

**1. REQUEST**

<b>Enquiry title:</b>	AsBo technical knowledge and competence requirements for the different areas <sup>(1)</sup>
<b>Enquiry description:</b>	<p>The requirements for the AsBo in Annex II of Regulation 402/2013, especially in its point 2, are too broad. This does not permit the National Accreditation and Recognition Bodies to verify in a harmonised way, and with a sufficient level of detail, that every AsBo has sufficient competence, experience and knowledge to fulfil its roles and responsibilities.</p> <p>For example for the Rolling Stock structural sub-system, it is necessary to define whether technical competence in its components or sub-parts is, or is not, to be demonstrated : e.g. dynamics and running behaviour, aero-dynamics, vehicle structure, braking system, wheelsets, electrical equipment, etc.</p> <p>Also, it is unclear whether an AsBo which demonstrates competence in all areas or structural sub-systems has automatically competence in the system safe integration, i.e. integration at the level of the railway system as a whole.</p> <p>In order to facilitate the accreditation/recognition, and to improve the assurance in the mutual recognition of the AsBo report, for every technical area it is necessary to develop and detail further the requirements for the technical knowledge and competence of the AsBos.</p> <p>A higher granularity of competence is necessary for every structural-sub-system, functional areas, overall consistency check and system approach, and finally system safe integration.</p>
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<b>Related documents:</b>	<p>{Ref. 1} Regulation 402/2013, Article 6</p> <p>{Ref. 2} <a href="#">Explanatory Note</a> on the roles and responsibilities of the AsBo</p> <p>{Ref. 3} ISO/IEC 17020:2012 standard and its subsequent amendments</p> <p>{Ref. 4} <a href="#">Recommendation for use 01 on the working method of the assessment body</a></p> <p>{Ref. 5} Recommendation for use 08 on the use of external experts and sub-contractors by the AsBo</p> <p>{Ref. 6} Recommendation for use 15 on the relations between the AsBo, NoBo and DeBo, and the mutual recognition of their work between those conformity assessment bodies</p> <p>{Ref. 7} <a href="#">Clarification note on safe integration (reference ERA1209-63)</a></p> <p>The recommendations for use and clarification note are available on the Agency web page under the following link <a href="https://www.era.europa.eu/common_safety_methods_for_risk_evaluation_and_assessment">https://www.era.europa.eu/common_safety_methods_for_risk_evaluation_and_assessment</a>, in case the hyperlinks do not work.</p> <p>It is to note that the recommendations for use 08 and 15 are not written yet at the moment of publication of the present recommendation.</p>

**2. TRACEABILITY**

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<sup>(1)</sup> The terminologies “area of competence of the AsBo” of Regulation 402/2013, and “scope of accreditation/recognition of the AsBo” of the ISO/IEC 17020:2012 standard, are synonymous.

### 3. SOLUTION

#### Specific competencies of the Assessment Body (AsBo) with respect to the requirements in Annex II of Regulation 402/2013 and the inspection body role of the AsBo

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#### I. Introduction

##### I.A. General reminders on the context and purpose of the document

1. This document is complementary to the requirements defined in Regulation 402/2013 and the ISO/IEC 17020:2012 standard referenced therein. As explicitly stated in that Regulation, “*the assessment body shall fulfil all requirements of the ISO/IEC 17020:2012 standard...*”. This document does not modify the generic requirements of the ISO/IEC 17020:2012 standard.
2. It clarifies the meaning of the specific competence requirements defined in bullets (a), (b) and (c) of point 1, and in points 2 and 3 of Annex II of Regulation 402/2013. Those requirements are necessary to enable the AsBo to perform the independent assessment specified in Article 6(1) and Article 6(2) of that Regulation. When compliance to a generic requirement of the ISO/IEC 17020:2012 standard permits also to fulfil another requirement of Annex II of Regulation 402/2013, the associated section of the ISO/IEC 17020:2012 standard is referenced.
3. Without describing how accreditation and recognition bodies work, it is worth reminding the following :

- (a) the required set of competence<sup>(2)</sup> is to be demonstrated by the AsBo as a body (i.e. as an organisation or company). This means that :
- (1) according to section § 8 of the ISO/IEC 17020:2012 standard, the AsBo organisation shall have a management system which makes it capable of setting up a “competent team” for every specific project in the areas/scope of its accreditation/recognition. For complex projects, this can require the involvement of a multidisciplinary team with several individual persons having different and complementary competencies;
  - (2) the AsBo as an organisation has to demonstrate the required competence. It is not necessary that every member/individual/assessor/inspector/person of the AsBo staff fulfils every competence requirement defined in this document [see bullet (1)];
- (b) the accreditation and recognition bodies are expected to assess also the following points :
- (1) according to section § 6.1 of the ISO/IEC 17020:2012 standard, the AsBo has in place documented evidence of a competence management system which defines :
    - (i) the competence requirements for all personnel involved in inspection activities, including the requirements for education, training, technical knowledge, skills and experience;
    - (ii) the process for assigning staff with the right competencies to a task (an assessment) in a project. For that, according to clause § 6.1.2 of the ISO/IEC 17020:2012 standard, “*to perform the type, range and volume of its inspection activities*”, at the moment of application for the accreditation or recognition, the AsBo shall either :
      - ↳ employ a sufficient number of own staff with the required competence, knowing that by virtue of clause § 6.3.1 of the ISO/IEC 17020:2012 standard, the AsBo “*shall itself normally perform the inspections that it contracts to undertake*” without sub-contracting<sup>(3)</sup>, or;
      - ↳ have a process and contracts in place enabling it to hire-in external competent experts to work under the AsBo management system;

That includes, where needed, the competence of the assigned staff to make professional judgements, and to perform the inspection activities in the scope of their competencies;
  - (2) the cases where the AsBo would use resources outside its own company :
 

Although the ISO/IEC 17020:2012 standard requests the AsBo to normally perform all inspection activities itself, with its own staff :

    - (i) clause § 6.1.2 of the standard allows the AsBo to hire-in<sup>(4)</sup> external experts who will operate under the AsBo management system. This is not sub-contracting;
    - (ii) clause § 6.3.1 of the standard allows the AsBo to (exceptionally) sub-contract a part of the inspection.

In those two cases, the AsBo shall have necessary competence and procedures in place to ensure and demonstrate that the external resources, or the sub-contractor, are competent to perform the inspection activities in question and, where applicable, comply with the relevant requirements stipulated in the ISO/IEC 17020:2012 standard.

(2) “Competence” is the combination of knowledge, skills and practical experience which a person, a team of persons or an organisation shall have to be able to do a particular task properly.

(3) The terms “sub-contracting” and “outsourcing” are considered to be synonyms.

(4) Clause § 6.1.2 of the ISO/IEC 17020:2012 states that “*The inspection body shall employ, or have contracts with, a sufficient number of persons with the required competencies,... , to perform the type, range and volume of its inspection activities*”. The meaning of that requirement is further clarified in note 3 in clause § 6.3.1 of the ISO/IEC 17020:2012 standard,. That note 3 states that where the AsBo “*...engages individuals or employees of other organisations to provide additional resources or expertise, these individuals are not considered to be subcontractors provided they are formally contracted to operate under the ... management system*” of the AsBo.

Hiring in of resources outside the AsBo organisation, or sub-contracting of any part of the independent assessment activities, is described in recommendation for use 08.

(3) the AsBo as a body (i.e. as an organisation or company), has :

- (i) knowledge, skills and practical experience to make professional judgements, to perform the type, range and volume of its inspection activities for the whole scope and all areas of the AsBo accreditation/recognition, and;
- (ii) actual ability to apply them in practice;

4. The assessment of the AsBo competence by the accreditation/recognition body should consist of at least the following three main checks :

- (a) review of objective evidence of the competence of the AsBo staff as defined in section § I.A-3 above;
- (b) sample interviews of AsBo staff selected by the accreditation/recognition body;
- (c) sample review or monitoring of the reports/work done (previously) by the AsBo.

### I.B. Reminder on the roles and responsibilities of the AsBo

1. The “independent safety assessment by an AsBo” is an activity distinct from (refer to recommendation for use 01) :

- (a) the design, risk assessment, risk management, manufacturing, installation, verification and validation, and testing activities to be done by the proposer.
- (b) the “conformity assessment with a **technical specification** for interoperability (TSI)” to be done by a notified body (NoBo);
- (c) the “conformity assessment with (notified) **national (technical and/or safety) rules**” to be done by a designated body (DeBo) as referred to in Article 15(8) of the Interoperability Directive 2016/797;

The independent safety assessment by an AsBo has also a different purpose and a different scope. This requires sufficient railway technical knowledge, and understanding of the overall functioning of the railway system and of the interactions between its technical, operational and organisational components. But above all, independent safety assessment mainly requires a different mind-set, specific competence and different working methods from those to be applied by the proposer, NoBo, or DeBo.

