2 Railway conformity assessment bodies (CABs) : NoBos, DeBos, AsBos

- [L 1.] To provide the assurance that railway products and sub-systems comply with both the applicable technical legislation (TSIs and national rules) and safety legislation (including Safety Directive 2016/798 and Regulation 402/2013), the European railway legislation requires an independent assessment by competent second “pairs of eyes” of their compliance with the applicable requirements.
- [L 2.] According to the Interoperability Directive 2016/797, before an interoperability constituent, or a structural sub-system, is placed on the market or, where relevant, before it is placed into service:
  - (a) a Notified Body (NoBo) shall carry out an ‘EC’ verification of conformity of the interoperability constituent (and where applicable of its suitability for use), or of a structural sub-system, with the requirements contained in the applicable TSIs.  
*The NoBo assessment includes the verification of compliance with the essential requirements related to safety, as far as such requirements are explicitly specified in the TSI for the achievement of interoperability across the European Union;*
  - (b) a Designated Body (DeBo) shall carry out a verification in respect of national rules for open points that are not explicitly covered by requirements of the applicable TSIs.
- [L 3.] According to Regulation 402/2013 on the CSM for risk assessment (CSM-RA), whenever an applicant/proposer makes a technical, operational or organisational significant change to the railway system (or where another legal text explicitly requires so), an assessment body (AsBo) shall carry out an independent assessment of:
  - (a) the correct application by the applicant/proposer of the risk management process in Annex I of the CSM-RA and its effectiveness to successfully and systematically:
    - (1) identify the hazards and risks that arise from the change, including those resulting from technical design choices.  
*It is to note that:*
      - (i) *some of those risks might be satisfactorily controlled by the compliance with TSIs, or national rules. If the applicant/proposer demonstrates that the compliance with TSIs, or national rules, controls some risks to an acceptable level, additional risk control measures are not required for those risks;*

- (ii) *most of the hazards and risks will neither be covered by TSIs, nor national rules, especially risks shared across interfaces between structural sub-systems, or with actors impacted by the change. Those hazards and risks shall then be controlled by additional risk control measures to be defined by the applicant's/proposer's risk assessment, where necessary in cooperation, or jointly, with those other actors;*
- (2) identify, register in, and manage through, the Hazard Record all safety requirements necessary for controlling all identified risks to an acceptable level.  
*This will include the safety requirements contained in TSIs, or national rules, as well as all additional safety requirements defined by the risk assessment, and which are essential for the safe design of the change, its safe integration into the railway system, its safe operation and safe maintenance;*
- (3) allocate the safety requirements down to the different constituting parts of the change under assessment;
- (4) manage the correct implementation and validation of all identified safety requirements throughout the entire development process of the change, including those assigned to other railway actors;
- (b) the suitability of the results from the risk assessment (i.e. an expert judgement) to enable the change under assessment as a whole to fulfil safely the intended objectives.

*The independent safety assessment by an AsBo, as meant in Regulation 402/2013, has thus a much broader scope than checking only the compliance with the essential requirements related to safety, specified in TSIs.*

[L 4.] The roles, responsibilities and interrelations between those three conformity assessment bodies are schematically represented in Figure 1.



**Figure 1: Conformity assessment activities carried out by NoBos, DeBos, AsBos.**



### A.3 Acknowledgment of competence of NoBos, DeBos and AsBos

[L 1.] **DeBo :**

The DeBo must have an appropriate knowledge and understanding of national laws. It is designated by the Member State according to Article 45 of the Interoperability Directive 2016/797. Those provisions provide the assurance on the competence of the DeBo.

[L 2.] **NoBo and AsBo differences :**

Considering that the NoBo and the AsBo are fundamentally two different types of conformity assessment bodies, with different purposes, objectives and scopes of work :

- (a) they fall under a different European law;
- (b) they shall have different knowledge, competencies, mind-sets and working methods;
- (c) they shall be accredited, or recognised, with respect to different ISO/IEC standards, and therefore different requirements and criteria.

[L 3.] **NoBo :**

- (a) Articles 30 to 36 of the Interoperability Directive 2016/797 define the requirements the NoBo must fulfil. Article 31(1) requires among others that the NoBo is a third-party body independent of the organisation, or of the manufacturer, of the product it assesses. The ERA assessment scheme [Ref. 000MRA1044], based on the ISO/IEC 17065:2012 standard, defines the necessary additional requirements the NoBo shall fulfil. Thereby, the Directive and ERA scheme define the technical knowledge, competence, independence and impartiality requirements a NoBo must fulfil.
- (b) The NoBo shall be notified by the Member State, based on a prior accreditation, or recognition. The accreditation, or recognition, complemented by regular supervision by the accreditation/recognition body, are the legal provisions that guarantee the NoBo competence, independence, impartiality and compliance with all applicable legal requirements.
- (c) NoBos are registered in the Commission NANDO database. They are not hosted by an ERA database.

