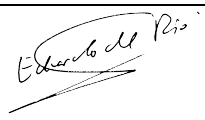
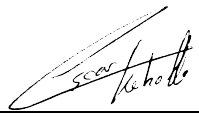
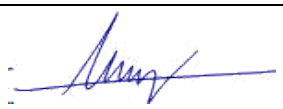
EUROPEAN UNION AGENCY FOR RAILWAYS

Making the railway system
work better for society.

Clarification note

Requirements capture

	Drafted by	*Validated by*	*Approved by*
Name	E. DEL RIO	O.REBOLLO	Í.MÉNDEZ
Position	Project Officer	Team Leader	Head of Unit
Date	20/12/2022	21/12/2022	21/12/2022
Signature			

Document History

Version	*Date*	*Comments*
0.1	01/03/2022	Initial version
0.2	30/03/2022	1st draft after internal review
0.3	01/04/2022	2nd draft after internal review
1.0	06/04/2022	Final version for publication
1.1	25/04/2022	Minor wording amendement in §2.1.2, 2.1.5, 2.1.6, 2.1.9 & 2.1.11 2.1.7 & 2.1.8 merged Minor wording amendment in §2.2.4 & 2.2.9 Minor wording amendment in §2.4.4 Text added in §2.5.6
1.2	20/12/2022	Amendments following workshop 12th July 2022 New sections 2.2.8 & 2.2.9 Update of Annex I following AsBo cooperation group discussions

The purpose of this document is to provide applicants and other external stakeholders of the vehicle authorisation business with information in regards to the specific topic referenced in the title. The clarifications contained in this document may be integrated in the next revision of the guidelines for the practical arrangements for the vehicle authorisation process, without prejudice of the formal process foreseen for updating the guideline.

The present document is a non-legally binding guidance of the European Union Agency for Railways. 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.

1. Description of the issue

The 4th Railway Package has introduced important changes to the legal framework of the European Union applicable to railways, in particular to the process for issuing vehicle and/or vehicle type authorisations. The main legal texts of the 4th Railway Package related to the authorisation process are:

- Directive (EU) 2016/797[1], (on the interoperability of the rail system within the European Union), as amended by Directive (EU) 2020/700[2];
- Regulation (EU) 2016/796[3] (on the European Union Agency for Railways)
- Regulation (EU) 2018/545[4] (establishing practical arrangements for the authorisation process), as amended by Regulation (EU) 2020/781[5], and
- Regulation (EU) 2019/250[6] (covering, inter-alia, the templates for 'EC' declarations and certificates for mobile subsystems and interoperability constituent, and declarations of conformity to type)

More specifically, the Regulation (EU) 2018/545 provides for a requirements capture process at article 13 to address the identification, assignment, implementation and validation of all applicable requirements, including safety requirements. In particular, the Regulation requires that:

- The applicant for vehicle and/or vehicle type authorisation (hereinafter applicant), or the entity managing a change in case of modifications (hereinafter EMC) that do not require an authorisation:
  - undertakes a process to identify and manage hazards, associated risks and requirements with the objective to ensure that the vehicle and/or vehicle type concerned meets the applicable legislation (including other EU legislation that not being railway specific is still applicable to railways) and the essential requirements described in Annex III of Directive (EU) 2016/797. This process will be referred to hereinafter as requirements capture process;
  - documents the requirements capture process (description of the process), its implementation in the concerned project and produces the necessary evidence of the application of the process for the concerned project;
  - hires an assessment body (CSM RA) (hereinafter, AsBo) for an independent assessment of the requirements capture process (for aspects related to safety and safe integration between subsystems) and its application;
  - establishes a declaration that all risks and requirements have been properly managed, and
  - includes the evidence above in the file accompanying the application for authorisation.

[1] Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (OJ L138, 26.5.2016, p.44-101)

[2] Directive (EU) 2020/700 of the European Parliament and of the Council of 25 May 2020 amending Directives (EU) 2016/797 and (EU) 2016/798, as regards the extension of their transposition periods (OJ L 165, 27.5.2020, p.27–30)

[3] Regulation (EU) 2016/796 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Railways and repealing Regulation (EC) No 881/2004 (OJ L 138, 26.5.2016, p. 1–43)

[4] 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, p. 66–104)

[5] Commission Implementing Regulation (EU) 2020/781 of 12 June 2020 amending Implementing Regulation (EU) 2018/545 as regards the dates of application and certain transitional provisions following the extension of the transposition deadline of Directive (EU) 2016/797 of the European Parliament and of the Council (OJ L 188, 15.6.2020, p. 11–13)

[6] Commission Implementing Regulation (EU) 2019/250 of 12 February 2019 on the templates for 'EC' declarations and certificates for railway interoperability constituents and subsystems, on the model of declaration of conformity to an authorised railway vehicle type and on the 'EC' verification procedures for subsystems in accordance with Directive (EU) 2016/797 of the European Parliament and of the Council and repealing Commission Regulation (EU) No 201/2011 (OJ L 42, 13.2.2019, p. 9–24)

- The AsBo assesses the requirements capture process for aspects related to safety and safe integration between subsystems, and produce an assessment report summarizing the results of the assessment;
- The authorising entity assesses the requirements capture process and/or the evidence related to requirements capture in the framework of issuing vehicle and/or vehicle type authorisations
- The NSAs for the area of use assess the evidence of the process for requirements capture related to the applicable national rules in the framework of the issuing of a vehicle and/or vehicle type authorisation when the Agency is the authorising entity

The document ERA-PRG-005/02-361 "Guidelines for the practical arrangements for the vehicle authorisation process" (hereinafter VA guidelines) provides guidance for authorising entities, NSAs for the area of use, holders of the vehicle type authorisation, entities managing changes, applicants and other concerned parties for the application of the vehicle authorisation process specified in Regulation (EU) 2018/545. In particular, the following sections of the VA guidelines provide further details on:

- §3.2.2.13 definition of requirements capture;
- §3.3.1 requirements capture process, its scope, in which cases it is mandatory to perform the requirements capture process, when an AsBo needs to be involved etc. It also covers a link to an informative list of relevant Union law, which is no longer of public domain;
- §3.5.1 role of the AsBo in the conformity assessment process;
- §3.7.9 & 3.7.10 check of the methodology and evidence related to the requirements capture process and other EU law (in particular non-railway related legislation) that may still be applicable;
- Annex I point 18.1 evidence for the requirements capture process, point 18.7 specification and description of the methodology for requirements capture, 18.8, 18.10, 18.11 & 18.12 assessment report and risk declaration;
- Annex II point 6 assessment of the methodology for requirements capture and point 8.6 other union law;
- Annex XIV assessment of notifications of changes to vehicles pursuant to Article 16(4), and
- Annex XV submission of notifications of changes to vehicles pursuant to Article 16(4)

Last but not least, the AsBo cooperation group has issued several Recommendations for Use (hereinafter RFU), covering:

- RFU no.1 Working method of the AsBo
- RFU no.3 AsBo technical knowledge and competence requirements for the different areas
- RFU no.11 Tracking (identification, recording and closing) of issues and non-compliances by the AsBo

However, the return of experience from the assessment of applications by the Agency since June 2019 shows that there are still doubts concerning several aspects of the requirements capture process, such as:

- Requirements to be taken into account (sources of applicable requirements);
- How to perform the requirements capture for essential requirements other than safety and safe integration between subsystems;
- The obligation to involve an AsBo for the assessment of the requirements capture process;
- Relationship between requirements capture and Regulation (EU) 402/2013;
- Role of the AsBo in the assessment of the requirements capture process (extent of the checks);
- Content of the assessment report to be issued by the AsBo;

- Assessments to be performed by the authorising entity and the NSAs for the area of use, and
- Content of the declaration concerning the requirements capture process

The objective of this document is to provide further clarifications to different topics identified by the Agency concerning the process for requirements capture. These clarifications are complementary to the ones already present in the VA guidelines or in the RFUs agreed by the AsBo cooperation group.

The clarification note follows a Frequently Asked Question (FAQ) structure. The main topics and subjects of discussion concerning requirements capture identified by the Agency during the exchanges with applicants, entities managing changes and NSAs in the framework of applications for authorisation are introduced by means of questions addressing specific aspects. After each question, the point of view of the Agency, when acting as authorising entity, will be presented.

2. Frequently asked questions

2.1. General principles

2.1.1 What is requirements capture?

Requirements capture is the process by which requirements applicable to a vehicle are systematically identified, implemented and validated, alongside with documenting all steps or the process and providing the necessary traceability.

The following diagram provides a simple overview of a requirements capture process. The concept of design, implementation and validation of requirements is central to requirements capture and management, which includes traceability to support the validation process.

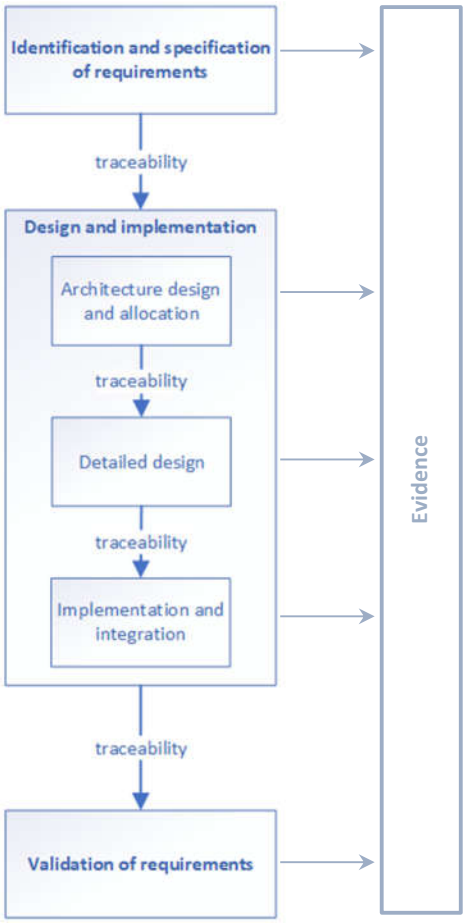


Figure 1: An outline requirements capture process

In addition to the concept of validation, to demonstrate that requirements have been fulfilled, the topics of design decomposition (allocation of requirements to components, functions, systems etc.), verification and integration, to show how requirements are addressed throughout the development life cycle to ensure that they are fulfilled, are key elements of a robust requirements capture process. Underlying all those concepts there are the general requirements of providing traceability and generating documentary evidence, which are necessary to support the system development process.

2.1.2 What is the difference between "requirements capture" and "requirements management"?

"Requirements capture" refers to a process by which requirements applicable to a vehicle are systematically identified, implemented and validated, alongside with documenting all steps or the process and providing the necessary traceability, albeit limited to the essential requirements laid down in Annex III of Directive (EU) 2016/797. "Requirements management" also refers to a process of identification, implementation and

validation (including the necessary traceability and documentation) of requirements but covering all requirements that need to be complied with independently of the source of the requirement or its nature.

This means that there are no fundamental differences between the processes behind the terms "requirements capture" and "requirements management", being the former the term used in the EU railway legislation as of today, in particular, in Regulation (EU) 2018/545, and the latter a term widely used in the industry.

The main difference lays with the fact that the term "requirements capture" is mandatory by law, and relates to:

- essential requirements
- evidence that needs to be included in an application file, and
- verifications to be performed by an authorising entity during the assessment of an application for authorisation

whereas "requirements management" relates to all requirements that should be complied with by the vehicle, it´s not required by law and the evidence does not need to be part of the application file nor needs to be assessed by an authorising entity.

From this point of view, the requirements covered by "requirements capture" are a subset of the requirements to be covered by "requirements management".

Some of the requirements identified by the requirements management process are safety related. The article 13 of the Regulation (EU) 2018/545 requires the use of the methodology described in Annex I of the CSM RA for requirements related to safety and safe integration between subsystems. It also requires an independent assessment by an AsBo, independently of the application of the CSM RA and the subsequent decision on the significance of the change to the railway system.

2.1.3 Why shall I perform a requirements capture process?

Requirements capture (and management) is the application of a systematic process for the identification, implementation, verification and validation of requirements, and the management of risks. This is to ensure, as far as is reasonably practicable, that when designing, manufacturing and testing a vehicle all considerations have been accounted for, and the vehicle or vehicle type meets the essential requirements.

The structured and systematic management of the applicable requirements for a project is a widespread practice in the industry since decades. This activity takes different names depending on the company (e.g., requirements management, system engineering, functional safety engineering etc.) being in all cases a structured, systematic and top-down approach/process for the specification and management of the implementation of the applicable requirements. It may be covered by a specific procedure or spread between different existing (and complementary) procedures. In the end, the objective is to have a process to ensure that all applicable requirements are properly considered and managed, and that nothing is left apart or forgotten.

The requirement capture activity requires that the applicant or the entity managing the change (and its suppliers) proactively define the applicable requirements early in the project and formalize their traceability (produce documentary evidence) throughout the life cycle of the project, with the involvement of the different actors that take part in the development of the product.

Now, under Article 13 of Regulation (EU) 2018/545, having this process developed, documented and implemented becomes mandatory for companies submitting applications for authorisation or managing changes to already authorised vehicles and/or vehicle types. It is also mandatory to include the evidence of the application of this process in the file accompanying an application for authorisation.

2.1.4 What is the objective the requirements capture process?

The objective of a requirements capture process is to ensure that all applicable requirements are systematically:

- identified;
- assigned to functions/subsystems/components;
- included in the specification for the design of the vehicle;
- implemented;
- verified;
- validated, and
- traced and documented.

For vehicle authorisation purposes, the aim is to ensure that the essential requirements, as defined in Annex III of Directive (EU) 2016/797 are met:

- safety;
- reliability/availability;
- health;
- environmental protection;
- technical compatibility; and
- accessibility.

2.1.5 In which cases shall I perform a requirements capture?

Requirements capture must be carried out even if there is no need to apply for an authorisation following a change to an already authorised vehicle or vehicle type. In other words, a requirements capture and management process must be performed for all vehicle projects, regardless of whether an authorisation is necessary or not, or whether a change is considered significant or not following the application of Regulation (EU) 402/2013.

Then, the supporting evidence for requirements capture only needs be included in the file accompanying the application for authorisation cases:

- First authorisation pursuant to Article 14(1)(a) of Regulation (EU) 2018/545;
- Extension of the area of use pursuant to Article 14(1)(c) of Regulation (EU) 2018/545;
- New authorisation pursuant to Article 14(1)(d) of Regulation (EU) 2018/545, and
- Combined application cases pursuant to Article 14(3) of Regulation (EU) 2018/545:
  - new authorisation and authorisation for an extended area of use, or
  - first authorisation and conformity to type.

The regulation (EU) 2018/545 provides an exception to the general principle above for the authorisation cases listed below, where there is a need to submit an application for authorisation but it is not necessary to perform a requirements capture process nor to include any evidence in the file accompanying the application for authorisation :

- Renewed vehicle type authorisation pursuant to Article 14(1)(b) of Regulation (EU) 2018/545, or
- Authorisation for placing on the market in conformity to an already authorised vehicle type pursuant to Article 14(1)(e) of Regulation (EU) 2018/545

2.1.6 Shall I perform a requirements capture process when the change I´m planning to implement does not require a new authorisation?