2. By virtue of Regulation 402/2013<sup>(5)</sup> and the ISO/IEC 17020:2012 standard<sup>(6)</sup>, the AsBo is an inspection body, which is to focus on a **correct and successful application of the risk management process by the proposer**, regardless of whether the application of risk management is requested by a TSI or not. According to

<sup>(5)</sup> Quotes from Regulation 402/2013 :

- (a) Article 3(14) : “assessment body’ means the independent and competent external or internal individual, organisation or entity which undertakes investigation to provide a judgement, based on evidence, of the suitability of a system to fulfil its safety requirements”;
- (b) Article 6(1) : “An assessment body shall carry out an independent assessment of the **suitability of both the application of the risk management process as set out in Annex I and of its results...**”.

<sup>(6)</sup> Quotes from the introductory section of the ISO/IEC 17020:2012 standard referenced to in Annex II of Regulation 402/2013 :

- (a) “This International Standard covers the activities of inspection bodies whose work can include the examination of ... processes, ... and the determination of their conformity with requirements ... Such work normally requires the exercise of professional judgement in performing inspection, in particular when assessing conformity with general requirements”, which is the case for the assessment of conformity with the general requirements of the risk assessment process in Annex I of Regulation 402/2013;
- (b) “Inspection activities can overlap with testing and certification activities where these activities have common characteristics. However, **an important difference is that many types of inspection involve professional judgement to determine acceptability against general requirements**, for which reason **the inspection body needs the necessary competence to perform the task**”. That competence differs therefore from the ones needed to assess testing and certification activities.

Article 6(1) of Regulation 402/2013, the AsBo is required to undertake investigations necessary to provide an expert (i.e. professional) judgement<sup>(7)</sup>, based on evidence to be provided by the proposer, of :

- (a) the conformity of the proposer's risk assessment activities with the general process requirements in Annex I of Regulation 402/2013, and;
- (b) the suitability of the results from the proposer's risk assessment to enable the system assessed to fulfil safely the intended objectives;

To provide that expert judgement, the AsBo needs specific knowledge and competence which are defined in the sections below.

3. In order not to compromise its independence, the AsBo must not redo the proposer's work. In particular, in the specific instance of the system under assessment, the AsBo shall not advise<sup>(8)</sup> the proposer on how to carry out the risk assessment and risk management, or how to design, verify, validate, test and demonstrate that the system under assessment achieves successfully and safely its intended functions.
4. Given that Article 6(3) of Regulation 402/2013 requires also to avoid the duplication of assessments, the AsBo should not redo the work of any other independent conformity assessment body (NoBo, DeBo or another AsBo) already performed for the same scope of assessment. Refer to recommendation for use<sup>°15</sup> for the relations between the AsBo, NoBo and DeBo, and where required, the mutual recognition of their respective works between those conformity assessment bodies.
5. Considering the specificities of the AsBo inspection work [refer to section § 2 above, and in particular to its footnote<sup>(6)</sup>], the AsBo does not need, and has not to demonstrate, the same railway technical knowledge and competence as the proposer, or as other conformity assessment bodies subject to different accreditation/recognition requirements like the NoBo or the DeBo. As required in the sections below, the AsBo has to demonstrate as a company :
  - (a) sufficient railway technical knowledge and understanding of the overall functioning of the railway system as a whole, including the interfaces with human operators and the interactions between the technical, operational and organisational components of the railway system;
  - (b) specific knowledge and competence in :
    - (1) risk assessment and risk management;
    - (2) correct application, or auditing, of safety and quality management systems.
6. As clearly explained in recommendation for use 01, and reminded in section § I.B-2 above, the AsBo is an inspection body which has to provide an expert judgement which gives the assurance that :
  - (a) the proposer has properly and successfully applied Regulation 402/2013;
  - (b) the system under assessment is capable to achieve successfully and safely its intended functions.

<sup>(7)</sup> Point 1 in Annex II of Regulation 402/2013 explicitly requires that “the assessment body shall exercise professional judgement in performing the inspection work defined in ...” the ISO/IEC 17020:2012 standard.

<sup>(8)</sup> This clause does not forbid the AsBo to interpret the requirements in Regulation 402/2013, or to provide general teaching and awareness on risk assessment and risk management to other stakeholders or other projects than the system under assessment. However, for such services, the AsBo is to be aware about limitations and obligations required by the different types of independence in Annex A of the ISO/IEC 17020:2012 standard. An AsBo of type A independence, or any expert hired in by the AsBo, is not allowed to provide training on how to carry out risk assessment and risk management, or other consultancy services that would compromise its independence defined in point A.1(b) in Annex A of that standard.

**I.C. Reminder of the fields of competence required for the AsBo in Regulation 402/2013**

1. Point 1 in Annex II of Regulation 402/2013 requires the AsBo to fulfil all the general requirements and criteria an inspection body, as meant by the ISO/IEC 17020:2012 standard, needs to demonstrate. This includes the general organisational, management system, management of the staff competence, and documentary evidence requirements. The present document does not need to develop it further.
2. In addition to those general requirements, for the purposes of Regulation 402/2013, Annex II of that Regulation requires that the AsBo demonstrates also specific competence requirements in the following three fields :

(a) **competence in risk assessment and risk management**

*[required in point 1(a) in Annex II of Regulation 402/2013 – Developed further in section § II below];*

- (b) **technical knowledge and competence** for the parts of the railway system covered by the scope of the AsBo accreditation/recognition, as well as the ability to understand the overall functioning of the railway system and the interactions between its technical, operational and organisational components *[required in points 1(b), 2 and 3 in Annex II of Regulation 402/2013 – Developed further in section § IV below].*

According to Article 2(1) and Article 6(1) of Regulation 402/2013, the AsBo shall be able to independently assess technical, operational and organisational changes. Taking into account points 2 and 3 in Annex II of Regulation 402/2013, the following areas of competence shall exist :

- (1) with reference to technical changes, competence in the field of one or several structural sub-systems *[required in points 1(b) and 2 in Annex II of Regulation 402/2013] :*

- (i) infrastructure;
- (ii) energy;
- (iii) trackside and on-board Control-Command and Signalling;
- (iv) Rolling Stock;

- (2) with respect to operational and organisational changes, competence in the field of functional sub-systems *[required in points 1(b) and 2 in Annex II of Regulation 402/2013] :*

- (i) operation and traffic management, and organisational changes which could impact the operational or maintenance processes;
- (ii) maintenance, as an inherent part of every structural sub-system in bullet (1) above;
- (iii) telematics applications for freight and passengers. **At present, there are no safety related functions in that functional sub-system which would justify the existence of this competence in the ERADIS database;**

- (3) other competencies *[required in points 1(b) and 3 in Annex II of Regulation 402/2013] :*

- (i) competence to assess the overall consistency of the risk management and the safe integration of the system elements under assessment into the railway system as a whole;
- (ii) as a result of the implementation of the requirements of the ECM Regulation 2019/779, there can be ASBos competent in vehicle maintenance and associated organisational aspects that could impact the maintenance processes of vehicles.

- (c) knowledge and competence in organisational matters related to the correct application of safety and quality **management systems, or to the auditing of management systems**

*[required in point 1(c) in Annex II of Regulation 402/2013 – Developed further in section § III below].*

The resulting classification in the ERADIS database, and the necessary competence requirements, are further detailed in sections § II, § III and § IV below



**I.D. Reminder of the specificities of the AsBo inspection activities**

1. Regulation 402/2013 on the CSM for risk assessment explicitly states that the AsBo is an inspection body in the field of railway safety (see section § I.B above). To provide the necessary expert judgement and the assurance that the proposer applied correctly Regulation 402/2013, and that the system under assessment can achieve successfully and safely the intended functions and objectives, the AsBo has to fulfil the requirements in the two paragraphs below.
2. According to definition (14) in Article 3, and the specific competence criteria in points 1 and 3 in Annex II, of Regulation 402/2013, the AsBo team must predominantly demonstrate knowledge, competence and professional judgement in the fields of risk assessment and risk management. For that, the AsBo has to demonstrate a thorough competence in the following fields :
  - (a) risk assessment and risk management techniques and tools (refer to section § II below);
  - (b) independent assessment of the correctness of the proposer's organisation and management of the system under assessment;
  - (c) independent assessment of the correct application by the proposer of its safety and quality processes for managing the change of the system under assessment;
  - (d) a right balance between knowledge and competence:
    - (1) on one hand in the fields of risk assessment, risk management and independent safety assessments as meant in bullet points (b) and (c) in section § I.D-2 above and,
    - (2) on the other hand, in the technical area of the AsBo accreditation/recognition for the assessments in those bullet points

in order to be able to :

    - (3) select the relevant samples of the proposer's risk assessment activities for the vertical slice-analyses based on risks, as recommended in recommendation for use 01;
    - (4) assess the correctness of the outcomes of the proposer's risk assessment processes for the selected samples;
3. According to bullet (b) in point 1, and point 2, in Annex II of Regulation 402/2013, the AsBo team needs also to have access to experts<sup>(9)</sup> with sufficient in-depth technical knowledge and competence in the railway technical area of its accreditation/recognition. This is necessary to enable the AsBo team to conduct a thorough independent assessment<sup>(10)</sup> of the correctness, and of the proper implementation by the proposer, of technical measures that control the risks arising from technical design choices. This implies that the technical railway experts of the AsBo team have a good overall knowledge and understanding of the relevant structural or technical sub-system(s), including the requirements in the applicable TSI(s) that are relevant to the AsBo assessment.