[L 4.] **AsBo :**

- (a) The notification process does not apply to the AsBo. Regulation 402/2013 on the CSM for risk assessment, and the ISO/IEC 17020:2012 standard referenced therein, define the technical knowledge, competence, independence and impartiality requirements an AsBo must fulfil. Among others:
  - (1) Regulation 402/2013 permits the existence, and appointment, of all three types of independence of the AsBo (A, B or C as defined in Annex A of the ISO/IEC 17020:2012 standard), without any discrimination or limitation on the mutual recognition of the AsBo report;
  - (2) regardless the type of independence (A, B or C), the AsBo staff must be technically competent;
  - (3) in function of the type of independence, the AsBo must comply with the relevant independence requirements defined in Annex A of the standard with respect to the design, manufacture, supply, installation, verification, validation, testing activities, servicing, maintenance, risk assessment and risk management of the product under inspection;
  - (4) regardless the type of independence (A, B or C), the AsBo must be impartial. It means that the AsBo must not have any conflict of interests and must be able to make unbiased expert judgements and decisions, despite it could be an in-house AsBo;

- (5) neither Regulation 402/2013, nor the ISO/IEC 17020:2012 standard, allow to make any ranking in terms of impartiality, or difference of quality of independent safety assessment and expert judgement between the three types of AsBo independence (A, B or C);
- (b) The accreditation, or recognition, and the subsequent regular supervision of the AsBo, by the accreditation/recognition body, are the legal provisions that guarantee the AsBo competence, independence, impartiality and compliance with all applicable requirements.
- (c) AsBos are registered in the ERA ERADIS database, in the "Safety documents\Assessment" field.

## A.4 Mutual recognition of reports and certificates issued by acknowledged CABs

[L 1.] Most of railway projects are complex in terms of technical architecture, and of their impacts on the organisation of the safe operation and maintenance of the railway system. Railway projects can involve one, several, or many structural or functional sub-systems, as well as several railway actors. Thereby, the project management can require:

- (a) complex project organisations, and close and regular cooperation with all involved actors, and
- (b) the appointment of several accredited or recognised conformity assessment bodies (NoBos, DeBos, AsBos), with the roles and responsibilities reminded in section § A.2 above.

[L 2.] An incomplete reading of requirements, outside the overall EU legislation context, could breach the legal obligations regarding the coordination and relationships between those conformity assessment bodies for achieving the project objectives.

[L 3.] To make it clear, and prevent wrong interpretation of requirements, the European railway legislation is fully in line with the principles of the Commission New Approach and Global Approach (the "Blue Guide"<sup>(8)</sup>). It explicitly requires, for the same scope of work, the mutual recognition of reports and certificates issued by conformity assessment bodies which are acknowledged with respect to the applicable European legislation.

[L 4.] The NoBo and the AsBo are explicitly requested to avoid unnecessary duplication of independent conformity assessments, unless the accepting body can justify and document its doubts concerning the assumptions made, or the appropriateness of the results, from the other body.

## A.5 Legal bases in EU laws for the mutual recognition between NoBos and AsBos

### A.5.1 Biased reading of specific requirements outside the overall context of EU legislation

[L 1.] Being responsible for the 'EC' verification of conformity with the applicable TSIs, the NoBo also provides a statement on the conformity with essential requirements related to safety, if the TSI explicitly specifies safety requirements for achieving the interoperability across the European Union.

[L 2.] **Recurrent problems** : refer to section § 2. above in the main part of the clarification note.

---

<sup>(8)</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C:2022:247:FULL&from=EN>

### A.5.2 Integrated set of requirements within the overall context of EU legislation

[L 1.] In practice, the Articles 30 to 34 of the Interoperability Directive 2016/797, the ERA assessment scheme [Ref. 000MRA1044], and the ISO/IEC 17065:2015 referenced therein, shall also consider the requirements in Table 3 below.