Yes. When a change requires a new authorisation pursuant to Article 21(12) of Directive (EU) 2016/797, the applicant shall perform a requirements capture process and must include related evidence in the file accompanying the application for authorisation.

On the other hand, Article 15 of Regulation (EU) 2018/545 outlines scenarios where changes to an already authorised vehicle and/or vehicle type do not require a new authorisation:

- A change occurs that does not introduce a deviation from the technical files accompanying the EC declarations for verification for the subsystems. In this case there is no need for verification by a conformity assessment body, and the initial EC declarations of verification for the subsystems and the vehicle type authorisation remains valid and unchanged.
- A change occurs that introduces a deviation from the technical files accompanying the EC declarations for verification for the subsystems which may require new checks and therefore require verification according to the applicable conformity assessment modules but which do not have any impact on the basic design characteristics of the vehicle type and does not require a new authorisation according to the criteria set out in Article 21(12) of Directive (EU) 2016/797.
- A change occurs in the basic design characteristics of the vehicle type that does not require a new authorisation according to the criteria set out in Article 21(12) of Directive (EU) 2016/797.

Even for these scenarios, applicants and/or entities managing changes will still need to go through a requirements capture process to ensure that the applicable requirements are managed in a systematic and structured way and that the decision on whether Article 21(12) of Directive (EU) 2016/797 is triggered or not is justified. The evidence of the requirements capture process will still need to be produced and retained by the entity managing the change.

2.1.7 Is requirements capture needed when performing a change that I classify pursuant to Article 15(1)(a), (b) or (c) of Regulation (EU) 2018/545? Is requirements capture needed for submitting a notification of changes to vehicles pursuant to Article 16(4) of Regulation (EU) 2018/545?

Yes. Requirements capture must be carried out even if there is no need to apply for an authorisation following a change to an already authorised vehicle or vehicle type. In other words, a requirements capture and management process must be performed for all vehicle projects, regardless of whether an authorisation is necessary or not, or whether a change is considered significant or not following the application of Regulation (EU) 402/2013.

Therefore, in case of changes classified pursuant to articles 15(1)(a), (b) of (c) or notifications of changes pursuant to Article 16(4) of Regulation (EU) 2018/545, the entity managing the change shall:

- Undertake a requirements capture process;
- Produce the concerned documentation, and
- Keep the documentation related to requirements capture at the disposal of the authorities.

Further details can be found in section 3.3.2.3 and Annexes XIII & XIV of the VA guidelines.

Concerning the independent assessment of the requirements capture process by an AsBo for changes classified pursuant to Regulation (EU) 2018/545 for articles:

- 15(1)(a): not required;
- 15(1)(b) and (c): required when there has been considerations around safety in the process for the categorisation of the change, such as a new risk assessment, a new safety analysis, new risks or

control measures for an existing risk assessment, new classification of existing risks, new risk declaration etc., or

› 15(1)(d): necessary for essential requirement safety and safe integration between subsystems, voluntary for other essential requirements.

2.1.8 When shall the requirements capture process start?

The requirements capture should start at an early stage of the process of design and development of the vehicle. This is the only way to ensure a proper management of requirements and risks.

The involvement of the AsBo for the independent assessment of the requirements capture process should start as early as possible in the project; a late intervention of the AsBo may lead to a late identification of non-compliances which could be difficult to solve when the project is at advanced stage of development. It may also lead, during the authorisation process, to further enquiries by the authorising entity and/or the NSAs for the area of use regarding the assessments performed by the AsBo related to activities that took place before its appointment.

For the purposes of vehicle authorisation, the requirements capture process finishes at the point at which a vehicle or vehicle type is authorised. The holder of the vehicle type authorisation is responsible for the configuration management of the vehicle type from that moment onwards.

2.1.9 What is the correct logic/timeline chain for the different conformity assessments (AsBo/DeBo/NoBo) in my project?

The involvement of the AsBo for the independent assessment of the requirements capture process should start as early as possible in the project; a late intervention of the AsBo may lead to a late identification of non-compliances which could be difficult to solve when the project is at advanced stage of development. It may also lead, during the authorisation process, to further enquiries by the authorising entity and/or the NSAs for the area of use regarding the assessments performed by the AsBo related to activities that took place before its appointment.

The AsBo should start assessing the requirements capture process even before the NoBo(s) and DeBo(s) start performing the conformity assessment against the TSIs and the applicable national rules. After all, the applicant (or the entity managing the change) is in a position to identify which requirements are covered by the application of mandatory rules even before its implementation, verification and validation.

Since the AsBo needs to assess not only the process but also the results of its application, its assessment can only end when the NoBo(s) and DeBo(s) have also finalised their assessments and have issued the relevant outcomes (certificates and files accompanying the certificates). Only at that time the associated requirements can be considered validated.

To avoid an unnecessary duplication of independent assessments by different bodies, the AsBo should, as far as possible, apply the principle of mutual recognition of the results from the NoBo(s) and DeBo(s) assessments for the same scope of work.

2.1.10 Shall I provide the NoBo/DeBo report for the mobile subsystem(s) to the AsBo to perform its tasks regarding the assessment of the requirements capture process?

The Regulations (EU) 402/2013 and (EU) 2018/545 do not require that the AsBo performs a complete and thorough assessment of all the identified requirements, nor that it reviews thoroughly all the outputs of the assessments performed by other conformity assessment bodies, namely NoBos and DeBos, or the risk assessment performed by the applicant or the entity managing the change. Furthermore, Article 6(3) of Regulation (EU) 402/2013 requires the avoidance of duplication of work between those different conformity assessment bodies.

The AsBo shall focus its assessment on:

- the process for the requirements capture, in order to ensure that the process is robust enough to allow for a proper identification and management of the requirements;
- the suitability of the results of the application of the process to the specific project under assessment.

To perform this work, the AsBo needs to perform sampling checks and in-depth vertical slice assessment[7] of the evidence related to selected requirements (samples) for in-depth assessment.

The outputs from NoBo(s) and DeBo(s), in particular the reports accompanying the certificates, contain the evidence that is necessary to prove that the requirements coming from the TSIs and the applicable national rules have been properly managed.

While the legal texts do not contain the obligation to provide the reports issued by NoBo and/or DeBo (and the related evidence) to the AsBo for requirements capture, the AsBo could need them for performing the necessary sampling. The applicant or the entity managing the change should agree with the AsBo whether to provide the complete evidence produced by NoBo and/or DeBo to the AsBo or to provide only the necessary elements upon request of the AsBo.

Some TSIs and/or national rules require the application of the risk assessment process of CSM RA for certain defined parameters (e.g., 4.2.4.2.2 of LOC&PAS TSI),

The final responsibility of the conformity assessment of the relevant TSIs and/ or national rules lies with the NoBo(s) and/ or DeBo(s). The assessment report issued by the AsBo, where the TSIs and/or the national rules require the application of the risk assessment process of CSM RA for certain aspects, should be treated by the NoBo(s) and/or DeBo(s) as any other evidence provided by the applicant or the entity managing the change in the framework of the EC verification procedure for other requirements (e.g., a test report where testing is required by TSIs and/or national rules).

2.1.11 What happens if a supplier does not provide the details of its requirements capture process to the applicant or the entity managing the change? Is it sufficient if it provides a report by an AsBo covering the requirements capture for the concerned parts? Is it sufficient if it provides a statement from its AsBo concerning the requirements capture process for the concerned parts?

The applicant for authorisation or the entity managing the change is responsible for:

- performing the requirements capture for the vehicle and/or vehicle type seeking authorisation, and
- ensuring that the vehicle and/or vehicle type meets all applicable requirements, including the essential requirements laid down in Annex III of Directive (EU) 2016/797.

In case of new authorisation, this is restricted to the changes and the interfaces with the unchanged parts.

To do so, the applicant or the entity managing the change needs to be sure that all suppliers (or other actors supporting them) are managing the requirements for the elements they are in charge of properly and in a way that is consistent with the management of requirements for the rest of the vehicle. It cannot simply rely on statements from other parties involved in the project. To avoid a situation where an applicant or an entity managing the change does not have all the information necessary to perform the requirements capture, it needs to set-up the necessary contractual arrangements with its suppliers in the early stages of the project.

Similarly, the AsBo responsible for the independent assessment of the requirements capture process needs to assess the whole process and its application to the whole vehicle and/or vehicle type (which comprises all

[7] Vertical slice assessment: thorough end-to-end review of the application of the requirement capture process for the selected samples. The purpose is to check a representative cross-sectional slice of the results from the actual implementation of the requirement capture process and to cover all the steps of the development process.

elements that conform it, such as components, parts, subsystems etc.). This includes performing the necessary sampling checks and in-depth vertical slice assessments. If there is no evidence of how requirements are managed by a supplier for some parts of the vehicle, and this is not properly considered in the requirements capture performed by the applicant or the entity managing the change, it would not be possible to arrive to the conclusion that the process was correctly applied and that the results of its application allow to properly manage all the requirements at vehicle and/or vehicle type level.

This does not mean that the suppliers shall perform a requirements capture process pursuant to Article 13 of Regulation (EU) 2018/545 (including the independent assessment by an AsBo). This obligation applies to applicants (and entities managing changes), who need to ensure that their suppliers or providers manage the applicable requirements in a way that is compatible with the requirements capture process in place for the vehicle and/or vehicle type (e.g., by means of contractual arrangements).

Whether an applicant, an entity managing a change or an AsBo are in a position or not to accept the outcomes from another party, without having access to the details needs to be evaluated on a case by case basis, considering in particular which is the level of detail provided by the supplier (e.g., it may not provide all the evidence because it contains sensitive or confidential information, but it may provide the evidence showing that the requirements have been properly and thoroughly identified and managed, such as hazard log for requirements related to safety and safe integration between subsystems, compliance matrix for requirements linked to essential requirements other than safety, etc.). In any case, the final responsibility for meeting the applicable requirements for the vehicle and/or vehicle type lies with the applicant for authorisation or with the entity managing the change.

During the assessment of the application, the Authorising Entity and/or the NSAs for the area of use may ask questions and request the documentation that they consider relevant in order to achieve reasonable assurance that all parties (the applicant or the entity managing the change, and the actors supporting them including suppliers) have fulfilled their legal duties and responsibilities.

2.1.12 How can I manage the requirements capture process for vehicles designed for general operation (modular design)? What is the boundary between the NoBo assessments covering the worst case scenarios for the conformity assessment, the work of the AsBo for the requirements capture process, the conditions for use and other restrictions and the possible train configurations?

Conditions for use and other restrictions are part of the design of a vehicle and form the boundaries for how it is intended to be used. There are three broad stages to the identification of conditions for use and other restrictions:

- During the design of the vehicle, the applicant or the entity managing the change should identify the intended conditions for use and other restrictions that are applicable to the vehicle seeking authorisation;
- It may be necessary to add further conditions and restrictions as a result of the conformity assessment in order to comply with the mandatory requirements, and
- The authorising entity and/ or the NSAs for the area of use can give further conditions for use and other restrictions as a result of their assessment of the application and the file accompanying the application.

For a vehicle designed for general operation that is seeking authorisation in isolation, independently of any train configuration, the conditions for use and other restrictions should cover the worst case scenario that it may face in real operation conditions. This worst case may be different depending on the aspect considered (e.g., for some aspects the most critical condition will occur where the vehicle is running empty, while for some others it will happen when it runs loaded).

The definition of the boundaries or the operational envelope (worst case scenario) for the vehicle and/or vehicle type considering all relevant aspects is the responsibility of the applicant or the entity managing the change; proposing the related necessary conditions for use and/or restrictions it´s also their responsibility. Then, the conformity assessment bodies (in particular, NoBos) shall take them into account while performing the conformity assessment for the mobile subsystems, confirming, adding or removing some additional ones upon agreement with the applicant or the entity managing the change.

The AsBo assessing the requirements capture process should not check whether the worst case scenarios for the conformity assessments of the mobile subsystems are correct or not; this is the responsibility of NoBos and DeBos, together with the applicant or the entity managing the change. The detailed assessment of the requirements capture process, including conditions for use and restrictions, is also out of the scope of the work to be performed by the AsBo. The AsBo should assess if:

- the requirements capture process followed by the applicant or entity managing the change for a particular project (vehicle and/or vehicle type) is robust enough to allow for a proper definition of the worst case scenarios and an adequate management of the conditions for use, in particular when they are safety related, and
- the conditions for use and/or restrictions:
  - do not create any additional risk, or if they create new risks, they are properly managed (as any other risk or requirement), and
  - are consistent with the results of the conformity assessment for the subsystems and with the proposal of the applicant in the application.

In the end, the different conditions for use and/or restrictions will reflect the boundaries and limits of use of the vehicle, in particular to ensure the compliance with the mandatory rules and with the essential requirements (in particular, safety and safety integration between subsystems). This means that when a vehicle is used within the operational envelope defined by such conditions for use and/or restrictions, the vehicle will meet the requirements of the mandatory rules, in particular TSIs, and will fulfil the essential requirements described in Annex III of Directive (EU) 2016/797.

The Railway Undertaking (RU) operating such vehicles shall consider the conditions for use and/or restrictions when incorporating it into a train formation, in order to ensure that the vehicle remains within the defined boundaries covered by the conformity assessment and the requirements capture process.

2.1.13 Who is responsible for performing the requirements capture? Can I delegate or subcontract it?

The roles and responsibilities with respect to the application of the requirements capture process and of its independent assessment differ in function of the concerned actor:

- Entities managing a change are responsible for the classification of the change pursuant to Article 15 of Regulation (EU) 2018/545;
- Proposers for changes are responsible for applying the Regulation (EU) 402/2013;
- Applicants submit applications for authorisation;
- Assessment body (CSM RA), hereinafter AsBo, is responsible for assessing independently the requirements capture process undertaken by the applicant or by the entity managing changes related to essential requirement safety and safe integration between subsystems (and for all other essential requirements when it is appointed to do so);
- AsBo is responsible for independently assessing significant changes according to Regulation (EU) 402/2013, and
- Authorising Entity (AE) / National Safety Authority (NSA) for the area of use are responsible for assessing the evidence of the applied requirements capture process.

Applicants or entities managing changes can subcontract the workload for both the development and implementation of the process, and its application for a particular project. However, applicants or entities managing changes cannot delegate their responsibility and remain responsible for ensuring that there is a proper requirements capture in place, that the process is applied to the concerned project and that the related documentary evidence is produced.

Similarly, applicants or entities managing changes are the sole responsible for establishing a declaration concerning the undertaken requirements capture; the issuing of this declaration cannot be subcontracted or delegated.

Last but not least, the role of the AsBo is to assess whether the process in place is robust enough to allow for a proper management of the requirements or not, and to evaluate the appropriateness of the results of the application of the process to the project under assessment. Defining the requirements capture process, applying it to a project, and producing the relevant documentation are tasks which are out of the scope of the independent assessment to be performed by the AsBo.

2.2. Scope of the requirements capture

2.2.1 Is meeting TSIs and national rules enough to fulfil the essential requirement ´safety´?

The essential requirement ´safety´, as referred to in Article 13(3) of Regulation (EU) 2018/545, has a wider scope than the mandatory rules (TSIs, notified national rules, other legislation of the Union): it covers all requirements which are necessary to achieve safety, thereby ensuring that the vehicle can be used safely in its area of use. From this point of view, TSIs, national rules and other legislation of the Union contain a subset of all the (safety related) requirements that are needed to meet the essential requirement ´safety´.