For that, the AsBo safety experts should have the capability to understand and break down complex systems<sup>(11)</sup> and complex applications of Regulation 402/2013 in order to identify the necessary suitable technical knowledge and competence that the team is to demonstrate as a whole for the independent safety assessment of a specific system. In terms of railway technical knowledge and competence in the area of the AsBo accreditation, or recognition :

- (a) it is more important that at least one member of the AsBo team has a good overall knowledge and understanding of the system under assessment, its interfaces and interactions with other parts of the railway system, including with human operators, than to be the best expert in a single field;
- (b) however, where the safety expert(s) of the AsBo team estimate in-depth railway technical support is deemed necessary, according to clause § 6.1.2 of the ISO/IEC 17020:2012 standard referenced in Regulation 402/2013, the AsBo company shall have access to a sufficient number of in-house or external railway technical experts, who are fully qualified to provide the AsBo safety specialists with railway technical opinions/advices on the quality and the robustness of the proposer's work.

## II. Core competencies related to risk assessment and risk management

### **[Point 1(a) in Annex II of Regulation 402/2013]**

#### II.A. Competence and understanding needed for a comprehensive independent assessment of the proposer's risk assessment and risk management

1. The AsBo is an inspection body which has to provide an expert judgement on a comprehensive identification and management of risks in the field of railway safety : see sections § I.B above and § I.D above.
2. For that purpose, the AsBo shall demonstrate knowledge, competence and understanding of :
  - (a) risk assessment and risk management fields [developed further in section § II.B below];
  - (b) systems engineering, functional safety engineering, and **H**uman and **O**rganisational **F**actors (**HOF**) [developed further in section § II.C below].

#### II.B. Knowledge, competence and understanding of risk assessment and risk management

1. This is the first key competence. The AsBo shall demonstrate its competence to carry out the tasks under its responsibility in Article 6(1) of Regulation 402/2013 (reminded above in section § I.B-2 above). Although preferable, it is not essential to have an educational background in the field of risk assessment and risk management. The AsBo can also demonstrate having knowledge, skills and practical experience in performing risk assessments and risk managements. This can be demonstrated for example with :
  - (a) experience as risk analyst;
  - (b) experience as coordinator of the risk assessment and risk management activities on complex projects;
  - (c) experience as responsible for the coordination and management of a safety team, and the critical peer review of their deliverables;
2. The AsBo team shall demonstrate :
  - (a) a thorough knowledge and understanding of [Regulation 402/2013](#) and [Regulation 2015/1136](#);
  - (b) awareness of the existence and content of the ERA guidance material on the CSM for risk assessment (list not exhaustive – all relevant documents are available on the Agency website under the link [https://www.era.europa.eu/common\\_safety\\_methods\\_for\\_risk\\_evaluation\\_and\\_assessment](https://www.era.europa.eu/common_safety_methods_for_risk_evaluation_and_assessment), in case the hyperlinks do not work) :
    - (1) the [guide for the application of the CSM for risk assessment](#);
    - (2) the [collection of examples of risk assessments and some possible tools supporting the CSM](#);
    - (3) the [guideline for the application of harmonised quantitative design targets for technical systems \(CSM-DT\) defined in Regulation 2015/1136](#);
    - (4) the [explanatory note on the CSM assessment body](#);
    - (5) the [recommendation for use 01 on the working method of the assessment body](#);
    - (6) the [clarification note on safe integration](#) (reference ERA1209-63);
    - (7) any other recommendation for use which will be agreed in future by the group of the AsBo cooperation and made available on the Agency web page under the following link [https://www.era.europa.eu/common\\_safety\\_methods\\_for\\_risk\\_evaluation\\_and\\_assessment](https://www.era.europa.eu/common_safety_methods_for_risk_evaluation_and_assessment).

- (9) *The technical experts of the AsBo team can be different persons from the experts with the risk assessment and independent assessment knowledge and competencies described in section § I.D.*
- (10) *The areas and samples for thorough vertical slice independent assessment are defined in the AsBo independent safety assessment plan and strategy of every project : refer to the recommendation for use 01 for more details.*
- (11) *This is fulfilled by the AsBo through the requirements in section § II.A-2(b) , which are further detailed in section § II.C concerning the AsBo knowledge, competence and understanding of systems engineering, functional safety engineering and human and organisational factors (HOF).*



3. In terms of methodology and further guidance on the processes for risk assessment, specification of applicable safety requirements and safety levels, and risk management, the AsBo team must demonstrate reasonable knowledge, competence, understanding and practical experience with either the CENELEC 50126-1 and 50126-2 standards, or with other equivalent guidelines or standards.
4. Knowledge of the following standards is also useful. However, those standards are examples; they are not mandatory, unless they are explicitly requested for a technical area in the table in section § IV below :
  - (a) CENELEC EN 50129 : Railway Applications – Communication, Signalling and Processing Systems – Safety related Electronic Systems for Signalling;
  - (b) ISO 31000 : Risk management — Principles and guidelines
  - (c) IEC 61508 : Functional safety of electrical/electronic/programmable electronic safety-related systems;
  - (d) other equivalent standards.
5. The standards above do not detail the actual techniques, instruments and tools on how to implement risk assessment and risk management. Other standards referenced in their bibliography explain specifically different tools or techniques usable for fulfilling the risk assessment and risk management requirements defined in the standards in section § 4 just here above. Here is a list of examples of dedicated standards. These standards are examples; they are not mandatory :
  - (a) ISO/IEC 31010 : Risk management – Risk assessment techniques;
  - (b) IEC 61882 : Hazard and operability studies (HAZOP studies) - Application guide;
  - (c) IEC 60812 : Analysis techniques for system reliability – Procedure for failure mode and effect analysis (FMEA);
  - (d) IEC 61025 : Fault tree analysis (FTA);
  - (e) IEC 62502 : Analysis techniques for dependability - Event tree analysis (ETA);
  - (f) IEC 62508 : Guidance on human aspects of dependability.

### **II.C. Knowledge, competence and understanding of systems engineering, functional safety engineering and human and organisational factors (HOF)**

1. This is the second key competence the AsBo must have to demonstrate its competence to carry out the tasks under its responsibility in Article 6(2) of Regulation 402/2013, and to apply the working methodology described in recommendation for use 01.
2. The AsBo shall have knowledge, competence and understanding of the following principles expected to be implemented by the proposer for the development of safety-related systems and sub-systems :
  - (a) systems engineering and functional safety engineering, and;
  - (b) process requirements for dealing with both the variability in human performance, and human and organisational factors, in all phases of the life-cycle of a system. *Those processes are an integral part of the systems engineering and functional safety engineering approaches of the CENELEC 50126–1 and 50126–2 standards.*

**Note :** knowing that the railway system is safety related, the proposer’s development process is expected to show a human-centred perspective to the specification of the system requirements and the design of effective user’s interfaces.

3. Systems engineering and functional safety engineering are based on a structured and systematic top-down approach (or process) to be implemented by the proposer. The objective is to specify in a systematic way the requirements (including organisational, performance and safety requirements) a system has to fulfil. The approach/process includes functional analysis and the allocation of functional safety requirements. Their purpose is to translate the system level requirements down into detailed sub-functions and performance requirements to be fulfilled by the underlying sub-systems, or services, of the architectural breakdown structure of the system.

The human behaviour and human performance play a central role in the safe and efficient design, risk assessment, risk management, manufacturing, installation, operation and maintenance of the railway

system. Given the variability of human performance, and the influence of human and organisational factors, it is essential that the AsBo is able to assess whether the proposer's risk assessment correctly captures and addresses :

- (a) the identification and control of HOF related risks that can arise during all phases of a system life-cycle until the acceptance of the system (i.e. until step 10 of the CENELEC 50126-1 V-cycle), and;
- (b) the identification of, and the measures for controlling, the risks that can arise during the operation and maintenance of the system in its environmental context (e.g. tasks to be carried out by human operators, working conditions, organisational arrangements, human capabilities and limitations, etc.).