**Table 3: Provisions in EU legislation for the compliance with other applicable legal acts.**

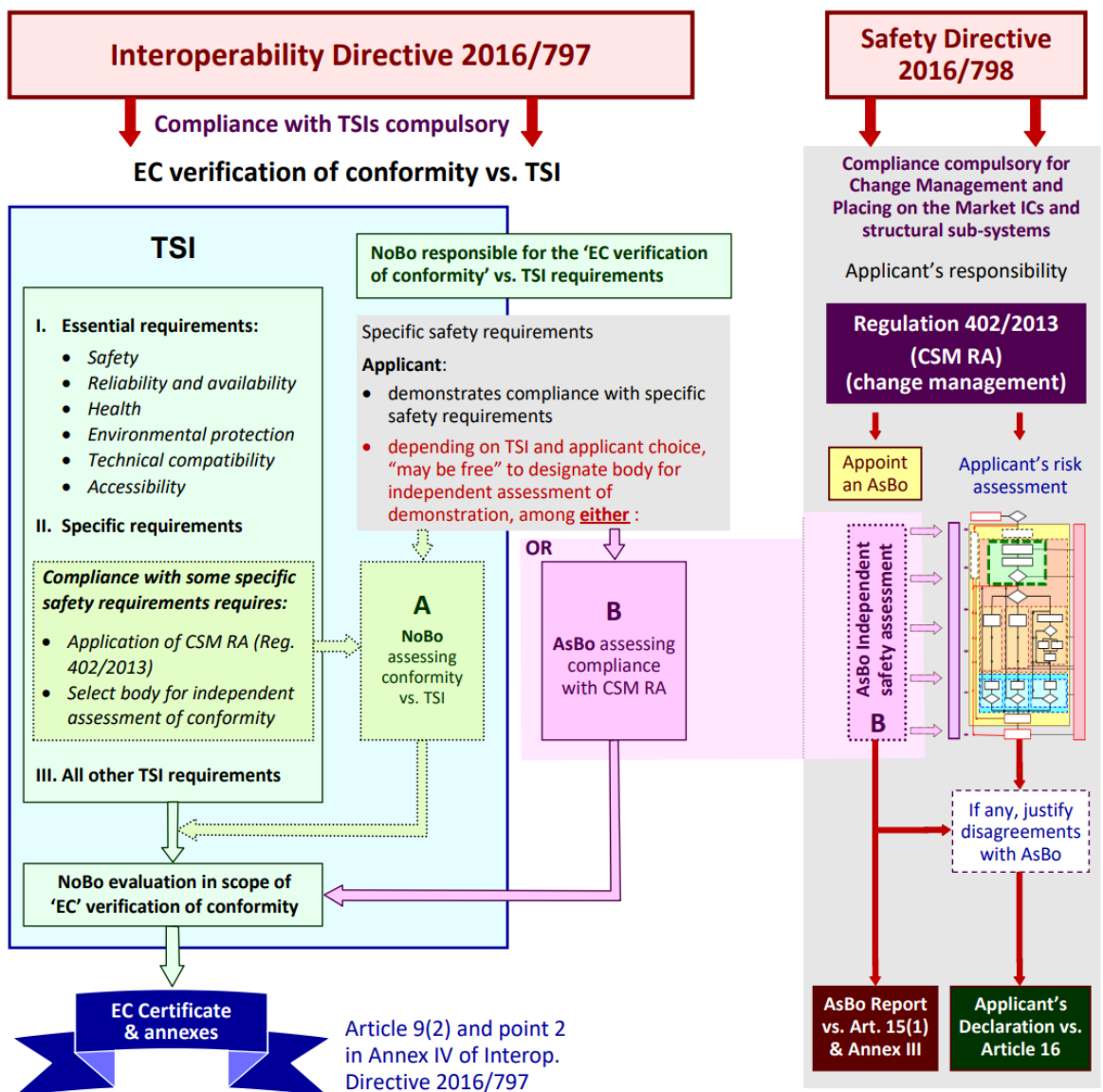
Provisions in the Interoperability Directive 2016/797	Provisions in Regulation 402/2013 on the CSM for risk assessment
<p style="text-align: center;">ANNEX IV</p> <p style="text-align: center;"><b>‘EC’ VERIFICATION PROCEDURE FOR SUBSYSTEMS</b></p> <p>...</p> <p>2. <b>CERTIFICATE OF VERIFICATION ISSUED BY A NOTIFIED BODY</b></p> <p>2.1. <i>Introduction</i></p> <p><i>For the purpose of this Directive, the verification by reference to TSIs is the procedure whereby a notified body checks and certifies that the subsystem complies with the relevant technical specifications for interoperability (TSI).</i></p> <p><i>This is without prejudice to the obligations of the applicant to comply with the other applicable legal acts of the Union and any verifications by the assessment bodies required by the other rules.</i></p>	<p style="text-align: center;">Article 6</p> <p style="text-align: center;"><b>Independent assessment</b></p> <p>3. <i>Duplication of work between the following assessments shall be avoided:</i></p> <p>...</p> <p>(b) <i>the conformity assessment carried out by a notified body ...; and</i></p> <p>(c) <i>any independent assessment carried out by the assessment body in accordance with this Regulation.</i></p> <p style="text-align: center;">Article 15</p> <p style="text-align: center;"><b>Safety assessment reports</b></p> <p>4. <i>In the case referred to in point (a) of Article 2(3), in accordance with paragraph 5 of this Article, the declaration referred to in Article 16 shall be accepted by the notified body in charge of delivering the conformity certificate, unless it justifies and documents its doubts concerning the assumptions made or the appropriateness of the results.</i></p>

### A.6 Compliance with other legal acts under the provisions of point 2.1 in Annex IV to the Interoperability Directive 2016/797

[L 1.] When in the scope of compliance with a TSI the applicant appoints an AsBo for the independent assessments of specific safety requirements, the provisions of point 2.1 in Annex IV to the Interoperability Directive, and Articles 6(3)(b) and 15(4) of Regulation 402/2013, shall apply.

[L 2.] This implies that the NoBo ‘EC’ verification of conformity shall not prejudice to the obligations of the applicant to comply with other legal acts. The NoBo shall mutually recognise the results of the independent assessments carried out by the AsBo on those specific safety requirements, without restrictions with respect to type A, B or C of independence of the AsBo.

[L 3.] The relations between the independent assessments carried out by the AsBo in the scope of TSIs, and the NoBo ‘EC’ verification of conformity, are represented on Figure 2 below.



**Figure 2: Mutual recognition by the NoBo of results from the AsBo report, in the scope of the 'EC' verification of conformity.**