Similarly, to fulfil essential requirements other than safety, there is a need to consider more sources of requirements than the TSIs and the (notified) national rules.

2.2.2 Which requirements shall I consider when performing the requirements capture?

The requirements management process covers all requirements that a vehicle type needs to fulfill, no matter where the requirements come from:

- requirements that can be found in mandatory laws (TSIs, national rules, other EU legislation), hence legally enforceable;
- contractual requirements;
- requirements that are necessary to control hazards and associated risks;
- requirements adopted on a voluntary basis, such as standards, codes of practice or company specifications (design codes, guidelines);
- etc.

Figure 2 gives an overview of the potential sources of requirements for the requirements management process, also making a difference between the sources that are mandatory and shall be fulfilled (legally enforceable requirements, such as TSIs or notified national rules), and those that are either voluntarily adopted by the applicant or entity managing the change, or imposed to the applicant or entity managing the change by means of contractual arrangements, that may be in addition necessary to meet other legal obligations, e.g. fulfil the essential requirements (e.g., safety).

Some requirements are not relevant for the authorisation process because they are not related to the essential requirements laid down in Annex III of Directive (EU) 2016/797, even if they need to be complied with for other reasons (e.g., contractual requirements). Some other, while not mandatory, may trigger the need to fulfil other requirements which are mandatory (e.g., a customer may require in the contract that the vehicle is fitted with a playground area for kids with toys, which is not compulsory; however, such toys shall fulfil Directive 2009/48/EC on the safety of toys). Similarly, some non-mandatory requirements may have an impact on mandatory requirements already applicable to railway vehicles (following the example of the toys, the fire safety requirements for the vehicle).

Another example of a requirement that could be voluntarily adopted to meet essential requirements is the cybersecurity standard IEC 62443-3-3, that would reduce risk of cyberattacks to trains that may result in a safety issue (e.g., train not braking due to an attack that prevents the correct functioning of the on-board signalling system).

For vehicle authorisation purposes, the requirements to be considered in the requirements management process are those that need to be fulfilled in order to meet the essential requirements, no matter if they derive from mandatory rules or not. The essential requirements are defined in Annex III of Directive (EU) 2016/797: safety, reliability/availability, health, environmental protection, technical compatibility and accessibility.

The voluntary requirements which are not necessary to meet an essential requirement, while being normally in the scope of the requirements management process (after all, they are requirements that the applicant or the entity managing the change has decided to fulfil), are out of the scope of the authorisation process and the requirements capture process; meeting them remains within the responsibility of the manufacturer and its suppliers and customers.

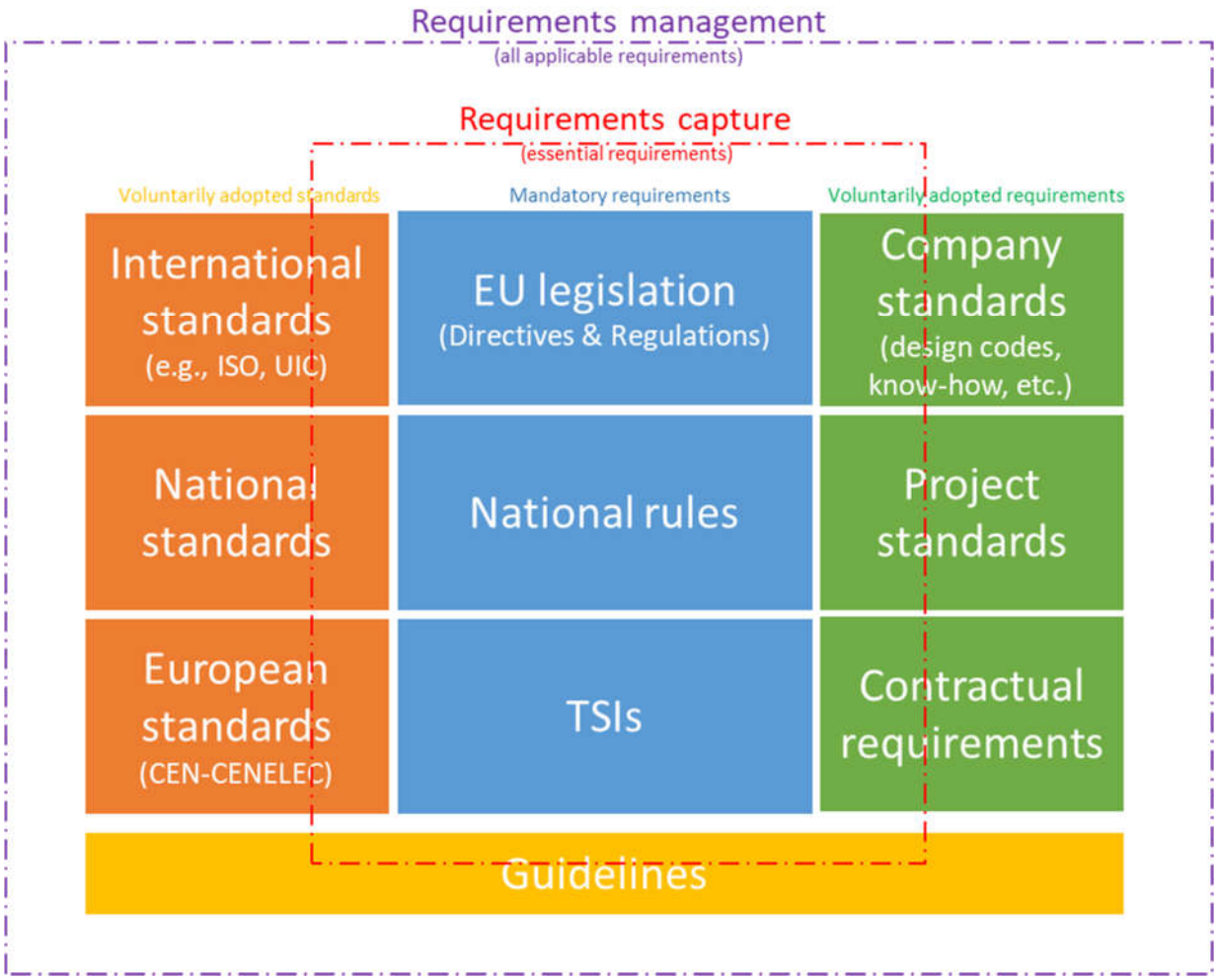


Figure 2: Sources and scope of requirements for vehicle authorisations

In the end, the requirements management process put in place by the applicant or the entity managing the change should cover all requirements. However, the independent assessment of the requirements capture process required by the Regulation (EU) 2018/545 should focus on how the process is applied to the requirements that are necessary to fulfil the essential requirements of Directive (EU) 2016/797.

2.2.3 Does the requirements capture process include the implementation and validation of the identified requirements?

Yes, it does. The concept of "requirements capture", pursuant to Article 13 of Regulation (EU) 2018/545, includes the systematic capture (identification) and the management (implementation, verification and validation) of all applicable requirements through the entire development process (e.g., V-Cycle of EN 50126-1, from step 1 to 10, see Figure 3), It also includes producing the necessary documentary evidence.

The management of requirements should be addressed throughout the design, implementation, verification and validation phases of the system development life cycle where requirements have been identified, allocated and subsystems/vehicles are specified.

The requirements capture is therefore not limited to:

- the identification of the requirements; it covers also the implementation, verification and validation, and producing the necessary evidence
- the mandatory rules (legal requirements), such as TSIs, national rules, other Union legislation; it covers also requirements which are necessary to meet the essential requirements

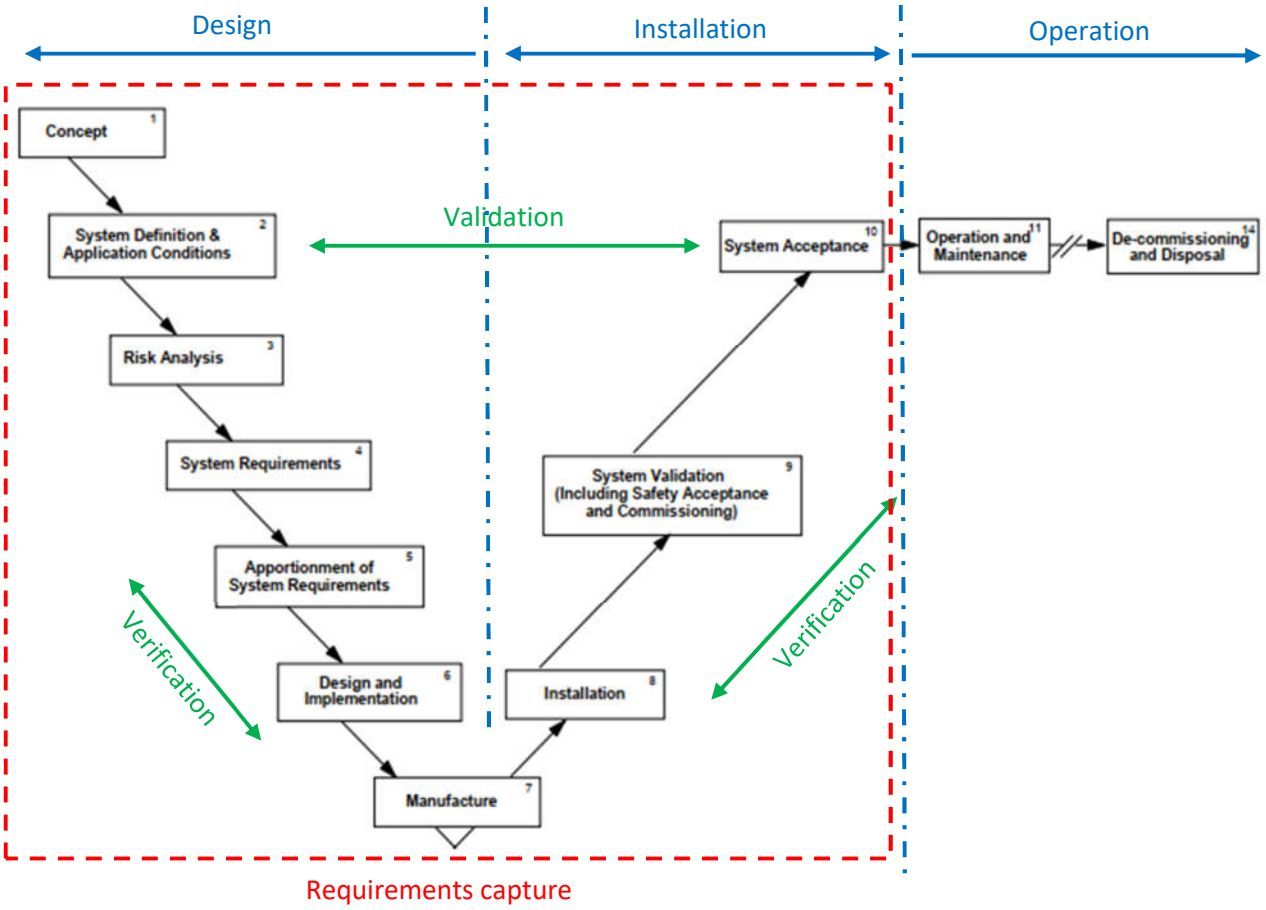


Figure 3: V-Cycle EN 50126-1

It should be noticed that in EN 50126-1 validation is defined as “confirmation, through the provision of objective evidence, that the requirements for an intended use of application have been fulfilled”. Requirements which have been identified, are then developed into a design and implemented, to later on be validated.

2.2.4 For wagons, can the requirements capture be a list of rules (e.g., a list of applicable standards)? If yes, why do I need an AsBo?

No. The requirements management process covers all requirements that a vehicle type needs to fulfill, no matter where the requirements come from:

- requirements that can be found in mandatory laws (TSIs, national rules, other EU legislation), hence legally enforceable;
- contractual requirements;
- requirements that are necessary to control hazards and associated risks;

- requirements adopted on a voluntary basis, such as standards, codes of practice or company specifications (design codes, guidelines);
- etc.

For vehicle authorisation purposes, the requirements to be considered in the requirements management process are those that need to be fulfilled in order to meet the essential requirements, no matter if they derive from mandatory rules or not. The essential requirements are defined in Annex III of Directive (EU) 2016/797: safety, reliability/availability, health, environmental protection, technical compatibility and accessibility.

From this point of view, a list of rules is not enough, although mandatory rules could be used to cover some aspects (e.g., mitigate certain safety risks). Even for wagons there are many other requirements not covered by rules, mandatory or not, that need to be fulfilled to ensure that the essential requirements are met. In addition, the requirements capture process shall cover the whole V-Cycle of the development process, including assigning requirements to systems/components/functions, risk analysis, implementation, verification, validation etc.

For the aspects related to essential requirement safety and safe integration between subsystems, the involvement of an AsBo for the assessment of the requirements capture process is mandatory, pursuant to Article 13 of Regulation (EU) 2018/545

2.2.5 How do I know which other EU law could be applicable to my case?

The applicant for placing on the market of a mobile subsystem, based on its knowledge and experience, and considering the characteristics of the subsystem, is the sole responsible for the identification of the applicable Union law and for ensuring that the law(s) is actually fulfilled.

Before placing a mobile subsystem on the market, the applicant shall take any necessary measure to ensure that the subsystem complies with the relevant Union law and national rules. The Union law includes Directives, Technical Specifications for Interoperability (TSIs), but also any other applicable Union law, that, not being railway specific, shall also be complied with.

As a result, the applicant for placing on the market the mobile subsystem shall issue an EC Declaration of Verification, where it shall declare that the subsystem complies with the relevant Union law and any relevant national rule. In other words, the EC Declaration of Verification shall contain the references to the Union law that the subsystem complies with, and the references to the outcomes required by such law (e.g., certificates, reports, etc.).

Similarly, the applicant for vehicle and/or vehicle type authorisation, or the entity managing the change, is responsible for ensuring that all applicable requirements, including other legislation of the Union, are met at vehicle level.

Notwithstanding the above, it should be noted that the following EU laws are often applicable to railway vehicles:

- Simple pressure vessels directive (SPVD) 2014/29/EU;
- Electromagnetic compatibility directive (EMC) 2014/30/EU;
- Emissions from non-road mobile machinery regulation (NRMM) (EU) 2016/1628;
- Registration, Evaluation, Authorisation and Restriction of Chemicals regulation (REACH), EC 1907/2006;
- Regulations concerning the international carriage of dangerous goods by rail (RID), and
- Radio Equipment Directive (RED) 2014/53/EU.

2.2.6 Are the driver's and/or the maintenance documentation part of the requirements capture?

Yes. The requirements management process covers all requirements that a vehicle type needs to fulfil, no matter where the requirements come from:

- requirements that can be found in mandatory laws (TSIs, national rules, other EU legislation), hence legally enforceable;
- contractual requirements;
- requirements that are necessary to control hazards and associated risks;
- requirements adopted on a voluntary basis, such as standards, codes of practice or company specifications (design codes, guidelines);
- etc.