4. The concepts of functional analysis and functional safety are well known and applied for the development of Electrical, Electronic and Programmable Electronic (E/E/PE) equipment and IT based systems. Specific industry standards (e.g. railways and electro-technics) cover those concepts. Although the definitions of "functional safety" slightly differ in those standards, they all convey equivalent information. Based on the definitions from the IEC 61508, CENELEC 50126-1, -2, 50128, 50657 (rolling stock applications) and 50129 standards :

**"functional safety can be considered as the functional and physical ability of a system to operate correctly in response to its inputs and not to present unacceptable risks due to a failure or faulty behaviour of the system".**

In order to be able to assess the achievement of functional safety, the AsBo shall have knowledge, competence and understanding concerning :

- (a) the specification of the functional requirements (including safety and any other performance requirements) a function has to fulfil, and;
- (b) the safety integrity requirements of a function, i.e. the likelihood of a (safety) function to be performed satisfactorily.

The higher the safety performance requirements of a system, the lower the likelihood of a dangerous failure must be, and the higher the safety integrity requirements are.

5. This means that safety-related systems that require higher levels of safety integrity require also :
- (a) on one hand, greater rigour in the proposer's systems engineering and functional safety engineering, including therefore more stringent requirements concerning the handling of human and organisational factors by the proposer for :
    - (1) the specification of the requirements of the system;
    - (2) the design, implementation and integration processes;
    - (3) the verification and validation processes;
    - (4) the configuration/parametrisation processes, where relevant;
    - (5) the production and servicing processes (i.e. maintenance and repairs);
    - (6) the evidence of proper risk assessment and risk management;
    - (7) stringent demonstration of meeting all requirements
  - (b) on the other hand, proportionate independent safety assessment by the AsBo of those proposer's system development activities.
6. As these concepts of "systems engineering and functional safety engineering" are also applicable for the development of any structural and functional sub-system defined in the Interoperability Directive 2016/797, the AsBo shall have knowledge, competence and understanding to independently assess any hazard/risk<sup>(12)</sup> regardless if it is caused by :
- (a) E/E/PE sub-system/equipment (covered by functional safety standards), or;

(12) This is without prejudice to the AsBo independent safety assessment plan defined in the [recommendation for use 01](#) on the AsBo working method.

- (b) deficiencies in civil works, or failures of a mechanical, hydraulic or pneumatic constituent/equipment (e.g. Directive 2006/42/EC on machinery), or;
- (c) human and organisational factors (HOF) impacting the operation and maintenance of any equipment;

As they could all result in safety concerns :

- (d) the proposer's demonstration of the proper control of those safety concerns requires a systematic and rigorous development engineering process to identify and manage properly all associated risks;
- (e) the AsBo has to independently assess the proposer's demonstration of the proper control of those risks according to the AsBo independent safety assessment plan, as described in the recommendation for use 01.

7. According to the explanations in section § II.C-4, the fulfilment of a specific safety integrity requirement requires the proposer :

- (a) on one hand, to demonstrate compliance with the associated likelihood of the safety-related failure;
- (b) on the other hand, to demonstrate the avoidance and control of systematic failures and errors that can be generated at the different steps of the development process listed in section § II-5 above and caused by the variability in human performance and human and organisational factors.

*Although primarily applicable to manufacturers, the CENELEC 50126-1 and 50126-2 standards can also be applied by other railway stakeholders for implementing the requirements of Regulation 402/2013. Those standards define the requirements the proposer shall fulfil for every step of the development process, as well as the evidence the proposer is expected to provide. Compliance with those two CENELEC standards enables therefore the proposer to fulfil the requirements reminded in section § II.C-2.*

8. Taking into account the sections § II.C-5(b) and § II.C-7, in order to be able to carry out the independent safety assessment, the AsBo shall have knowledge, competence and understanding of both sides of the proposer's demonstrations mentioned in section § II.C-7.

However, considering the following :

- (a) section § II.B-3 above requires the AsBo to have reasonable knowledge, competence, understanding and practical experience with either the CENELEC 50126-1 and 50126-2 standards, or with other equivalent guidelines or standards;
- (b) sections § 5.2, § 5.6 and § 5.6.4 CENELEC 50126-1 define the requirements dealt within section § II.C of the present document concerning the requirements on :

- (1) systems engineering and functional safety engineering, and;
- (2) process requirements for dealing with both the variability in human performance, and human and organisational factors;

- (c) the proposer has to provide to the AsBo the evidence of a proper management of those requirements;

if the AsBo fulfils the mandatory requirements in section § II.B-3 above, the AsBo has also the necessary knowledge, competence, understanding and practical experience to independently assess the correctness of the proposer's measures in terms of :

- (d) systems engineering and functional safety engineering, and;
- (e) processes for dealing with both the variability in human performance, and human and organisational factors.

9. There is no dedicated standard on human and organisational factors to be known by the AsBo. Although the awareness of the following relevant standards is useful, they are given only as examples. Those standards are not mandatory, and the accreditation/recognition body must neither impose their knowledge by the AsBo, nor the systematic presence of an HOF specialist (e.g. a psychologist) in every AsBo company or on every project :

- (a) although not specific to HOF, IEC 61508; and CENELEC 50128 and 50129 standards address also the process requirements for the control of risks arising during the design phases of a system life-cycle;

- (b) ISO 26800 on “Ergonomics — General approach, principles and concepts”;
- (c) ISO series 11064 on “ergonomic design of control centres”, and ISO series 9241 on “ergonomics of human-system interaction”;
- (d) awareness of methods and tools for risk assessments on human and organisational factors, such as human reliability analysis, task analysis, human error HAZOPs, usability analysis, simulation, bow-ties, etc.

### III. Core competencies related to knowledge and understanding of organisational matters, management systems and auditing of management systems

#### **[Point 1(c) in Annex II of Regulation 402/2013]**

1. This section is related to the competence in section § I.C-2(c) above. It deals with the third key competence the AsBo must have to demonstrate its competence to carry out the tasks under its responsibility in Article 6(2) of Regulation 402/2013. It defines also the additional specific knowledge and competence the AsBo must have in order to be able to apply the AsBo working methodology described in the recommendation for use 01, i.e. to :
  - (a) be able to assess the organisational matters, resource allocation, safety and quality processes and methodology the proposer puts in place for :
    - (1) carrying out safely and correctly risk assessments and risk management;
    - (2) managing the risks related to variability in human performance, and human and organisational factors.
  - (b) provide the expert judgement as referred to in section § I.B-2 above, in accordance with the methodology described in the recommendation for use 01;
2. The AsBo should be able to demonstrate the following :
  - (a) professional status and ability regarding :
    - (1) educational qualification<sup>(13)</sup>/professional status : e.g. vocational training, university degree, practical working experience gained by the experts in the considered domain;
    - (2) previous relevant training, e.g. experience in designing or auditing management systems (e.g. safety management system or maintenance system);
    - (3) thorough knowledge, understanding and ability to apply the principles of auditing and assessing the correct and effective implementation of the procedures and processes of a management system.

Note: Good general guidance for managing, planning and conducting the AsBo independent safety assessment activities can be found in the ISO 19011 standard. That standard also gives guidance on the competence and evaluation of an auditor and an audit team;

    - (4) previous relevant internal/external competence assessments;
    - (5) professional experience (e.g. as consultant, as assessor, as auditor, work as a NoBo, as a DeBo);
    - (6) preparation of checklists/reports/certificates/etc. based on samples from previous and current conformity assessment work of the candidate;
  - (b) professional knowledge, and ability to talk about it and demonstrate the knowledge, covering a suitable combination of the following :
    - (1) the definition of strategy for the independent safety assessment. This corresponds to the planning of the independent safety assessment in recommendation for use 01;

<sup>(13)</sup> Definition from dictionary : “Educational qualifications are the degrees, diplomas, certificates, professional titles and so forth that an individual has acquired whether by full-time study, part-time study or private study, whether conferred in the home country or abroad, and whether conferred by educational authorities, special examining bodies”. The term “qualification” is synonymous with “credential”.