In order to control certain hazards and risks, it is often necessary to define specific operational measures and maintenance activities, such as reductions in speed under certain degraded modes of operation of a vehicle, specific inspections of certain elements to a higher than usual periodicity or detail etc.

These measures are described in documents such as the driver´s or operation manual, the maintenance plan, etc. On the other hand, some specific operational provisions (e.g., due to contractual requirements) may as well create specific hazards and risks, which need to be properly managed.

All this envelope of measures, and the related risks, are in the scope of the requirements capture process, despite the fact that the driver´s and/or the maintenance documentation are not sources of requirements.

2.2.7 What is the level of detail that I need to consider when performing requirements capture concerning the identification of standards, if they are already mentioned in the applicable TSIs? Shall I also capture the requirements of the standards and explain how they are implemented, validated and verified?

The requirements management process covers all requirements that a vehicle type needs to fulfil, no matter where the requirements come from:

- requirements that can be found in mandatory laws (TSIs, national rules, other EU legislation), hence legally enforceable;
- contractual requirements;
- requirements that are necessary to control hazards and associated risks;
- requirements adopted on a voluntary basis, such as standards, codes of practice or company specifications (design codes, guidelines);
- etc.

The management of requirements should be addressed throughout the design, implementation, verification and validation phases of the system development life cycle where requirements have been identified, allocated and subsystems/vehicles are specified.

Therefore, identifying the applicable TSIs is neither enough nor identifying the different standards quoted by the TSIs. The level of detail and the granularity in the identification of the requirements shall be enough to allow the allocation of requirements to functions, components, systems, subsystems etc., and the subsequent implementation, verification and validation.

As a rule, it will be necessary to break down high level requirement (such as TSI or a EN standard) into smaller requirements that will be managed independently. Annex 4.1 of this document contains a conceptual example on which are the main aspects to consider for the management of the requirements (compliance matrix).

2.2.8 Can I use a requirements capture for a platform concept? Till what extend shall it be specific to the project?

The process(es) in place for capturing and managing the requirements should be applied to all projects to be developed by an applicant or entity managing the change, in order to ensure a systematic and structured management of the requirements. The requirements capture process shall apply to platforms or vehicle families and may have particularities aiming at simplifying or improving the way in which requirements are managed for projects that belong to the same platform or vehicle family.

However, and due to the fact that according to Article 13(1) of Regulation (EU) 2018/545 the requirements capture covers as well the implementation, verification and validation, and production of the necessary documentary evidence, it is necessary to consider not only the general aspects of the process applied for a vehicle platform, but also the application of the process to the specific project under assessment. Consequently, the evidence of the application of the requirements capture process to a specific project shall also reflect the implementation, verification and validation for that specific project.

The AsBo responsible for the independent assessment of the requirements capture for the essential requirements safety and for the safe integration of the subsystems shall also assess the assignment, implementation, verification and validation steps. The independent assessment may require sample checks and in-depth vertical slice assessments to be carried out by the AsBo in order to build its expert judgement on whether the process is robust enough, has been thoroughly and consistently applied and its application leads to satisfactory results in terms of management of the (safety) requirements.

That being said, it is possible to make a distinction between:

- a generic platform for which the requirements capture process was formally applied and documented by the applicant or the entity managing the change, and independently assessed by an AsBo, and
- a specific application of the requirements capture process (already assessed for a generic platform) to specific vehicles and/or vehicle types belonging to the platform.

The requirements capture process of the generic platform do not need to be reassessed for every specific vehicle type, vehicle type variant and/or vehicle type version belonging to the platform or vehicle family. The AsBo performing the independent assessment of the specific application should mutually recognise the work performed by the AsBo for the generic platform, and the independent assessment should be limited to the application of the requirements capture process to the specific project (vehicle type/variant/version) under consideration and to the applicability and validity of the independent assessment of the generic platform. This approach is commonly known in the industry under the terminology “1 + Δ” (“1 + Delta”), where “Δ” represents the gap/difference between the generic platform and the specific application.

In order to do so, the AsBo independently assessing the specific application shall have access to the outcomes of the independent assessment of the generic platform if this was done by another AsBo.

The independent assessment of the generic platform should remain valid unless there are changes in the main elements of the requirements capture process, such as the:

- Applicability of the process for the generic platform to the specific project under consideration (vehicle type/variant/version);
- Applicable legal framework;
- Requirements capture process (identification, assignment, implementation and validation);
- Organisational changes (e.g., design and/or manufacturing locations, subcontracting of engineering activities, etc.);
- Suppliers;
- Tools supporting the process, and/or
- Roles and responsibilities of the actors involved in the process.

The entity managing the change should inform the AsBo that performed the independent assessment of the generic platform in case of modification of the requirements capture process. The AsBo will decide if there is a need to perform a new independent assessment and to produce the necessary evidence (new or amended assessment report) or not.

2.2.9 Can I cover different 15(1)(b) changes with one independent assessment of the requirements capture process?

Requirements capture must be carried out even if there is no need to apply for an authorisation following a change to an already authorised vehicle or vehicle type. In other words, a requirements capture and management process must be performed for all vehicle projects, regardless of whether an authorisation is necessary or not, or whether a change is considered significant or not following the application of Regulation (EU) 402/2013.

If during the process of categorisation of the change pursuant to Article 15(1) of Regulation (EU) 2018/545 there has been considerations around safety (e.g., to decide whether there is a potential impact on safety triggering Article 21(12)(b) of Directive (EU) 2016/797 or not), the requirements capture process for the essential requirement safety (and the safe integration between subsystems) shall be independently assessed by an AsBo, pursuant to Article 13 of Regulation (EU) 2018/545 (risk assessment process in Annex I of CSM RA applies).

Please note that for other essential requirements, the entity managing the change can decide whether to apply the methodology in Annex I of CSM RA or use another methodology that provides the same level of assurance.

When, with the support of the requirements capture process, a change is classified pursuant to Article 15(1)(b) of Regulation (EU) 2018/545, there is no need for the entity managing the change to submit an application for authorisation through the OSS. Still, the entity managing the change shall:

- Undertake a requirements capture process;
- Produce the concerned documentation, and
- Keep the documentation related to requirements capture at the disposal of the authorities.

Further details can be found in section 3.3.2.3 and Annexes XIII & XIV of the VA guidelines.

In such cases, the entity managing the change, under its sole responsibility, can decide to cover the aspects related to the independent assessment of the requirements capture process for a number of individual 15(1)(b) changes implemented over time within one single independent assessment by an AsBo.

Grouping the independent assessment of the requirements capture process for a number of 15(1)(b) changes should be limited to:

- Changes related to the same vehicle and/or vehicle type (including its variants and versions), and
- Changes not considered significant according to CSM RA.

The time elapsed between the implementation of the first change and the issuing of the safety assessment report for a batch of successive changes (i.e., a group changes) falling under Article 15(1)(b) of Regulation (EU) 2018/545 should be agreed with the concerned AsBo, although it is recommended that changes are not grouped beyond a time span of 4 months [8].

[8] Proposed 4 months timeframe by analogy to the timeframe set-up in Article 16(4) of Regulation (EU) 2018/545 for authorising entities to issue a reasoned decision concerning notifications of changes to vehicles: entities managing the changes can implement 15(1)(b) changes after submitting the notification, and the modified vehicles can restart operation immediately after, without waiting for such reasoned decision from the authorising entity.

Concerning the independent assessment of the requirements capture process for a batch of different 15(1)(b) changes implemented over time, the entity managing the change can proceed in a step wise approach, provided that:

› There is a well-established baseline (starting point), be it :
  - the last vehicle type authorisation pursuant to Regulation (EU) 2018/545, thus supported by a requirements capture process and the relevant independent assessment by an AsBo, or
  - the latest modification of the vehicle and/or vehicle type implementing a batch of Article 15(1)(b) changes, where the requirements capture process was independently assessed by an AsBo who has produced the relevant independent assessment report.

› The requirements capture process describes in an explicit way:
  - the modular approach for grouping in a single independent assessment by an AsBo a number of 15(1)(b) changes implemented over time, and
  - the conditions under which this can be done (aspect normally covered by the change management process of the applicant or of the entity managing the change).

› The entity managing the changes:
  - Documents the application of the requirements capture process to every change, and
  - Keeps a register of all successive 15(1)(b) changes that will form the batch of changes

When the conditions above are met, the entity managing the change, rather than appointing AsBo for the independent assessment of the requirements capture process related to each and every specific 15(1)(b) change at the moment they are implemented, can instead appoint an AsBo for “one” independent assessment covering all changes in the batch. In that case:

› the AsBo does not need to assess again the content of the previous baseline;

› the AsBo should mutually recognise the results of the independent assessment of the previous baseline; as far as this is possible, and in order to limit the independent assessment workload, the entity managing the change can appoint for the independent assessment of a batch of changes the same AsBo that assessed the previous baseline.

› The independent assessment by the AsBo shall be limited to:
  - the application of the requirements capture process to all the changes grouped in a batch;
  - the safe integration of those changes with the previous baseline, and
  - the verification of the applicability and validity of the independent assessment of the previous baseline.

2.2.10 For the installation on an on-board CCS system in an existing vehicle, should I cover the rolling stock (RS) subsystem part in my requirements capture? What the AsBo should cover (only control-command and signalling (CCS) subsystem or both CCS and RS subsystems)?

The requirements capture process covers all the relevant requirements for a vehicle and/ or a vehicle type. In case of a first authorisation, the whole vehicle type and/ or vehicle should be covered by the requirements capture process. In case of a new authorisation as a consequence of a change, the requirements capture process should cover the changed parts, but also the interfaces between the changed and the unchanged parts.

According to Articles 39(4) and 40(3) of Regulation (EU) 2018/545, the checks to be performed by the Authorising Entity and the NSAs for the area of use concerning the evidence for requirements capture in case of a new authorisation should cover the parts that are changed but also the impact of such changes in the unchanged parts.

The Article 13(2) of Regulation (EU) 2018/545 clarifies that the requirements capture process shall cover the technical compatibility and the safe integration of the subsystems within the vehicle.

In most cases, the retrofitting a vehicle with on-board CCS requires also to perform changes in the rolling stock subsystem (e.g., driver´s desk, DMI, brake system, train interface unit, etc.). In addition, , the requirements capture process should cover both mobile subsystems, rolling stock and on-board control-command and signalling, even if the rolling stock subsystem is not changed because safety integration needs to be ensured. As a consequence, the independent assessments to be performed concerning the requirements capture process should cover both subsystems as well, and because essential requirement safety and safe integration between subsystems are at stake, an AsBo should be involved.

It should be noted that the CCS TSI requires that an AsBo independently assesses the correct application of the risk management process set out in Annex I of CSM RA, as well as the appropriateness of the results from this application, to the CCS mobile subsystem. This is additional to the requirements capture process related to the essential requirement safety and the safe integration between subsystems, although there are clear synergies and overlaps between the two independent assessments.

However, the independent assessment for both aspects can be performed by the same AsBo. The legal framework does not oblige to have the same company playing the role of AsBo for both topics. However, contracting the same AsBo may bring synergies between the independent assessment of the risk management process as defined in the CSM RA for the requirements capture process for the essential requirement safety and the safe integration between subsystems prescribed in the Regulation (EU) 2018/545 and for the safety specific aspect of the CCS subsystem according to §3.2.1 of CCS TSI .

When there are different AsBos involved, the AsBo for the requirements capture remains the sole responsible for this assessment, although it shall mutually recognise the work performed by the AsBo mandated by the CCS TSI (for the same scope of work).

2.2.11 Do I need an AsBo for my ETCS installation if I already considered the ETCS hazard log (SS-113) for developing the generic product?

According to Article 13(3), an AsBo shall be involved for the assessment of the requirements capture process for the essential requirement safety and the safe integration between mobile subsystems (rolling stock and on-board control-command and signalling).

Subset 113 “ETCS hazard log” is a list of scenarios possibly leading to hazards when implementing an ETCS system being composed of on-board and trackside but does not explicitly cover the installation of on-board ETCS into a vehicle neither provides presumption of conformity with CCS TSI, ensures fulfilment of essential requirement safety or guarantees the safe integration with the rolling stock subsystem. In addition, section 3.1.1.3 reads “*Each application project is responsible to have an exhaustive risk assessment for its scope. The present hazard log is not claimed to be an exhaustive list of causes for hazards but shall be considered as one input among others to the application project’s risk assessment.*”

As a consequence, the independent assessment concerning the requirements capture process related to safety and safe integration between subsystems should be performed by an AsBo, regardless the fact that the subset-113 has been considered in the design of the on-board ETCS.

2.2.12 For a new cab radio installation on an existing vehicle, do I need an AsBo considering that the cab radio is not a safety related element?

Yes. The installation of a cab radio in an existing vehicle may have safety impacts in the rolling stock subsystem (e.g., installation of antennas, redesign of the driver´s desk, interfaces with the ETCS on-board in case of EDOR, etc.). As a consequence, the independent assessment of the requirements capture process related to essential requirement safety and safe integration between subsystems needs to be performed by an AsBo. Let alone the fact that a lack of communication between the driver and the signaller can derive in a safety issue. This independently of the fact that the cab radio is not a (intrinsic) safety device.

2.3. Use of the Regulation (EU) 402/2013 for requirements capture

2.3.1 What does Regulation (EU) 2018/545 actually mean when asking to apply the methodology in Annex I of Regulation 402/2013 for the requirements capture?

Article 13 of Regulation (EU) 2018/545 requires that, for the capture of requirements related to safety and safe integration between subsystems, the risk management process described in Annex I of Regulation (EU) 402/2013 (CSM RA) is used to identify and implement safety requirements and ensure safe integration of a vehicle's subsystems.

In other words, the applicant or entity managing the change must carry out a risk assessment following the process depicted in Annex I of CSM RA, subject to an independent assessment by an AsBo. This independent assessment is required to give assurance that the risk management process has been applied, and that all safety requirements have been properly managed.

The application of the risk management process in the CSM RA for the requirements capture process related to safety and safe integration between subsystems always requires an independent assessment by an AsBo, regardless of whether the change is considered significant or not, or whether the change triggers a new authorisation of the modified vehicle and/or vehicle type or not, in order to ensure that the risk management process:

- is compliant with the risk management process in Annex I of the CSM RA Regulation;
- allows the systematic identification of all safety risks and associated safety requirements, and
- covers the implementation, verification and validation of the safety requirements.

However, a systematic and system engineering-based approach is needed to address all vehicle requirements, not just the safety requirements. An applicant or an entity managing the change has two options to address requirements capture and management for the essential requirements other than safety:

- Follow the fundamental elements of the risk management process in the CSM RA for all requirements, with some adaptations that are necessary, as risk assessment and evaluation is not typically applicable to requirements other than safety requirements.

  This includes the independent assessment of the requirements capture, that can be carried out by an AsBo (this may be a straightforward addition to the AsBo's scope of assessment for essential requirement safety), but also by an independent assessor other than an AsBo.

  If an AsBo has not been appointed for the independent assessment of the requirements capture, the applicant will need to submit the evidence related to the requirements capture to the authorising entity as part of the authorisation process. The authorising entity will assess the evidence as part of the authorisation process to verify that a requirements capture process has been undertaken, and that it systematically identified and managed all requirements throughout the entire development process, including verification and validation.

- Use another, equivalent, process, which fits in the development practices of the applicant or of the entity managing the change. It is important that the methodology used provides the same level of assurance as the CSM RA and is subject to independent assessment. The independent assessor (which could be an AsBo) is required to perform a detailed assessment of the process and its application.

  When the methodology does not include an independent assessment, the demonstration that it provides the same level of assurance will face many challenges. Even if the authorising entity and the NSAs for the area of use will perform a detailed assessment of both the methodology and the results of its application (likewise an independent assessor), it cannot properly cover the whole life cycle of the vehicle and/or vehicle type (at this point, the vehicle and/or vehicle is already designed, manufactured and tested). In addition, solving eventual non-compliances found at this late stage of

the process may be difficult, time consuming and in some cases not feasible without an important delay in the authorisation process and/or additional costs.

When considering whether another methodology provides the same level of assurance, an applicant or an entity managing the change should take into account whether the process implemented incorporates the fundamental elements of a requirements capture process in EN 50126-1 standard and CSM RA.

2.3.2 What is the relationship between requirements capture and the CSM RA Regulation?

Article 13 of Regulation (EU) 2018/545 requires that, for the capture of requirements related to safety and safe integration between subsystems, the risk management process described in Annex I of Regulation (EU) 402/2013 (CSM RA) is used to identify and implement safety requirements and ensure safe integration of a vehicle's subsystems.

The risk management process, as defined in Annex I of the CSM RA, is a requirements capture process, albeit a process having a specific focus on safety. The application of this specific process for the identification, implementation and validation of safety requirements ensures that a requirements capture process is performed for the essential requirement safety and the safe integration between subsystems.

However, a systematic and system engineering-based approach is needed to address all vehicle requirements, not just the safety requirements. An applicant or an entity managing the change has two options to address requirements capture and management for the essential requirements other than safety:

- Follow the fundamental elements of the risk management process in the CSM RA for all requirements, with some adaptations that are necessary, as risk assessment and evaluation is not typically applicable to requirements other than safety requirements.

  This includes the independent assessment of the requirements capture, that can be carried out by an AsBo (this may be a straightforward addition to the AsBo's scope of assessment for essential requirement safety), but also by an independent assessor other than an AsBo.

- Use another, equivalent, process, which fits in the development practices of the applicant or of the entity managing the change. It is important that the methodology used provides the same level of assurance as the CSM RA and is subject to independent assessment. The independent assessor (which could be an AsBo) is required to perform a detailed assessment of the process and its application.

2.3.3 Is there a link between a significant change according to CSM RA and the need or not to perform requirements capture?

No. Article 13 of Regulation (EU) 2018/545 requires that, for the capture of requirements related to safety and safe integration between subsystems, the risk management process described in Annex I of Regulation (EU) 402/2013 (CSM RA) is used to identify and implement safety requirements and ensure safe integration of a vehicle's subsystems. The need to perform a risk assessment is then independent of Articles 2 and 4 of the CSM RA concerning the significance of the change.

In other words, the applicant or entity managing the change must carry out a risk assessment following the process depicted in Annex I of CSM RA, subject to an independent assessment by an AsBo.

2.3.4 In case of a change considered as significant according to the CSM RA, can the same AsBo assess the application of the CSM RA to the change and the requirements capture process?

Article 13 of Regulation (EU) 2018/545 requires that, for the capture of requirements related to safety and safe integration between subsystems, the risk management process described in Annex I of Regulation (EU) 402/2013 (CSM RA) is used to identify and implement safety requirements and ensure safe integration of a vehicle's subsystems.

In other words, the applicant or entity managing the change must carry out a risk assessment following the process depicted in Annex I of CSM RA, subject to an independent assessment by an AsBo. This independent assessment is required to give assurance that the risk management process has been applied, and that all safety requirements have been properly managed.

On the other hand, in the case of a change to an existing vehicle and/ or vehicle type, the CSM RA shall be applied. If the change is considered significant, the risk management process of CSM RA shall be applied, an AsBo shall independently assess the risk management process and shall issue a safety assessment report pursuant to Article 15 of the CSM RA.

The independent assessment for both aspects can be performed by the same AsBo, although the legal framework does not oblige to have the same company playing the role of AsBo for both topics. However, contracting the same AsBo may bring synergies between the independent assessment of the risk management process as defined in the CSM RA and the assessment of the requirements capture process for the essential requirement safety and the safe integration between subsystems prescribed in Article 13 of Regulation (EU) 2018/545. This may be a straightforward addition to an AsBo's role in particular if the CSM RA process is also used for requirements capture of all essential requirements, with the necessary adaptations.

2.3.5 Is the methodology of Annex I of CSM RA the only acceptable one for requirements capture of essential requirements other than safety? Which other methodologies may be acceptable?

Article 13 of Regulation (EU) 2018/545 requires that, for the capture of requirements related to safety and safe integration between subsystems, the risk management process described in Annex I of Regulation (EU) 402/2013 (CSM RA) is used to identify and implement safety requirements and ensure safe integration of a vehicle's subsystems.

For the other essential requirements, the applicant or the entity managing the change can choose the methodology to apply. Whilst a requirements capture process based on the CSM RA risk management process is preferred, an applicant or an entity managing the change can choose to apply different requirements capture processes to fit in with their project.

However, since the risk management process in the CSM RA must be applied by an applicant or the entity managing the change for the requirements capture related to the essential requirement safety and to the safe integration between subsystems, it is expected that requirements capture for essential requirements other than safety could be addressed with the same (or a very similar) process to that defined in the CSM RA, **with some adaptations**, and encompass then all essential requirements.

When an alternative methodology for requirements capture and management is chosen to be applied to the other essential requirements, an applicant or an entity managing the change needs to ensure that the chosen approach is based on a recognised and well-established development method and that it satisfies the following basic requirements (the fundamental elements) of a requirements capture process:

- System Definition - The system and/or change being implemented needs to be defined in the context of the railway network and its area of use.

› Specification of Requirements - All requirements to address the essential requirements need to be captured in requirements specifications and, as appropriate, fed into design specifications.

› Implementation of Requirements - Requirements need to be implemented, and design traceability, from the requirements through design specifications and into verification and testing needs to be performed.

› Demonstration of Compliance - All requirements need to be validated and evidence needs to be gathered to demonstrate that requirements are met.

If a novel or poorly-defined process is adopted, then there is a strong risk that those principal characteristics required of requirements capture and management will not be met, and the process of assessment by an AsBo or the authorising entity will take significantly longer. Examples of development methods that could be considered an appropriate basis for a requirements capture process would be those that are compliant with the systems engineering method defined in EN 50126-1. The more standardized is the process (closer to the principles of Annex I of CSM RA, e.g., EN 50126-1), the fewer issues will be raised by the AsBo and/or authorising entity during the assessment of the evidence of the requirements capture process.

The Figure 4 provides a schematic view of the relationships between Regulation (EU) 2018/545, Regulation (EU) 402/2013 and EN 50126-1 life cycle in terms of main steps of the requirements capture process related to the essential requirement safety and the safe integration between subsystems.

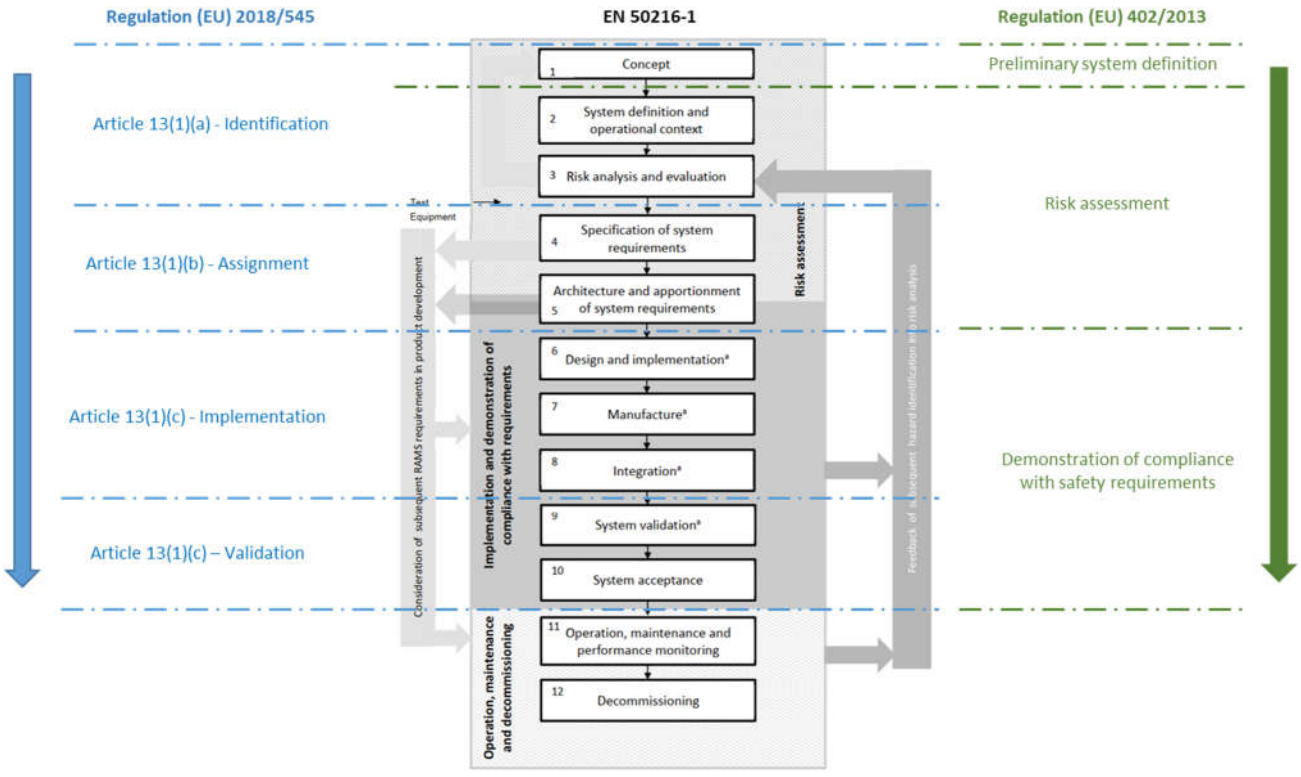


Figure 4: requirements capture in Regulation (EU) 2018/545 vs CSM RA process and system life cycle in EN 50126-1

The Figure 5 provides a graphical description of how the system life cycle in EN 50126-1 fits with the risk management process in Annex I of CSM RA. The fundamental elements of a requirements capture process are addressed by the main boxes (implementation of requirements and demonstration of compliance are covered by a single box), with the numbers in the individual boxes providing an indication of where these processes align with the phases of the EN50126-1 system life cycle.

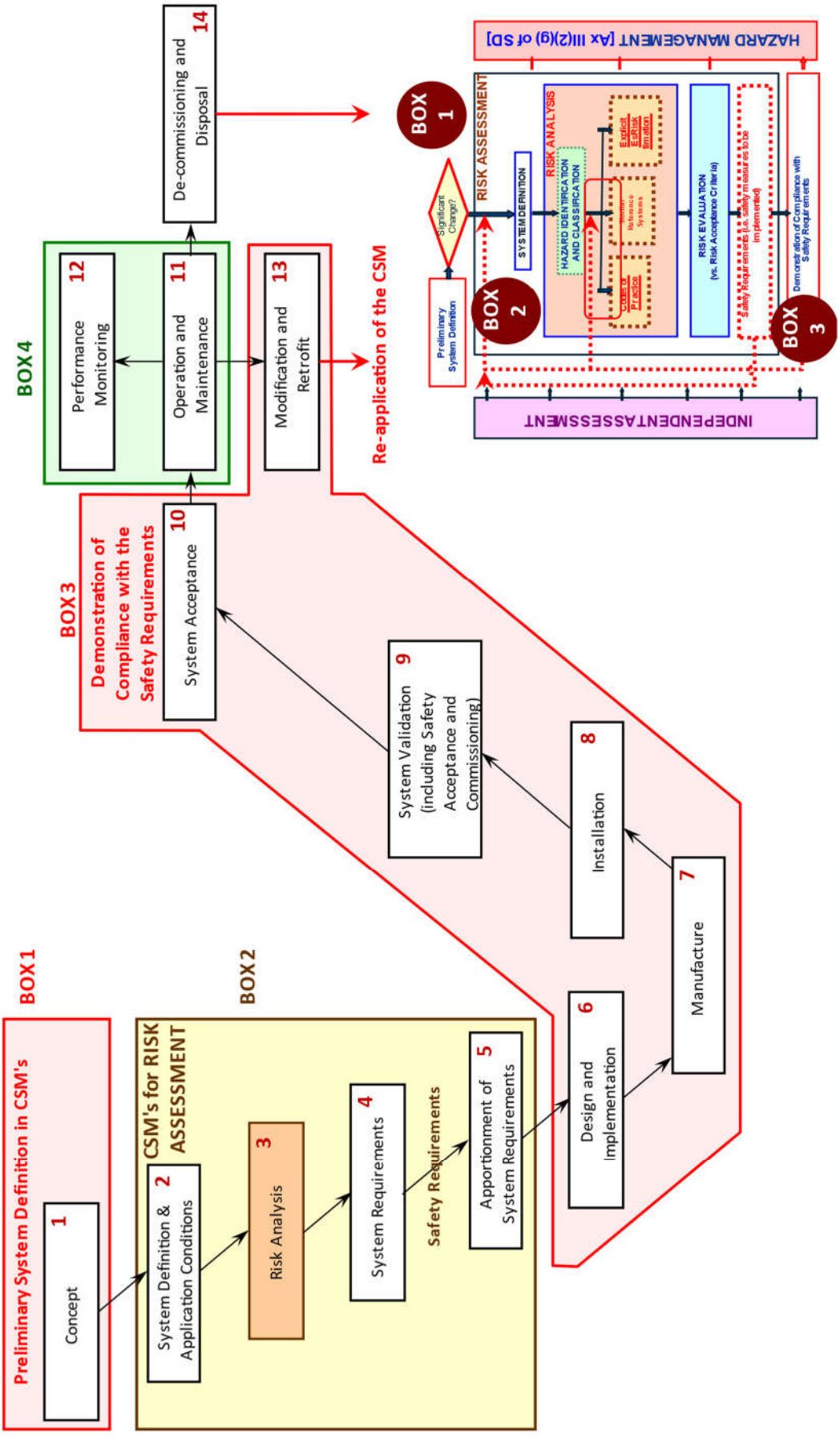


Figure 5: A requirements capture process based on the CSM RA process

2.3.6 What shall I do if I want to apply the CSM RA for essential requirements not related to safety?

Article 13 of Regulation (EU) 2018/545 requires that, for the capture of requirements related to safety and safe integration between subsystems, the risk management process described in Annex I of Regulation (EU) 402/2013 (CSM RA) is used to identify and implement safety requirements and ensure safe integration of a vehicle's subsystems.

For the other essential requirements, the applicant or the entity managing the change can choose the methodology to apply. Whilst a requirements capture process based on the CSM RA risk management process is preferred, an applicant or an entity managing the change can choose to apply different requirements capture processes to fit in with their project.