- (2) the content of parts of the AsBo quality management system (QMS) and management system (section § 8 of the ISO/IEC 17020:2012 standard) relevant for the independent safety assessment;
- (3) the ability to understand, coordinate and implement the role(s), responsibilities and duties of the AsBo staff assigned to a project;
- (4) the independent safety assessment activities of the AsBo on previous or current projects;
- (5) for the railway technical areas in the scope of the AsBo accreditation/recognition :
  - (i) the technology and processes used for the design, production, testing, operation, maintenance of the corresponding technical items;
  - (ii) the relevant safety critical failures/defects which may occur during the use of the corresponding technical items (e.g. a frozen LCD screen not refreshing the train speed, relay contacts stuck, processor crash down, etc.);
  - (iii) the significance of typical non-conformities of the corresponding technical items which may be found during the conformity assessments;
- (6) the professional ability to make sound and comprehensible professional judgements;
- (7) the professional ability to :
  - (i) write/talk about the approach of their conformity assessment and the related findings in the independent safety assessment reports;
  - (ii) present the approach and the findings to other experts in the field (e.g. towards client experts, other involved conformity assessment bodies, authorising entities, Investigation bodies following incidents or accidents where a technical item is involved);
- (c) the self-awareness of the limits of personal skills, professional competence and ability to understand a railway technical area, and constantly reflect on those limits during every conformity assessment activity. This includes for example the ability to :
  - (1) where necessary, double check the strategy and priorities for the independent safety assessment;
  - (2) stop and discuss with other experts/Lead Assessor/Lead Auditor/Technical Manager if the AsBo expert is in doubt;
  - (3) where necessary, consult other relevant technical experts for additional support, e.g. for assessing the relevance and completeness of the results from the risk assessments and risk management, for checking the comprehensiveness of the system definition, suitability of the used (railway) Codes of Practice or Similar Reference Systems, the appropriateness of risk control measures, for example the appropriateness of technical measures for the control of risks arising from proposer's technical design choices, etc.;
  - (4) demand any relevant additional training, e.g. to (re)gain the required level of competence;
  - (5) perform self-study on new legislation and standards;
- (d) where auditing organisational matters and management systems, have additional competence relevant to the type of the management systems to be assessed and competence relevant to the technical and geographic areas associated with the management system.

#### **IV. Relevant railway technical knowledge and competence per technical area**

##### ***[Points 1(b) and 2 in Annex II of Regulation 402/2013]***

##### **IV.A. Possible structural or functional areas for accreditation/recognition**

1. The possible areas of the railway technical knowledge and competence are listed in section § I.C-2(b) above.
2. The accreditation/recognition body must assess the level of railway technical knowledge and competence based on the specificities of the AsBo roles and responsibilities described in sections § I.B-1, -2, -3 and § I.D above
3. The sections below list the necessary level of detail of railway technical knowledge and competence for every area of the AsBo scope of accreditation/recognition.

4. The present recommendation for use defines the minimum level of competence criteria and requirements the AsBo shall fulfil. It includes the necessary level of technical knowledge and understanding of the system to be assessed, to enable the AsBo to fulfil the specific roles and responsibilities reminded in section § I.B above, and summarised by the two objectives in sub-section § 6 of section § I.B above.

The technical level of the AsBo knowledge does not need to be on an engineering level equivalent to the proposer's one, but has to be at a sufficient level that makes the AsBo able to :

- (a) understand, based on the technical documentation provided by the proposer, the functioning and use of the technical system, including its interfaces with human operators and its interactions within the physical, functional, environmental, operational, and maintenance context of the railway system;
- (b) interpret the results from the proposer's risk assessment and determine whether they are suitable for controlling adequately the risks associated with the system under assessment;
- (c) form an expert judgement of the expected safety performance to be reached by the system.

5. The accreditation/recognition body shall not request a more detailed technical knowledge and competence than the requirements below. In particular, as stated in section § I.A-3(a) above, railway technical knowledge and competence has to be available in the AsBo organisation/company and for each assessment project, including where a particular structural sub-system may need a subset of the disciplines listed in the sections below. It is thus not necessary that every member/individual/assessor/inspector/person of the AsBo staff fulfils every competence requirement, as an individual, defined in this document.
6. The accreditation/recognition body shall accept the demonstration of knowledge and competence by either educational qualification of the AsBo experts, or practical working experience gained by the experts in the considered domain, or a suitable combination of both.

#### IV.B. Infrastructure structural sub-system and safe integration at the level of that sub-system

1. This competence refers to the AsBo ability to assess a change of technical nature.
2. The AsBo company shall fulfil all the requirements defined in this section.

3. Classification in the ERADIS database : **infrastructure**

4. Specific criteria/discipline to be fulfilled :

(a) *the requirements already defined in sections § II and § III above*

With respect to the **core specific competence criteria on "risk management, and quality and safety management systems"** in points 1(a) and 1(c) in Annex II of Regulation 402/2013 :

- (1) core competencies related to risk assessment and risk management as defined in sections § II and § II.A above. This includes :
  - (i) knowledge, competence and understanding of risk assessment and risk management disciplines as defined in section § II.B above. That includes reasonable knowledge, competence, understanding and practical experience with either the CENELEC 50126-1 and 50126-2 standards, or with other equivalent guidelines or standards;
  - (ii) knowledge, competence and understanding of systems engineering, functional safety engineering and human and organisational factors (HOF) as defined in section § II.C above;
- (2) core competencies related to knowledge and understanding of organisational matters, management systems and auditing of management systems as defined in section § III above;



(b) with respect to the **specific technical criteria** in points 1(b) and 2 in Annex II of Regulation 402/2013 :

- (1) mechanical engineering;
- (2) electrical engineering;
- (3) civil works engineering;
- (4) overall knowledge and understanding of matters related to traffic management and maintenance of the infrastructure structural sub-system;
- (5) overall knowledge and understanding of the infrastructure structural sub-system, including the requirements in the applicable TSI(s) that are relevant to the AsBo assessment.

#### 5. **AsBo competence concerning the safe integration at the level of the structural sub-system**

Based on the explanations in sections § V.A and § V.B below, an AsBo accredited/recognised for the infrastructure structural sub-system has also the competence to independently assess the **safe integration at the level of the infrastructure sub-system**, provided that the AsBo applies the working method of recommendation for use 01. This includes the AsBo competence to :

- (a) assess the proposer's safe integration of all internal parts that constitute the infrastructure sub-system, including all internal interfaces between those individual parts of the infrastructure sub-system;
- (b) assess the proposer's safe integration of the infrastructure sub-system within its direct physical, functional, environmental, operational and maintenance context;
- (c) assess and interpret the results of independent assessment activities carried out, where required, by other AsBos concerning risks that could arise across both internal and external interfaces of the infrastructure structural sub-system (refer to section § V.B-2 below).

There is no additional and dedicated field to be filled in for this competence in the ERADIS database.

In addition to that, the accreditation/recognition body shall not fill-in the "System Safe Integration" field in section "5. Classification" of the ERADIS database when the AsBo is accredited/recognised only for the infrastructure structural sub-system. The entitlements that enable the AsBo to pretend accreditation/recognition in the "System Safe Integration" area are specified in section § V.C below.

#### IV.C. **Energy structural sub-system and safe integration at the level of that sub-system**

1. This competence refers to the AsBo ability to assess a change of technical nature.
2. The AsBo company shall fulfil all the requirements defined in this section.

3. Classification in the ERADIS database : **energy**

4. Specific criteria/discipline to be fulfilled :

(a) *the requirements already defined in sections § II and § III above*

With respect to the **core specific competence criteria** on "risk management, and quality and safety management systems" in points 1(a) and 1(c) in Annex II of Regulation 402/2013 :

- (1) core competencies related to risk assessment and risk management as defined in sections § II and § II.A above. This includes :
  - (i) knowledge, competence and understanding of risk assessment and risk management disciplines as defined in section § II.B above. That includes reasonable knowledge, competence, understanding and practical experience with either the CENELEC 50126-1 and 50126-2 standards, or with other equivalent guidelines or standards;

<ul style="list-style-type: none"> <li>(ii) knowledge, competence and understanding of systems engineering, functional safety engineering and human and organisational factors (HOF) as defined in section § II.C above;</li> <li>(2) core competencies related to knowledge and understanding of organisational matters, management systems and auditing of management systems as defined in section § III above;</li> </ul>
<p>(b) with respect to the <b>specific technical criteria</b> in points 1(b) and 2 in Annex II of Regulation 402/2013 :</p> <ul style="list-style-type: none"> <li>(1) mechanical engineering;</li> <li>(2) electrical engineering;</li> <li>(3) overall knowledge and understanding of matters related to maintenance of the energy structural sub-system;</li> <li>(4) CENELEC EN 50562 : Railway applications. Fixed installations - Process, protective measures and demonstration of safety for electric traction systems</li> <li>(5) overall knowledge and understanding of the energy structural sub-system, including the requirements in the applicable TSI(s) that are relevant to the AsBo assessment.</li> </ul>

5. **AsBo competence concerning the safe integration at the level of the structural sub-system**

Based on the explanations in sections § V.A and § V.B below, an AsBo accredited/recognised for the energy structural sub-system has also the competence to independently assess the **safe integration at the level of the energy sub-system**, provided that the AsBo applies the working method of recommendation for use 01. This includes the AsBo competence to :

- (a) assess the proposer’s safe integration of all internal parts that constitute the energy sub-system, including all internal interfaces between those individual parts of the energy sub-system;
- (b) assess the proposer’s safe integration of the energy sub-system within its direct physical, functional, environmental, operational and maintenance context;
- (c) assess and interpret the results of independent assessment activities carried out, where required, by other AsBos concerning risks that could arise across both internal and external interfaces of the energy structural sub-system (refer to section § V.B-2 below).