However, since the risk management process in the CSM RA must be applied by an applicant or the entity managing the change for the requirements capture related to the essential requirement safety and to the safe integration between subsystems, it is expected that requirements capture for essential requirements other than safety could be addressed with the same (or a very similar) process to that defined in the CSM RA, with some adaptations, and encompass then all essential requirements.

This is because the process and the diagram contained in Annex I of the CSM RA describe a process that is directly applicable to risk management, hence to the requirements capture related to the essential requirement safety and that contains some fundamental elements, such as System Definition, Identification and Specification of Requirements, Implementation of Requirements, and Demonstration of Compliance.

These elements are the fundamental elements of every requirements capture process and can be applied to address requirements capture for all essential requirements described in Annex III of Directive (EU) 2016/797. However, some adaptations are necessary, as the risk assessment process as defined in the CSM RA cannot be directly applied to requirements other than safety requirements (e.g., using a hazard record is not suitable for essential requirements other than safety, although the underlying principles are similar).

The following table contains different terms and concepts used in the CSM RA and their correspondence with Regulation (EU) 2018/545:

Step/Logic	Regulation (EU) 402/2013	Regulation (EU) 2018/545
Overall process	Risk management process in Annex I	Article 13(1) requires the applicant or the entity managing the change to have a systematic process for capturing all necessary requirements covering the design of the vehicle for its life cycle : • as regards to the essential requirements related to "safety" and to the safe integration between sub-systems, Article 13(3) requires the applicant or the entity managing the change to apply the methodology of Annex I of Regulation (EU) 402/2013. • for the essential requirements other than those in the bullet point above, point 18.1 in Annex I of Regulation (EU) 2018/545 suggests to follow the key principles in Annex I of Regulation (EU) 402/2013, nevertheless with the understanding that the deliverables would be named differently. Regulation (EU) 2018/545 allows the actors who do not see how to transpose the logic of the CSM RA to use other requirement capture methodologies, if they provide the same level of assurance, including an expert judgement of an independent assessor.
Objectives	Identify, assess and control systematically all reasonably foreseeable hazards and risks	Capture, manage implementation and validate systematically all the essential requirements (i.e., not only the safety related ones) covering the design of the vehicle for its life cycle, with the objective to : • identify, manage and mitigate all risks to an acceptable level; • capture, manage and demonstrate the compliance with all functional, technical and legal requirements for the design of the vehicle that are necessary to meet the essential requirements.
Understand the context	§ 1.1.1(a) & § 2.1.1(a) in Annex I : System definition	Article 13(1)(a) : understand the regulatory, customer's, and applicant's or EMC´s internal (if any) requirements, including any relevant specificities
Crucial	§ 1.1.1(a), § 2.1.1(b) & § 2.2.1 in Annex I : systematic and "exhaustive" hazard identification	Article 13(1)(a) : systematic and "exhaustive" inventory of all requirements from the applicable European laws, national specificities (areas of use), and customer that the vehicle design shall satisfy. Of course, all requirements include laws, rules, codes of practice, but also internal design codes of the

Step/Logic	Regulation (EU) 402/2013	Regulation (EU) 2018/545
		applicant or of the entity managing the change, guidelines, etc. that are not only legal requirements but the applicant or the entity managing the change decides to use.
Assessment and acceptance	§ 1.1.1(a), § 2.1.1(b) & § 2.1.1(c) in Annex I : risk analysis and estimation of risk control measures based on three possible risk acceptance principles : • codes of practice; • similar reference systems; • explicit risk estimation; Risk acceptance (through codes of practice and/or reference systems) and explicit qualitative or quantitative criteria	Article 13(1)(b) : agreed allocation of requirements down to areas of expertise, and/or subsystems, of the breakdown structure of the vehicle architecture, or exporting necessary conditions for use or other restrictions. As regards to the essential requirements related to "safety" and to the safe integration between sub-systems, Article 13(3) requires the application of the methodology in Annex I of Regulation 402/2013. It permits the applicant or the entity managing the change to use a risk acceptance principle among three possible ones : codes of practice, comparison with similar reference systems, explicit risk estimation. The principles/logic of those three pillars of the CSM RA can be used as well for the management and implementation of all other requirements that are not related to safety. Indeed, usually, the manufacturers largely use : • their in-house know-how, as well as existing principles and requirements from similar vehicles (*i.e., similar reference systems*), modelled within in-house data bases, registers, and checklists, that are continually updated with the experience gained on each new vehicle design (previous project); • well-known "*codes of practice*", or in-house standards and/or rules, and; • the approach "1 + Δ" ("one plus delta", *equivalent to an "explicit analysis" of new requirements*), where each new requirement and specificity is systematically identified, registered for the project, but also populated into in-house databases, registers, and checklists for further re-use on future projects.
Implementation	§ 1.1.1(b) & § 3 in Annex I : demonstration of the compliance of the system with the identified safety requirements	Article 13(1)(c) : implementation and validation of all identified requirements Demonstration of compliance requires the use of tools for tracing the requirements identified/captured at the start of the project down to the validation evidence (e.g., tests results)
Systematic management of requirements	§ 1.1.1(c) & § 4 in Annex I : management of all identified hazards and the associated safety measures through a **Hazard Log/Record**	The CSM RA specifies a hazard record as the central document to manage safety requirements. It shall be "created or updated by the proposer during design and implementation". The hazard record acts as a safety requirements management document and is used to show the status of the safety requirements and provide traceability into the design and implementation of those safety requirements. A similar mechanism (in terms of a tool that allows the proper management of the requirements) is required for the requirements capture process of essential requirements other than safety. Although the literal reading of Regulation 2018/545 would suggest the use of a Hazard Log/Record for registering all requirements, i.e., not only the safety related information, in practice this is not mandatory. Regulation 2018/545 allows to use any other means or tools (e.g., a centralised repository tool) which enable the applicant or the entity managing the change to demonstrate a systematic recording and management of the non-safety requirements. Usually for that purpose, the manufacturers largely use specific IT tools, or in-house data bases, registers, check lists, and tools for systematically tracing down, and managing the implementation of, the requirements identified/captured at the start of the project till the associated validation tests are done to demonstrate the actual and correct implementation of every requirement. This logic and systematic management of all essential requirements is equivalent to the concept of a Hazard Log/Record, which ensures that no requirement is forgotten. Annex 4.1 of this document contains a conceptual example on which are the main aspects to consider for the management of the requirements (compliance matrix).
Statement of proper management	Article 16 : declaration by the proposer that all identified hazards and associated risks are controlled to an acceptable level	Point 18.10 and 18.12 of Annex I of Regulation 2018/545 require that according to Article 13 of that Regulation, the Risk Declaration of Article 16 of Regulation 402/2013 covers at least the capture and the management of : • requirements related to safety and to safe integration between sub-systems, but also; • requirements associated to the essential requirements other than safety. Thereby, concerning the applicant's (or EMC´s) declaration, according to point 7 in Annex II of Regulation 2018/545, either :

Step/Logic	Regulation (EU) 402/2013	Regulation (EU) 2018/545
		• point 7.1 : the applicant or the entity managing the change uses the methodology in Annex I of Regulation 402/2013 for all essential requirements. It extends then the scope of the declaration of its Article 16 to state that, based on the results of the requirement capture process and the AsBo assessment report, all identified requirements are successfully implemented and all identified hazards and associated risks are controlled to an acceptable level, or • point 7.2 : the applicant or the entity managing the change uses another methodology than Annex I of Regulation 402/2013 for the requirement capture and requirement management of the essential requirements other than safety and other than safe integration between subsystems. In this case, there is no obligation for the applicant or the entity managing the change to establish any declaration. Annex 4.3 of this document presents a template for such (risk) declaration, covering all essential requirements.

2.4. AsBo

2.4.1 Concerning the requirements capture process, do I always have to involve an AsBo? In which cases am I allowed not to involve an AsBo for the requirements capture process? Do I have to appoint an AsBo if I decide to use a methodology different than CSM RA?

Article 13 of Regulation (EU) 2018/545 requires that, for the capture of requirements related to safety and safe integration between subsystems, the risk management process described in Annex I of Regulation (EU) 402/2013 (CSM RA) is used to identify and implement safety requirements and ensure safe integration of a vehicle's subsystems.

In other words, the applicant or entity managing the change must carry out a risk assessment following the process depicted in Annex I of CSM RA, subject to an independent assessment by an AsBo. This independent assessment is required to give assurance that the risk management process has been applied, and that all safety requirements have been properly managed.

However, a systematic and system engineering-based approach is needed to address all vehicle requirements, not just the safety requirements. An applicant or an entity managing the change has two options to address requirements capture and management for the essential requirements other than safety:

- Follow the fundamental elements of the risk management process in the CSM RA for all requirements, with some adaptations that are necessary, as risk assessment and evaluation is not typically applicable to requirements other than safety requirements.

  This includes the independent assessment of the requirements capture, that can be carried out by an AsBo (this may be a straightforward addition to the AsBo's scope of assessment for essential requirement safety), but also by an independent assessor other than an AsBo.

- Use another, equivalent, process, which fits in the development practices of the applicant or of the entity managing the change. It is important that the methodology used provides the same level of assurance as the CSM RA and is subject to independent assessment. The independent assessor (which could be an AsBo) is required to perform a detailed assessment of the process and its application.

This means that for the independent assessment of the requirements capture process for essential requirements other than safety and safe integration between subsystems, when the methodology applied does not follow the process described in Annex I of the CSM RA, the applicant or the entity managing the change is allowed not to involve an AsBo and use other independent assessment instead. It should be noted that even in such case, an AsBo can perform the independent assessment too.

When a change to an existing vehicle and/or vehicle type does not have any potential impact in safety and/or safe integration between subsystems, and this can be demonstrated without the need to perform a risk assessment, it is not mandatory that the requirements capture process for essential requirements other than safety follows the process of Annex I of CSM RA. This means that the involvement of an AsBo for the independent assessment of such requirements capture process is not mandatory.

2.4.2 Do I have to involve an AsBo if I classify the change to an already authorised vehicle as non-significant according to CSM RA regulation?

Article 13 of Regulation (EU) 2018/545 requires that, for the capture of requirements related to safety and safe integration between subsystems, the risk management process described in Annex I of Regulation (EU) 402/2013 (CSM RA) is used to identify and implement safety requirements and ensure safe integration of a vehicle's subsystems.

In other words, the applicant or entity managing the change must carry out a risk assessment following the process depicted in Annex I of CSM RA, subject to an independent assessment by an AsBo. This independent

assessment is required to give assurance that the risk management process has been applied, and that all safety requirements have been properly managed.

The application of the risk management process in the CSM RA for the requirements capture process related to safety and safe integration between subsystems always requires an independent assessment by an AsBo, regardless of whether the change is considered significant or not, or whether the change triggers a new authorisation of the modified vehicle and/or vehicle type or not, in order to ensure that the risk management process:

- is compliant with the risk management process in Annex I of the CSM RA Regulation;
- allows the systematic identification of all safety risks and associated safety requirements, and
- covers the implementation, verification and validation of the safety requirements.

When a change to an existing vehicle and/or vehicle type does not have any potential impact in safety and/or safe integration between subsystems, and this can be demonstrated without the need to perform a risk assessment, it is not mandatory that the requirements capture process for essential requirements other than safety follows the process of Annex I of CSM RA. This means that the involvement of an AsBo for the independent assessment of such requirements capture process is not mandatory.

2.4.3 What shall I do if I don´t want to involve an AsBo for essential requirements not related to safety?

Article 13 of Regulation (EU) 2018/545 requires that, for the capture of requirements related to safety and safe integration between subsystems, the risk management process described in Annex I of Regulation (EU) 402/2013 (CSM RA) is used to identify and implement safety requirements and ensure safe integration of a vehicle's subsystems.

However, a systematic and system engineering-based approach is needed to address all vehicle requirements, not just the safety requirements. An applicant or an entity managing the change has two options to address requirements capture and management for the essential requirements other than safety:

- Follow the fundamental elements of the risk management process in the CSM RA for all requirements, with some adaptations that are necessary, as risk assessment and evaluation is not typically applicable to requirements other than safety requirements.
- Use another, equivalent, process, which fits in the development practices of the applicant or of the entity managing the change. It is important that the methodology used provides the same level of assurance as the CSM RA and is subject to independent assessment. The independent assessor (which could be an AsBo) is required to perform a detailed assessment of the process and its application.

In order for requirements capture to take place, there needs to be an appropriate traceability of all requirements that have been identified and captured, so that the identification, implementation, verification and validation, demonstration of implementation of the requirements is documented. The applicant or the entity managing the change has to document and produce evidence for the whole requirements capture process, covering all the steps of the EN 50126-1 V-Cycle.

There is no obligation to use a specific tool or approach to produce the evidence of the application of the requirements capture process, as long as the applicant or the entity managing the change demonstrates that all the aspects above have been followed.

The CSM RA specifies a hazard record as the central document to manage safety requirements. It shall be "created or updated by the proposer during design and implementation". The hazard record acts as a safety requirements management document and is used to show the status of the safety requirements and provide traceability into the design and implementation of those safety requirements. A similar mechanism (in terms

of a tool that allows the proper management of the requirements) is required for the requirements capture process of essential requirements other than safety.

Although the literal reading of Regulation 2018/545 would suggest the use of a Hazard Log/Record for registering all requirements, i.e., not only the safety related information, in practice this is not mandatory. Regulation 2018/545 allows to use any other means or tools (e.g., a centralised repository tool) which enable the applicant or the entity managing the change to demonstrate a systematic recording and management of the non-safety requirements.

Usually for that purpose, the manufacturers largely use specific IT tools, or in-house data bases, registers, check lists, and tools for systematically tracing down, and managing the implementation of, the requirements identified/captured at the start of the project till the associated validation tests are done to demonstrate the actual and correct implementation of every requirement. This logic and systematic management of all essential requirements is equivalent to the concept of a Hazard Log/Record, which ensures that no requirement is forgotten.

Annex 4.1 of this document contains a conceptual example on which are the main aspects to consider for the management of the requirements (compliance matrix).

2.4.4 Which competences shall an AsBo have for assessing the requirements capture process?

Annex II of the CSM RA requires the AsBo to fulfil the following requirements :

- all requirements of the ISO/IEC 17020:2012 standard; those are general criteria and requirements concerning the AsBo "independence, competence, integrity and impartiality";
- specific criteria and requirements needed for carrying out the independent assessments requested in Article 6 of the CSM RA

AsBos are accredited or recognised, pursuant to Article 7 of CSM RA, which means that the criteria in Annex II of the CSM RA are met, for one, several or all areas of competence related to the different subsystems (structural and functional) that compose the EU railway system:

- Infrastructure
- Energy
- Control-command and signalling
- Rolling stock
- Traffic operation and management
- Maintenance
- System safe integration
- Other

Additionally, point 3 in Annex II of the CSM RA requires that the AsBo shall be accredited or recognised for wider or transversal competencies, such as the competence needed to assess the overall consistency of the risk management and the safe integration of the system under assessment, which includes the ability of the AsBo to check the following :

- the organisation or arrangements put in place by the proposer to ensure a coordinated approach;
- the methodology for the evaluation of methods and resources deployed by various stakeholders, and
- the technical aspects necessary for assessing the system as a whole.