There is no additional and dedicated field to be filled in for this competence in the ERADIS database.

In addition to that, the accreditation/recognition body shall not fill-in the “System Safe Integration” field in section “5. Classification” of the ERADIS database when the AsBo is accredited/recognised only for the energy structural sub-system. The entitlements that enable the AsBo to pretend accreditation/recognition in the “System Safe Integration” area are specified in section § V.C below.

**IV.D.Trackside and on-board CCS structural sub-systems and safe integration at the level of those sub-systems**

- 1. This competence refers to the AsBo ability to assess a change of technical nature.
- 2. The AsBo company shall fulfil all the requirements defined in this section.

3.	Classification in the ERADIS database : <b>control command and signalling</b>
4.	Specific criteria/discipline to be fulfilled :
	<ul style="list-style-type: none"> <li>(a) <i>the requirements already defined in sections § II and § III above</i></li> </ul> <p>With respect to the <b>core specific competence criteria on “risk management, and quality and safety management systems”</b> in points 1(a) and 1(c) in Annex II of Regulation 402/2013 :</p> <ul style="list-style-type: none"> <li>(1) core competencies related to risk assessment and risk management as defined in sections § II and § II.A above. This includes :</li> </ul>

- (i) knowledge, competence and understanding of risk assessment and risk management disciplines as defined in section § II.B above. That includes reasonable knowledge, competence, understanding and practical experience with either the CENELEC 50126-1 and 50126-2 standards, or with other equivalent guidelines or standards;
  - (ii) knowledge, competence and understanding of systems engineering, functional safety engineering and human and organisational factors (HOF) as defined in section § II.C above;
- (2) core competencies related to knowledge and understanding of organisational matters, management systems and auditing of management systems as defined in section § III above;

(b) with respect to the **specific technical criteria** in points 1(b) and 2 in Annex II of Regulation 402/2013 :

- (1) electrical engineering;
- (2) IT/software engineering;
- (3) mechanical engineering;
- (4) overall knowledge and understanding of matters related to maintenance of the trackside and on-board Control-Command and Signalling structural sub-systems;
- (5) *(already included in section § IV.D-4(a) of this table)* CENELEC EN 50126-1 : Railway applications —The specification and demonstration of reliability, availability, maintainability and safety (RAMS) – Part 1: Generic RAMS Process;
- (6) *(already included in section § IV.D-4(a) of this table)* CENELEC EN 50126-2 : Railway Applications - The specification and demonstration of reliability, availability, maintainability and safety (RAMS) – Part 2: Systems Approach to Safety;
- (7) CENELEC EN 50128 : Railway applications — Communication, signalling and processing systems — Software for railway control and protection systems;
- (8) CENELEC EN 50129 : Railway applications — Communication, signalling and processing systems — Safety related electronic systems for signalling;
- (9) CENELEC EN 50159 : Railway applications - Communication, signalling and processing systems;
- (10) overall knowledge and understanding of the trackside and on-board CCS structural sub-systems, including the requirements in the applicable TSI(s) that are relevant to the AsBo assessment.

#### 5. **AsBo competence concerning the safe integration at the level of the structural sub-system**

Based on the explanations in sections § V.A and § V.B below, an AsBo accredited/recognised for the control command and signalling structural sub-systems has also the competence to independently assess the **safe integration at the level of the CCS sub-systems**, provided that the AsBo applies the working method of recommendation for use 01. This includes the AsBo competence to :

- (a) assess the proposer’s safe integration of all internal parts that constitute the CCS sub-systems, including all internal interfaces between those individual parts of the CCS sub-systems;
- (b) assess the proposer’s safe integration of the CCS sub-systems within its direct physical, functional, environmental, operational and maintenance context;
- (c) assess and interpret the results of independent assessment activities carried out, where required, by other ASBos concerning risks that could arise across both internal and external interfaces of the control command and signalling structural sub-system (refer to section § V.B-2 below).

There is no additional and dedicated field to be filled in for this competence in the ERADIS database.

In addition to that, the accreditation/recognition body shall not fill-in the “System Safe Integration” field in section “5. Classification” of the ERADIS database when the AsBo is accredited/recognised only for the CCS structural sub-systems. The entitlements that enable the AsBo to pretend accreditation/recognition in the “System Safe Integration” area are specified in section § V.C below.

**IV.E. Rolling Stock structural sub-system and safe integration at the level of that sub-system**

1. This competence refers to the AsBo ability to assess a change of technical nature.
2. The AsBo company shall fulfil all the requirements defined in this section.

3. Classification in the ERADIS database : **rolling stock**

4. Specific criteria/discipline to be fulfilled :

(a) *the requirements already defined in sections § II and § III above*

With respect to the **core specific competence criteria** on “**risk management, and quality and safety management systems**” in points 1(a) and 1(c) in Annex II of Regulation 402/2013 :

- (1) core competencies related to risk assessment and risk management as defined in sections § II and § II.A above. This includes :
  - (i) knowledge, competence and understanding of risk assessment and risk management disciplines as defined in section § II.B above. That includes reasonable knowledge, competence, understanding and practical experience with either the CENELEC 50126-1 and 50126-2 standards, or with other equivalent guidelines or standards;
  - (ii) knowledge, competence and understanding of systems engineering, functional safety engineering and human and organisational factors (HOF) as defined in section § II.C above;
- (2) core competencies related to knowledge and understanding of organisational matters, management systems and auditing of management systems as defined in section § III above;

(b) with respect to the **specific technical criteria** in points 1(b) and 2 in Annex II of Regulation 402/2013 :

- (1) mechanical engineering;
- (2) electrical engineering;
- (3) IT/software engineering;
- (4) overall knowledge and understanding of matters related to maintenance of the rolling stock sub-system;
- (5) CENELEC EN 50657 : Railway applications – Rolling stock applications – Software on board Rolling Stock;
- (6) overall knowledge and understanding of the rolling stock structural sub-system, including the requirements in the applicable TSI(s) that are relevant to the AsBo assessment;
- (7) overall knowledge and understanding of the (EU) Regulation 2018/545 on railway vehicle authorisations;
- (8) where relevant<sup>(14)</sup> overall knowledge and understanding of the integration aspects of an on-board CCS structural sub-systems, including the requirements in the applicable TSI(s) that are relevant to the AsBo assessment.

**5. AsBo competence concerning the safe integration at the level of the structural sub-system**

Based on the explanations in sections § V.A and § V.B below, an AsBo accredited/recognised for the rolling stock structural sub-system has also the competence to independently assess the **safe integration at the level of the rolling stock sub-system**, provided that the AsBo applies the working method of recommendation for use 01. This includes the AsBo competence to :

(14) “Where relevant” refers to EMUs and locomotives. Freight wagons are not fitted with on-board ETCS sub-systems

- (a) assess the proposer's safe integration of all internal parts that constitute the rolling stock sub-system, including all internal interfaces between those individual parts of the rolling stock sub-system;
- (b) assess the proposer's safe integration of the rolling stock sub-system within its direct physical, functional, environmental, operational and maintenance context;
- (c) assess and interpret the results of independent assessment activities carried out, where required, by other AsBos concerning risks that could arise across both internal and external interfaces of the rolling stock structural sub-system (refer to section § V.B-2 below).

#### 6. **AsBo competence for independent assessment of a railway vehicle requirement capture process**

A rolling stock AsBo, that fulfils the requirements and criteria specified in this document, has automatically the competence to independently assess the proposer's<sup>(15)</sup> **requirement capture process** of (EU) Regulation 2018/545 on railway vehicle authorisations. The AsBo shall not be obliged to demonstrate additional competence requirements and criteria.

Indeed, taking into account the following requirements from sections § II and § III above :

- (a) the AsBo must fulfil the **core specific competence criteria** in section § IV.E-4(a) above. The AsBo has thus knowledge, competence and understanding of systems engineering and functional safety engineering approaches the proposer applies for systematically identifying and managing the requirements that a safety related sub-system must fulfil;
- (b) the AsBo has to apply the working method of recommendation for use 01 in order to independently assess the appropriateness and correct application of the proposer's processes for a safe management of the change;

the AsBo has thereby the competence to independently assess :

- (c) the appropriateness, and correct application by the proposer, of the proposer's **requirement capture process** of (EU) Regulation 2018/545 on railway vehicle authorisations, and;
- (d) the proposer's management, traceability, and demonstration of actual and correct implementation of all vehicle requirements through all steps of the development process of the vehicle (steps 1 to 10 of the CENELEC V Cycle).

There is no additional and dedicated field to be filled in for this competence in the ERADIS database.