To fulfil the requirements of the CSM RA, an AsBo should be accredited or recognised for "at least one technical area of competence in point 2 in Annex II and the competence in point 3 in Annex II for assessing the overall consistency of the risk management and the safe integration of the system under assessment into the railway system as a whole".

It is important to know that the CSM RA does not give details for the competence requirements defined in its Annex II, which are broad requirements. For example, it does not specify the specific engineering disciplines, such as embedded real-time systems, telecommunications, hardware, software, human factor, etc. necessary for every structural sub-system. This makes it difficult to ascertain whether an AsBo has sufficient competence, experience, and knowledge to fulfil its roles and responsibilities. For those reasons, further details about the requirements for the technical knowledge and competence of the AsBos can be found in the Recommendation for Use (RFU) number 3, developed by the Agency and the AsBo Cooperation group. This RFU is publicly available at ERA website:

https://www.era.europa.eu/sites/default/files/activities/docs/recommendation-for-use-03_en.pdf

The abovementioned RFU number 3 defines explicitly the competence requirements necessary for an AsBo to be allowed to independently assess the requirement capture process covering a whole vehicle (and the safe integration between subsystems).

For the purposes of the independent assessment of the requirements capture process of a vehicle and/or vehicle type, the AsBo should include in the scope of its accreditation or recognition all the subsystems that compose the vehicle. In case of new authorisation case (changes to an existing vehicle and/or vehicle type), where only one of the subsystems is impacted, only the competences for the subsystems impacted by the change are considered necessary, although the independent assessment shall also cover the safe integration between mobile subsystems. Needless to say, for vehicles that are only composed of the rolling stock subsystem (e.g., wagons), the AsBo performing the independent assessment of the requirements capture process only needs the competence related to rolling stock in the scope of its accreditation / recognition.

However, due to the systemic nature (process oriented, sample checks and in-depth vertical slice assessments) of the independent assessment to be performed concerning the requirements capture process, an accredited or recognised AsBo whose competences cover at least the rolling stock subsystem is capable of assessing the requirements capture process for the whole vehicle. An AsBo is not obliged to have internally, within its organisation or entity, all the technical competences necessary for carrying out the independent assessment. Pursuant to the conditions in clauses 6.1 and 6.3 of ISO/IEC 17020:2012, the AsBo can either hire-in external experts, or subcontract parts of the assessment.

In this case, the AsBo does not have the competence which is subcontracted in the scope of its accreditation or recognition the full scope of the subcontracted parts. Therefore, the AsBo has to ensure and be able to demonstrate that the subcontractor is competent to perform the activities in question and, where applicable, complies with the relevant requirements stipulated in the ISO/IEC 17020:2012 or in other relevant conformity assessment standards. In any case, the AsBo remains responsible for the whole independent assessment, including the subcontracted part. When the subcontracted part is an entire structural subsystem (e.g., control-command and signalling) fully covered by a TSI, the AsBo should mutually recognise the assessments performed by another AsBo, accredited or recognised for at least the subcontracted scope.

Clauses 6.1 and 6.3 are of ISO/IEC 17020:2012 standard are further discussed in the Recommendation for Use (RFU) number 8, which is under development by the Agency and the AsBo Cooperation group. The RFU will be publicly available at ERA website.

The information concerning the areas covered by the accreditation or recognition of the AsBo recorded in ERADIS (https://eradis.era.europa.eu/safety_docs/assessments/bodies/default.aspx, section 5 "Classification") should be up to date and consistent with the evidence of the accreditation or recognition issued by the competent body, to avoid unnecessary delays during the authorisation process. This aspect is assessed by the authorising entity in the framework of an application for authorisation.

2.4.5 Are in-house AsBos allowed for the assessment of the requirements capture process?

The CSM RA allows the use of all three types (A, B and C) of inspection bodies as defined in section § 4.1.6 and Annex A of the ISO/IEC 17020:2012 standard. In all cases, the AsBo must be accredited or recognised, pursuant to Article 7 of CSM RA, which provides assurance about their competence, independence and impartiality.

"In-house" AsBos of both types B and C, according to points A.2 and A.3 of ISO/IEC 17020:2012 standard, are allowed to perform the assessment of the requirements capture process. It is worth underlining that type B AsBos can only provide services to the organisation of which they form part. Type C AsBos can also provide services to other parties.

2.4.6 When shall the AsBo begin the assessment of the requirements capture process?

The involvement of the AsBo for the independent assessment of the requirements capture process should start as early as possible in the project; a late intervention of the AsBo may lead to a late identification of non-compliances which could be difficult to solve when the project is at advanced stage of development. It may also lead, during the authorisation process, to further enquiries by the authorising entity and/or the NSAs for the area of use regarding the assessments performed by the AsBo related to activities that took place before its appointment.

When the applicant or the entity managing the change appoints the AsBo at the very early stages of the project, the AsBo independent assessment activities are proactive. This allows the AsBo to identify as early as possible non-compliances in either the applicant's or EMC's organisation and processes supporting the requirement capture process, or in the correct application of those processes by the project team.

If the applicant or the entity managing the change appoints the AsBo very late in the project, e.g., when all developments are almost finished, the independent assessment cannot be proactive. It will consist in giving a final photo of the applicant's or EMC's requirement capture, with the identified non-compliances, not leaving room for improvements in the design of the vehicle type.

2.4.7 What should an AsBo provide to another AsBo? If I have two AsBos involved in my project (e.g., AsBo from my CCS supplier and my RS AsBo), is there an obligation of cooperation (sharing information) between AsBos? Can an AsBo raise questions to another AsBo?

The CSM RA indicates that safety assessment reports shall not be called into question by other AsBos performing new assessments with the same scope, upon demonstration of the equivalence of the conditions for use (functional, operational and environmental) and risk acceptance criteria. In order to avoid unnecessary duplication of assessment of the same element by different bodies, the CSM RA requests the application of the mutual recognition principle.

Therefore, in terms of the assessment report covering the requirements capture process, the same principle should apply, mutatis mutandis, notwithstanding that the responsibility of the independent assessment for the requirements capture process lies solely with the AsBo hired by the applicant or entity managing the change for this purpose.

For those reasons, at the beginning of the project, the applicant or the entity managing the change has to decide and agree with the different parties involved how to organise and manage the mutual recognition between the various conformity assessment bodies involved in the project. That will allow the AsBo in charge of the independent assessment of the requirements capture to plan any coordination measures (e.g., meetings) necessary for the acceptance of the assessments performed by other AsBos and/or conformity assessment bodies for other subsystems, elements, components, etc.

In any case, if the AsBo for the requirements capture process has justified and documented doubts on the process followed by other AsBos and cannot arrive to a conclusion for the requirements capture of the vehicle

and/or vehicle type as a whole unless the doubts are solved, it should raise questions through the channel agreed between the parties (e.g., through the party that hired the AsBo whose assessment is called into question, through its customer, directly to the concerned AsBo, etc.).

The CSM RA nor the Regulation (EU) 2018/545 do not impose any obligation between the parties in terms of cooperation or obligation to share information. The applicant or entity managing the change is the sole responsible for ensuring that the vehicle and/or vehicle type meets the essential requirements, and to ensure that its suppliers fulfil their legal duties, including the fostering of collaboration between them when needed.

2.4.8 How detailed shall the AsBo independent assessment of the requirements capture process be?

Some stakeholders and AsBos have a proper understanding of the extent, and the depth of the independent assessment and of the inspection methods (sampling and vertical slice assessments principles) to apply in order to arrive at the expert judgement on the correctness of the requirements capture process and, on the suitability, or appropriateness of the results of its application.

Other stakeholders and AsBos consider that the AsBos have rather a superficial role in checking just that the different steps of a requirements capture process are gone through but without the necessity to carry out any assessment of any part nor assessing the requirements capture process itself.

Concerning the independent assessment of the requirements capture process, it is not envisaged that the AsBo performs an exhaustive check of all the evidence supporting the requirements capture. Its role should be more systemic, focused on the process followed by the applicant or the entity managing the change to capture the requirements and ensure that all risks are covered and controlled. To do so, the AsBo needs to check in detail not only the process followed but some of the supporting evidence, both by sampling but also by means of a vertical slice assessment: detailed end-to-end review of the application of the requirements capture process for selected requirements, in order to check a representative “cross-sectional slice” of the results from the requirements capture process covering all the step, from identification to verification and validation.

The work to be performed by the AsBo is to:

- Give assurance that the requirements capture process for the essential requirement safety and safe integration between subsystems meets the requirements laid down in Annex I of the CSM RA;
- Give assurance that the requirements capture process for essential requirements other than safety either meets the requirements in Annex I of CSM RA when the applicant or the entity managing the change decides to apply this methodology, or provides a similar level of assurance when another methodology is used;
- Give the assurance that requirements capture process is systematic and allows a proper identification and management of the requirements (implementation, verification and validation) throughout the entire development process;
- Form an expert judgement on the correct application of the requirements capture process for the concerned project and on the suitability of the results:
- Form an expert judgment on the suitability of the vehicle and/or vehicle type to meet the essential requirements (at least for safety and safe integration between subsystems), and
- Deliver an assessment report that contains the results of the independent assessment concerning the points mentioned above (see annex 4.2 for further information about the extent of the assessments to be performed by the AsBo)

Compared to the conformity assessments for a TSI performed by a NoBo, which aims at checking that all the requirements of the TSIs are met, the independent assessment by an AsBo of the requirements capture process is more about checking the process put in place by the applicant or the entity managing the change to manage all requirements (and risks).

It should be noticed that when the requirements capture concerns a change to an already authorised vehicle and/or vehicle type, CSM RA applies, and the risk assessment process in Annex I of the CSM RA should be applied to changes that are considered significant. In such case, the work of the AsBo is twofold: independent assessment of the significant change and independent assessment of the requirements process. There are however obvious synergies for the essential requirement safety, where both aspects overlap: following the CSM RA for the significant change means that the essential requirement safety is properly managed.

Further details about the working method for AsBos can be found in the Recommendation for Use (RFU) number 1 issued by the AsBo Cooperation group, available at ERA website:

https://www.era.europa.eu/sites/default/files/activities/docs/recommendation_for_use-01_en.pdf

Similarly, more information about the AsBo independent assessment can be found in Annex 4.2 (§3.3).

2.4.9 What is the expected content of the AsBo report covering the assessment of the requirements capture process? Is there a template?

The independent assessment report for the requirements capture process to be issued by the AsBo should contain:

- a description of the AsBo's understanding of the scope of the project, and the scope of assessment that has been performed, including the life cycle phases that have been assessed;
- the assessment activities that have been performed, in assessing requirements capture, including the samples or vertical slices taken, and choices made for spot checks of compliance evidence;
- the other assessment reports and/or audit reports that have been mutually recognised or considered in the assessment of requirements capture; and
- relevant detailed findings and a conclusion concerning the appropriateness of the requirements capture process to fulfil the provisions in Article 13 of regulation (EU) 2018/545 and the essential requirements specified in Annex III of Directive (EU) 2016/797 .

In the conclusions of its assessment of the requirements capture process, the AsBo needs to clearly state if:

- the requirements capture process was systematic and has been applied to identify relevant sets of requirements (including EU legislation, standards and guidelines) that apply;
- detailed requirements arising have been fed into the requirements specification, documentation specification and actions lists and that there is evidence to show that these requirements have been complied with and implemented; and
- risks have been assessed following the process depicted in Annex I of the CSM RA.

The minimum content or the required structure for the assessment report to be issued by AsBos is not defined in the legal texts. In Annex 4.2 of the document, a model template is proposed, summarising the main elements of the assessment report for the requirements capture process.

The proposed structure can be adapted to the AsBo documentation management system, provided that the template used by the AsBo contains all the necessary information and the document meets the usual requirements concerning quality and traceability (unique reference of the document, date of issuing, version/issue, history of changes etc.).

The AsBo which does not agree with some parts, is free to amend, or delete, them provided it reliably and unambiguously reports on how they actually performed the independent assessment, and what are all limits and conclusions of the independent assessment of the requirement capture.

In the template, guidance and/or explanatory text is identified in italics and grey colour. Standard texts which are proposed to be included (with the necessary adaptations) are regular font and black colour. The parts that need to be customized for the particularities of the project (e.g., applicant´s name, name of the project) are identified in blue colour and between brackets.

The AsBo cooperation group is working on a Recommendation for Use further defining the structure and content of the assessment report to be issued by AsBo. Once this recommendation is issued, the Annex 4.2 will be adapted accordingly.

2.4.10 Shall the AsBo report provide a judgement on the conditions of use and/or the risk mitigation measures?

The applicant or the entity managing the change is responsible for identifying and proposing the conditions for use of the vehicle and other restrictions, that should come from the EC verification procedure for the mobile subsystems and the application of the requirements capture process for the vehicle and/or vehicle type (including the risk assessment necessary to fulfil the essential requirement safety).

Conditions for use and other restrictions are part of the design of the vehicle and form the boundaries for how the vehicle is intended to be used. There are three broad stages to the identification of conditions for use and other restrictions:

- Identified at the design stage.

  During the design and development of a vehicle and/or a vehicle type, the applicant or the entity managing the change should identify the intended conditions for use and other restrictions (such as gauge, maximum speed, speed limits arising from the isolation of parts of the braking system, temperature range etc.) that are applicable, considering the design of the vehicle and its intended operational conditions. Some of the conditions and restrictions for use will be derived from the requirements capture as well as the risk assessment process for the safety related requirements (essential requirement safety within the subsystems and safe integration of subsystems).

- Derived from the conformity assessment of the mobile subsystems;

  It may be necessary to add further conditions and restrictions as a result of the conformity assessment (EC verification procedure and independent assessment of the requirements capture process). These conditions and restrictions should be agreed between the applicant/entity managing the change and the concerned assessment bodies (NoBo(s), DeBo(s) and/or AsBo(s)).

  Conditions for use are not a way to deviate from the mandatory requirements (e.g., TSIs, national rules), but in some cases, they can be used to define particulars conditions that shall be respected to meet the requirements of the mandatory rules (see clarification note ERA1209/115).

  The applicant will then compile the file accompanying the application for authorisation and submit the application for authorisation through the one-stop shop. All the conditions and restrictions for use identified until this stage should be specified in the application for authorisation.

- Imposed by the authorising entity and the concerned NSAs for the area of use.

  The authorising entity and/ or the NSAs for the area of use can give further conditions for use and other restrictions as a result of their assessment of the application and the file accompanying the application. The issued vehicle type authorisation and/ or vehicle authorisation for placing on the market should reflect all the conditions for use of the vehicle and other restrictions identified.

When conditions for use are safety related, they should be cross-checked by the AsBo responsible for the independent assessment of the requirements capture process, in order to ensure that they have been properly managed by applying the risk assessment process described in Annex I of CSM RA.

When an AsBo is appointed for the independent assessment of the requirements capture of essential requirements other than safety, it should verify if the requirements capture process properly covers conditions for use related to other essential requirements and they have been properly managed in application of the process.

It is not envisaged that the AsBo performs an exhaustive check of all the evidence supporting the requirements capture. Its role should be more systemic, focused on the process followed by the applicant or the entity managing the change to capture the requirements and ensure that all risks are covered and controlled. To do so, the AsBo needs to check in detail not only the process followed but some of the supporting evidence, both by sampling but also by means of a vertical slice assessment: detailed end-to-end review of the application of the requirements capture process for selected requirements, in order to check a representative “cross-sectional slice” of the results from the requirements capture process covering all the step, from identification to verification and validation.