In addition to that, the accreditation/recognition body shall not fill-in the "System Safe Integration" field in section "5. Classification" of the ERADIS database when the AsBo is accredited/recognised only for the rolling stock structural sub-system. The entitlements that enable the AsBo to pretend accreditation/recognition in the "System Safe Integration" area are specified in section § V.C below.

(15) When dealing with the authorisation of a railway vehicle, the term "proposer" of (EU) Regulation 402/2013 on the CSM RA corresponds to the term "applicant" of (EU) Regulation 2018/545 on railway vehicle authorisations.

**IV.F. Operation, traffic management and organisational aspects impacting operational processes**

1. This competence refers to the AsBo ability to assess a change of operational and/or organisational nature. It corresponds to a functional sub-system.
2. The AsBo company shall fulfil all the requirements defined in this section.

3. Classification in the ERADIS database : although the ERADIS database does not have a special field for this competence, it can be registered as “**Operational and Organisational**” in the field “other” in section “5. Classification” of the ERADIS database.

4. Specific criteria/discipline to be fulfilled :

(a) *the requirements already defined in sections § II and § III above*

With respect to the **core specific competence criteria on “risk management, and quality and safety management systems”** in points 1(a) and 1(c) in Annex II of Regulation 402/2013 :

- (1) core competencies related to risk assessment and risk management as defined in sections § II and § II.A above. This includes :
  - (i) knowledge, competence and understanding of risk assessment and risk management disciplines as defined in section § II.B above. That includes reasonable knowledge, competence, understanding and practical experience with either the CENELEC 50126-1 and 50126-2 standards, or with other equivalent guidelines or standards;
  - (ii) knowledge, competence and understanding of systems engineering, functional safety engineering and human and organisational factors (HOF) as defined in section § II.C above;
- (2) core competencies related to knowledge and understanding of organisational matters, management systems and auditing of management systems as defined in section § III above;

(b) with respect to the **specific technical criteria** in points 1(b) and 2 in Annex II of Regulation 402/2013 :

- (1) overall knowledge and understanding of all structural and functional sub-systems of the railway system;
- (2) overall knowledge and understanding of railway transport operation (freight, freight/dangerous goods, passenger, conventional speed, high speed) and traffic management;
- (3) overall knowledge and understanding of human and organisational factors within the context of railway operation and traffic management system;
- (4) awareness of human capabilities and limitations and how to manage risks arising from the variability in human performance, applying human and organisational factors knowledge, and using recognised methods and tools;
- (5) a thorough knowledge and understanding of Regulation 2018/762 on the CSM for SMS;
- (6) a thorough knowledge and understanding of associated organisational aspects that could impact the operational and traffic management processes of the safety management system.

5. **AsBo competence concerning the safe integration at the level of the functional sub-system**

Based on the explanations in sections § V.A and § V.B below, and provided that the AsBo applies the working method of recommendation for use 01, an AsBo accredited/recognised for this functional sub-system related to operation, traffic management and organisational has matters also the competence to :

- (a) assess the **safe integration at the level of that functional sub-system**;
- (b) **assess and interpret the results** of independent assessment activities **carried out by other AsBos** on risks shared across interfaces between different structural and functional sub-systems (refer to section § V.B-2 below).



6. The accreditation/recognition body shall not fill-in the “System Safe Integration” field in section “5. Classification” of the ERADIS database when the AsBo is accredited/recognised only for this functional sub-system. The entitlements that enable the AsBo to pretend accreditation recognition in the “System Safe Integration” area are specified in section § V.C below.

#### IV.G. Telematics applications for freight and passengers

1. At present, there are no safety related functions in the telematics applications for freight and passengers functional sub-system. There is thus no justification for the existence of this competence in the ERADIS database.
2. Therefore, there is no justification for seeking accreditation/recognition in this area

#### IV.H. (Vehicle) Maintenance and associated organisational aspects impacting maintenance processes

1. This competence refers to the AsBo ability to assess a change of operational and/or organisational nature in the field of maintenance of vehicles. This competence is a direct result of the implementation of the ECM Regulation 2019/779 which repeals Regulation 445/2011.
2. There are no overall maintenance standards and regulations which specify the maintenance requirements for all structural sub-systems. Every structural sub-system has its own maintenance requirements which result mainly from technical choices made during the design of the considered structural sub-system. Thereby, the sections § IV.B, § IV.C, § IV.D and § IV.E above require the AsBo to have an overall knowledge and understanding of matters related to maintenance of every specific structural sub-system. Those competencies do not need to be checked in the scope of the present section.
3. For the specific scope addressed in this section, the AsBo company shall fulfil all the requirements defined in the next paragraphs of this section.

4. Classification in the ERADIS database : **maintenance**

5. Specific criteria/discipline to be fulfilled :

(a) *the requirements already defined in sections § II and § III above*

With respect to the **core specific competence criteria on “risk management, and quality and safety management systems”** in points 1(a) and 1(c) in Annex II of Regulation 402/2013 :

- (1) core competencies related to risk assessment and risk management as defined in sections § II and § II.A above. This includes :
  - (i) knowledge, competence and understanding of risk assessment and risk management disciplines as defined in section § II.B above. That includes reasonable knowledge, competence, understanding and practical experience with either the CENELEC 50126-1 and 50126-2 standards, or with other equivalent guidelines or standards;
  - (ii) knowledge, competence and understanding of systems engineering, functional safety engineering and human and organisational factors (HOF) as defined in section § II.C;
- (2) core competencies related to knowledge and understanding of organisational matters, management systems and auditing of management systems as defined in section § III above;

(b) with respect to the **specific technical criteria** in points 1(b) and 2 in Annex II of Regulation 402/2013 :

Considering the specificities of vehicle maintenance as defined in the ECM Regulation 2019/779, there can be AsBos specialised in this field. This competence in the ERADIS database refers therefore specifically to AsBos with in-depth railway knowledge and understanding of rolling stock design and maintenance. The following disciplines must be demonstrated :

- (1) mechanical engineering;
- (2) electrical engineering;
- (3) IT/software engineering;
- (4) overall knowledge and understanding of the rolling stock structural sub-system, including the requirements in the applicable TSI(s) that are relevant to the AsBo assessment;
- (5) a thorough knowledge and understanding of ECM Regulation 2019/779;
- (6) a thorough knowledge and understanding of associated organisational aspects that could impact the maintenance processes of a maintenance system;
- (7) overall knowledge and understanding of the EN 17023 standard on “Railway applications – Railway vehicle maintenance – Creating and modification of maintenance plan”.

#### 6. **AsBo competence concerning the safe integration at the level of the functional sub-system**

Based on the explanations in sections § V.A and § V.B below, and provided that the AsBo applies the working method of recommendation for use 01, an AsBo accredited/recognised for this functional sub-system related to operational and/or organisational matters of vehicle maintenance has also the competence to :

- (a) assess the **safe integration at the level of that functional sub-system**;
- (b) **assess and interpret the results** of independent assessment activities **carried out by other AsBos** on risks shared across interfaces between the rolling stock structural sub-system and this functional sub-system (refer to section § V.B-2 below).

7. The accreditation/recognition body shall not fill-in the “System Safe Integration” field in section “5. Classification” of the ERADIS database when the AsBo is accredited/recognised only for this functional sub-system in the field of rolling stock maintenance. The entitlements that enable the AsBo to pretend accreditation recognition in the “System Safe Integration” area are specified in section § V.C below.

## V. Competence in Safe integration

**[Points 1(a), 1(b) and 3 in Annex II of Regulation 402/2013]**

### V.A. Levels of safe integration

1. Concerning the necessary AsBo competence for the assessment of safe integration, point § 3 in Annex II of Regulation 402/2013 specifies the competence requirements only for the highest level of safe integration. It sets out the requirements concerning the AsBo competence to assess the “overall consistency of the risk management and of the safe integration of a change, or of the introduction of a new part, into the railway system as a whole”.
2. In practice, as described in the Agency [clarification note on safe integration](#) (available on the Agency website under the link [https://www.era.europa.eu/common\\_safety\\_methods\\_for\\_risk\\_evaluation\\_and\\_assessment](https://www.era.europa.eu/common_safety_methods_for_risk_evaluation_and_assessment), in case the hyperlinks do not work), safe integration is a generic concept. It exists at all levels of the architectural break down structure of the railway system.
3. In relation to the railway technical areas defined in section § IV above, the following two cases of competence for the safe integration have to be distinguished :
  - (a) safe integration at the level of every structural or functional sub-system.  
*There is no dedicated field for this competence in the ERADIS database;*
  - (b) safe integration at the level of the railway system as a whole.  
*This competence corresponds to the “System Safe Integration” field in section “5. Classification” in the ERADIS database.*

## V.B. Competence in safe integration at the level of every structural or functional sub-system

### [Points 1(a) and 1(b) in Annex II of Regulation 402/2013]

1. **For every structural or functional sub-system** [points 1(a) and 1(b) in Annex II of Regulation 402/2013], the AsBo needs competence for assessing :
  - (a) the proposer's safe integration of all internal parts constituting the sub-system<sup>(16)</sup>, including all internal interfaces between those individual parts of the sub-system;
  - (b) the proposer's safe integration of the sub-system within the directly connected layer (direct interfaces) with the other sub-systems, human operators and human actions.
2. Based on the arguments described in the Agency [clarification note on safe integration](#) referenced to in section § V.A-2 above, the following can be concluded.

An AsBo accredited/recognised for the technical area of a railway structural or functional sub-system has the competence to independently assess :

- (a) the correctness of the proposer's risk assessment, and suitability of its results, within the area of the structural or functional sub-system, and;
- (b) the proposer's safe integration at the level of that structural or functional sub-system.

Provided that the AsBo applies the working method of recommendation for use 01, then :

- (1) the AsBo has the competence to independently assess both parts of the proposer's risk assessment referenced in bullet points (a) and (b) in section §V.B-1 above;
- (2) the AsBo has the "**competence to assess and interpret the results**" of independent assessment activities carried out, where required, by other AsBos<sup>(17)</sup> for :
  - (i) risks that could arise across external interfaces (bullet (b) in section § V.B-1 above) of the structural or functional sub-system with the directly connected layer (direct interfaces) with other sub-systems, human operators and human actions;
  - (ii) risks that could arise across the internal interfaces (bullet (a) in section § V.B-1 above) between the different parts that constitute the structural or functional sub-system.

Thereby, the accreditation/recognition body has to :

- (c) acknowledge automatically this fundamental AsBo competence for independent assessment of safe integration at the level of the structural or functional sub-system covered by its accreditation/recognition;
- (d) accept, without additional requirements, that the AsBo has the "competence to assess and interpret the results" of independent assessment activities carried out, where required, by other AsBos<sup>(17)</sup> concerning risks that could arise across both internal and external interfaces of the structural or functional sub-system.

(16) (Bigger) systems composed of several smaller sub-systems is also referenced as the concept of "nested systems" in section § 5.2.1 the CENELEC 50126-1:2017 standard.

(17) The acknowledgement of this competence of the AsBo is essential to demonstrate the AsBo compliance with the requirement in the last sentence of section § 6.3.1 n1 of the ILAC-P15:05/2020-1.

### **Extract of section § 6.3.1 n1 from ILAC-P15:05/2020-1:**

*"By definition (ISO/IEC 17011, clause 3.1), accreditation is limited to conformity assessment tasks which the inspection body has demonstrated competence to perform itself. Thus, accreditation cannot be granted for activities referred to in the fourth bullet point under note 1 ..." (of clause 6.3.1 in the ISO/IEC 17020:2012 standard) "... , if the inspection body does not have the required competence and/or resources. However, the task of **assessing and interpreting the results of such activities** for the purpose of determining conformity may be **included in the scope of accreditation**, provided adequate competence for this has been demonstrated".*

**There is no additional and dedicated field to be filled in for this competence in the ERADIS database.**

3. For example, the AsBo independent safety assessment of an on-board CCS sub-system automatically includes the assessment of :
  - (a) the safe integration by the proposer of all internal parts constituting the architecture of the on-board CCS sub-system;
  - (b) the safe integration by the proposer of human operators and human actions at all levels of the development process. Indeed, the proposer's risk assessment is expected to include any necessary "safety related application conditions" (SRACs) exported for the safe operation and safe maintenance of the on-board CCS sub-system;
  - (c) the correct identification by the proposer of the impacts of the integration of the on-board CCS sub-system into a vehicle. Indeed, the proposer should assess the direct interfaces of the on-board CCS sub-system with all parts of the vehicle to which it is interconnected (e.g. the interface with the train braking control and traction cut-off functions) and export any necessary "safety related application conditions" (SRACs). The AsBo of the CCS sub-system work stops there;
  - (d) However, the necessary changes to the vehicle that arise from the incorporation of the on-board CCS sub-system (e.g. moving other train components to allow the on-board CCS antenna to comply with the necessary safety distance from the front end of the train) is outside the scope of the CCS risk assessment and CCS AsBo independent assessment. The rolling stock risk assessment must take the "exported safety related application constraints" into account, and the rolling stock AsBo has to independently assess it.

**V.C. System Safe Integration or competence in safe integration at the level of the railway system as a whole**  
**[Point 3 in Annex II of Regulation 402/2013]**

1. This competence is associated to the AsBo ability to independently assess the proposer's risk assessment of the impacts of a change at the level **of the railway system as a whole**. It is associated to points 1(a), 1(b) and 3 in Annex II of Regulation 402/2013.
2. This is an additional and specific competence, referred to in point § 3 in Annex II of Regulation 402/2013. As listed in the table below, the AsBo needs less "railway technical knowledge and competence" for every sub-system<sup>(18)</sup> but needs a broader overall railway knowledge of the different components of the railway system and of its environment. This is essential for being able to assess the correct identification and proper management by the proposer of the impacts, and potential risks on non-modified parts, that could arise from a change of any constituting part of the railway system.
3. In particular, the AsBo shall have a thorough knowledge and understanding of the "system based and top-down approach" concepts requiring a proper organisation, development process and management of the technical parts, as well of the risk management activities, of a (complex) project in order to :
  - (a) fulfil the requirements in point § 3 in Annex II of Regulation 402/2013, and;
  - (b) assess that the proposer's risk management effectively demonstrates that the introduction of a new, or the modification of an existing element, into its physical, functional, environmental, operational, and maintenance context does not have unintended, adverse and unacceptable effects on the safety of the railway system into which it is being incorporated.

**The AsBo must be accredited/recognised specifically for this competence.** It is **not automatically part** of the accreditation/recognition **of a single railway technical area**. The Agency [clarification note on safe integration](#) (available on the Agency website under the link <https://www.era.europa.eu/common-safety-methods-for-risk-evaluation-and-assessment>, in case the hyperlinks do not work), gives additional guidance on safe integration. It explains the roles and responsibilities for the safe integration of the proposer, as well as of the AsBo.

This competence corresponds to the “System Safe Integration” field in section “5. Classification” in the ERADIS database.

By analogy to section § V.B-2 above, an AsBo accredited/recognised for “System Safe Integration” has automatically the “**competence to assess and interpret the results**” of independent assessment activities carried out by other AsBos<sup>(17)</sup> on risks shared across the interfaces between the different structural and functional sub-systems.

4. The AsBo company shall fulfil all the requirements defined in this section.

5. Classification in the ERADIS database : **system safe integration**

6. Specific criteria/discipline to be fulfilled :

(a) *the requirements already defined in sections § II and § III above*

With respect to the **core specific competence criteria** on “**risk management, and quality and safety management systems**” in points 1(a) and 1(c) in Annex II of Regulation 402/2013 :

- (1) core competencies related to risk assessment and risk management as defined in sections § II and § II.A above. This includes :
  - (i) knowledge, competence and understanding of risk assessment and risk management disciplines as defined in section § II.B above. That includes reasonable knowledge, competence, understanding and practical experience with either the CENELEC 50126-1 and 50126-2 standards, or with other equivalent guidelines or standards;
  - (ii) knowledge, competence and understanding of systems engineering, functional safety engineering and human and organisational factors (HOF) as defined in section § II.C above;
- (2) core competencies related to knowledge and understanding of organisational matters, management systems and auditing of management systems as defined in section § III above;

(b) with respect to the **specific technical criteria** in point 3 in Annex II of Regulation 402/2013 :

- (1) overall technical knowledge and understanding of the overall functioning of the railway system as a whole, and of the interactions between its technical, operational and organisational components;
- (2) overall knowledge and understanding of the interfaces and interactions between the structural and functional sub-systems, including the interactions with human operators;
- (3) a thorough knowledge and understanding of a “system based and top-down approach” to the organisation, development and management of both the technical and risk management parts of a project;
- (4) overall knowledge and understanding of human and organisational factors within the context of railway maintenance, operation and traffic management;
- (5) thorough knowledge of the Agency [clarification note on safe integration](#) (ref. ERA1209-063);
- (6) the accreditation/recognition in all other fields is not necessary for the demonstration of this area of competence.

(18) *The AsBo accreditation/recognition in all other fields is not necessary for the demonstration of its competence in the system level safe integration area.*

**4. DECISION**

<b>Cooperation decision:</b>	Accepted
<b>Plenary meeting nr:</b>	12
<b>Date of decision:</b>	30 March 2022

**5. ANNEX**

<b>Additional details on the solution:</b>	
No further details needed	
<b>Annex documents:</b>	There are no annexed documents