Further details can be found in Annex 4.2 of this document (suggested content of the independent assessment report to be issued by the AsBo).

2.4.11 What is the expected content of the (risk) declaration by the applicant or the entity managing the change concerning the requirements capture process? Is there a template?

An EC declaration of verification (which is required to be made by applicants or entities managing the change for placing on the market the mobile subsystems in accordance with Directive (EU) 2016/797) must address all relevant European Union laws and national rules. Requirements capture and management requires a wider declaration of compliance, ensuring that a vehicle has satisfied all relevant requirements that are necessary to meet the essential requirements. This also incorporates all necessary harmonised standards, international standards, design codes and guidelines required.

From this point of view, the declaration to be established by the applicant for authorisation or by the entity managing the change concerning the requirements capture process can be considered as an equivalent declaration, although with a wider scope as compared the EC declaration(s) of verification: the vehicle as a whole, rather than covering only the individual mobile subsystems.

The minimum content or the required structure for the declaration to be issued by the applicant or by the entity managing the change pursuant to point 18.10 of Annex I of Regulation (EU) 2018/545 is not defined in the legal texts. In Annex 4.3 of the document, a model template is proposed, summarising the main elements of the assessment report for the requirements capture process.

2.4.12 Can the same conformity assessment body play the role of AsBo/DeBo and NoBo in my project? Is there any conflict?

The CSM RA does not forbid that the same company plays several roles (e.g., NoBo, DeBo and/or AsBo), as long as it fulfils the necessary requirements and is properly accredited or recognised with respect to the relevant requirements for each of those roles. Following the CSM RA definition, an AsBo is a competent external or internal (“in-house”) individual, organisation or entity which is at least independent from the "design, risk assessment, risk management, manufacture, supply, installation, operation/use, servicing and maintenance" of the vehicle and/or vehicle type under assessment.

Hence, one of the key requirements that an AsBo needs to fulfil for being accredited or recognised is independence and impartiality. This means that AsBos should have in place the necessary measures and barriers to ensure independency from other companies, or parts of the company to which it belongs (for types B and C AsBos).

2.4.13 Can I apply CENELEC standards (EN 5012x series) for CCS to prove compliance with CSM RA? If so, can I use an ISA (Independent Safety Assessor)?

The European railway legislation does not define any role for the CENELEC independent safety assessor (ISA). Furthermore, the section 3.2.1 of the CCS TSI (Regulation (EU) 2016/919) makes compulsory the independent safety assessment by an AsBo. Hence, this independent assessment cannot be performed by a CENELEC ISA. In addition to that, section 3.2.1 the CCS TSI states explicitly that "[…] *the application of the specifications as referred to in Appendix A, Table A 3 […]"* (i.e. of the CENELEC 5012x series standards) *"[…] is an appropriate means to fully comply to the risk management process […]*" of the CSM RA for *"[…] interoperability constituents and subsystems […]*", provided the independent assessments are carried out by an AsBo accredited or recognised for the CCS scope instead of a CENELEC ISA.

The methodologies described in CSM RA and the CEN/CENELEC standards (EN 50126/50128/50129) are not contradicting each other and should not be considered as two separate and consecutive tools. On the contrary, it is reasonable to use them in an integrated and complementary way.

However, the AsBo and the CENELEC independent safety assessor (ISA) are not equivalent, although their roles and working methods have many similarities.

Furthermore, the scope of work of the AsBo is broader than the CENELEC ISA. The CENELEC 50128 and 50129 standards request an ISA only for signalling systems. The CSM RA makes compulsory the appointment of the AsBo for the independent safety assessment of all significant changes, regardless of whether they relate to control-command and signalling subsystem, rolling stock subsystem, infrastructure subsystem etc. Article 13 of Regulation (EU) 2018/545 also requires the appointment of an AsBo for the independent assessment of the requirements capture process related to the essential requirement safety and the safe integration between subsystems.

Consequently, when the EU legislation requires the appointment of an AsBo to a project, and when contractually, or through a notified national rule, the use of CENELEC 50126, 50128 and 50129 standards (with an independent safety assessor) is also required, the applicant or the entity managing the change is required to appoint an AsBo which:

- is accredited or recognised according to the CSM RA, and
- fulfils also the competence requirements of a CENELEC ISA.

In that case, the independent safety assessment carried out by such an AsBo shall include also all necessary independent safety assessment activities that should be fulfilled by the CENELEC ISA.

In case an applicant or an entity managing the change would appoint an ISA, whereas that shall not be possible for a scope of work already covered by EU legislation, it is important to keep in mind that an AsBo is not obliged to mutually recognise the work and the report of a CENELEC ISA. Pursuant to clause 6.3 of the ISO/IEC 17020:2012 standard, the AsBo is:

- responsible for verifying itself that the ISA has the right level of competence and independence, and that the ISA uses working methods similar to the ones in CSM RA, or
- allowed to perform additional checks or assessments, if deemed necessary.

2.5. Evidence and documentation

2.5.1 How can an applicant or an entity managing the change document the requirements capture process, and the results of its application to a particular project?

Article 13 of Regulation (EU) 2018/545 requires that, for the capture of requirements related to safety and safe integration between subsystems, the risk management process described in Annex I of Regulation (EU) 402/2013 (CSM RA) is used to identify and implement safety requirements and ensure safe integration of a vehicle's subsystems.

However, a systematic and system engineering-based approach is needed to address all vehicle requirements, not just the safety requirements. An applicant or an entity managing the change has two options to address requirements capture and management for the essential requirements other than safety:

- Follow the fundamental elements of the risk management process in the CSM RA for all requirements, with some adaptations that are necessary, as risk assessment and evaluation is not typically applicable to requirements other than safety requirements.
- Use another, equivalent, process, which fits in the development practices of the applicant or of the entity managing the change. It is important that the methodology used provides the same level of assurance as the CSM RA and is subject to independent assessment. The independent assessor (which could be an AsBo) is required to perform a detailed assessment of the process and its application.

In order for requirements capture to take place, there needs to be an appropriate traceability of all requirements that have been identified and captured, so that the identification, implementation, verification and validation, demonstration of implementation of the requirements is documented. The applicant or the entity managing the change has to document and produce evidence for the whole requirements capture process, covering all the steps of the EN 50126-1 V-Cycle.

General evidence of the identification of requirements and their validation will not be sufficient. The requirements capture process adopted must be seen to support the principles identified above down to the level of individual requirements, and the set of specified design and validation actions required to implement these requirements.

To achieve this objective, there should be an appropriate centralised tool (repository), which can be either a physical tool or an IT tool (table, spreadsheet, database, register, etc.). There is no requirement to use any specific solution to document evidence of requirements capture as long as the applicant or the entity managing the change can show that the principles mentioned above are followed. In this guidance a requirements compliance matrix is proposed as an illustrative example of which aspects need to be considered, see Annex 4.1. The amount of documentation and/or traceability needed depends on the complexity of the project (e.g., number and complexity of requirements for a new design of high speed train will be higher than for a wagon for or a small modification of an existing vehicle type).

The evidence should demonstrate that the requirements capture applied covers all the essential requirements, not only the essential requirement safety.

In addition to the evidence of the application of the requirements capture process, the applicant or the entity managing the change should document (describe) the process and its application to the concerned project, in particular for cases where it does not follow the principles of Annex I of CSM RA. This because the authorising entity will need to assess whether the process respects the main principles of points 6 and 7 of Annex I of Regulation (EU) 2018/545 or not:

- Degree of independent assessment applied
- System definition

› For essential requirement safety and safe integration between subsystems:
  - Hazard identification, classification and management (hazard log, hazard record)
  - Risk acceptance principles
  - Risk evaluation

› For all other essential requirements, appropriate centralised tool (table, spreadsheet, database, register, etc.) for the identification and management of requirements.

References to generic company standards which are applied for requirements capture and management are not considered sufficient evidence of requirements capture as they do not provide sufficient detail and evidence of the process that has been implemented and applied to a given project. However, the description can refer to or re-use, where needed, existing documents generated in the framework of other processes already established by the manufacturer/ supplier that in the end compose the process for managing requirements (e.g., quality management, change management, requirement management processes, etc.).

2.5.2 Which evidence of the requirements capture process shall I submit through the OSS?

Regulation (EU) 2018/545 requires applicants and entities managing changes to perform a requirements capture process. The evidence of requirements capture performed need to be part of the file accompanying the application for authorisation in the OSS, when an application is required.

It is necessary to make a distinction concerning whether the principles of the methodology in Annex I of the CSM RA are used for all essential requirements or not:

› If the principles of the methodology in Annex I of CSM RA are used for all essential requirements, the supporting evidence consists of the declaration(s) referred to in Article 16 of CSM RA (points 18.10 and 18.12 of Regulation (EU) 2018/545) and the assessment report referred to in Article 15 of CSM RA (points 18.8 and 18.11 of Regulation (EU) 2018/545).

  As a rule, the evidence describing the details of the process and the evidence produced by the applicant or the entity managing the change as a result of the application of the requirements capture process (which should the basis of the independent assessment performed by the AsBo) does not need to be included in the file accompanying the application for authorisation. Should there be any justified doubt or need for further clarification, the necessary documentation can be provided by the applicant or the entity managing the change upon request of the authorising entity

  In any case, it is recommended that the applicant includes in the file accompanying the application for authorisation an extract, printout, export and/or detailed description or examples of the central repository tool used, so that the authorising entity has a better view on the methodology and workflow for managing hazards and requirements.

› If another methodology is used for essential requirements other than safety, the evidence that needs to be submitted through the OSS should be enough to demonstrate that it provides the same level of assurance as the principles in the methodology of Annex I of CSM RA. The declaration referred to in point 18.10 of Annex I of Regulation (EU) 2018/545 is not part of the evidence to be submitted in this case.

  The required evidence can consist of a specific document describing the process in a detailed way, procedures, work instructions, templates, checklists, application guides, other documentation of processes already in place, an independent assessment report (where applicable), etc. In the end, everything that is needed to allow the authorising entity to assess whether the process respects the main principles of points 6 and 7 of Annex I of Regulation (EU) 2018/545 or not:
  - Degree of independent assessment applied

- System definition
- For essential requirement safety and safe integration between subsystems:
  - Hazard identification, classification and management (hazard log, hazard record)
  - Risk acceptance principles
  - Risk evaluation
- For all other essential requirements, appropriate centralised tool (table, spreadsheet, database, register, etc.) for the identification and management of requirements.

In addition to this, it is necessary to include in the file accompanying application all the documentary evidence generated as a result of the application of the methodology (reports, logs, records, printouts of IT tools, lists, etc.). This is because when an unknown methodology is used, and in particular where no or poor independent assessment takes place, the authorising entity needs to do a similar work as the AsBo for the requirements capture of essential requirement safety, including checking that the process implemented provides the same level of assurance as the principles in the methodology of Annex I of CSM RA, performing spot-checks (sampling, vertical slice assessments, etc). to understand how requirements are managed from beginning to end.

2.5.3 Concerning the declarations required in points 18.10 and 18.12 of Annex I of Regulation (EU) 2018/545, can I cover them both in a single document, or shall I issue two independent documents?

Article 13 of Regulation (EU) 2018/545 requires the applicant or the entity managing the change to perform a requirements capture process. Concerning the requirements capture process for the essential requirement "safety" within subsystems and safe integration between subsystems, the risk assessment process described in Annex I of CSM RA should be applied, which means that:

› an AsBo shall perform an independent assessment and issue a (safety) assessment report, and

› the applicant or the entity managing the change shall issue a (risk) declaration.

Both documents shall be included in the file accompanying the application for authorisation, according to points 18.8 and 18.10 of Annex I of Regulation (EU) 2018/545.

For cases where there is a need to obtain an authorisation pursuant to Article 21(12) of Directive (EU) 2016/797 (new authorisation following a change to an already authorised vehicle and/or vehicle type, pursuant to Article 14(1)(d) of Regulation (EU) 2018/545), the application of CSM RA is mandatory as well. If the change is considered significant, the safety assessment report to be issued by an AsBo referred to in Article 15 of CSM RA and the risk declaration to be established by the proposer (applicant/entity managing the change) according to Article 16 of the CSM RA should be included in the file accompanying the application for authorisation, as described in points 18.11 and 18.12 of Regulation (EU) 2018/545.

However, the (safety) assessment report covering the requirements capture should cover the aspects related to safety and safe integration between subsystems of the significant change too. Similarly, the (risk) declaration to be established by the applicant or by the entity managing the change for requirements capture process should cover safety and safe integration between subsystems too.

Due to this, and to avoid duplication of works and reduce the number of documents to be produced, the information referred to in points 18.8 and 18.11 (assessment report) on one hand, and 18.10 and 18.12 on the other (declaration) can be included in one single assessment report and one single declaration. But it is also possible that the information is covered by four independent documents (e.g., when the AsBo for the significant change in application of the CSM RA is different than the AsBo for the requirements capture process). The applicant or the entity managing the change, in agreement with the concerned AsBo(s), is free to decide which option is more suitable.

In any case, the assessment to be performed by the AsBo for the requirements capture process shall cover the essential requirement safety and the safe integration between subsystems. The AsBo for the requirements capture remains the sole responsible for this assessment, although it shall mutually recognise the work performed by another AsBo in the framework of the significant change according to CSM RA (for the same scope of work).

The minimum content or the required structure for the declaration to be issued by the applicant or by the entity managing the change pursuant to point 18.10 of Annex I of Regulation (EU) 2018/545 is not defined in the legal texts. In Annex 4.3 of the document, a model template is proposed, summarising the main elements of the assessment report for the requirements capture process.

When points 18.10 and 18.12 of the Annex I of Regulation (EU) 2018/545 are covered by one single declaration, the model template proposed in Annex 4.3 should be adapted accordingly, by making explicit reference to the Article 16 of the CSM RA and point 18.12 of Regulation (EU) 2018/545.

2.5.4 In case of a change considered as significant according to the CSM RA, can I combine the evidence for the CSM RA and the evidence for the requirements capture?

Yes. The EU legal texts do neither oblige, nor forbid, the applicants, entities managing the change and AsBos to produce either a single report or two separate reports for the following assessment activities:

- the independent assessment activities of the applicant's or EMC's requirement capture process, pursuant to point 18.8 of Regulation (EU) 2018/545 and;
- the independent safety assessment of the applicant's or EMC's risk identification and management of safety according to Annex I of CSM RA for significant changes, pursuant to Article 15 of the CSM RA and point 18.11 of Regulation (EU) 2018/545;

In addition, the work to be performed by the applicant or the entity managing the change and the AsBo for both aspects is the same. Thereby, when the applicant or the entity managing the change contracts the same AsBo for both activities, this can be documented in either two separate reports (one for each scope), or a single report, provided the single report clearly states and identifies the two specific scopes and differentiates the assessment activities and the conclusions for each element in the scope of the report when needed, so that it can be determined the basis on which the two sets of conclusions have been made.

Same principle applies to all other documentation and evidence to be produced (e.g., hazard log/record, compliance matrix, description of the methodology, description of the process, declaration by the applicant/proposer etc.). The applicant or the entity managing the change, in agreement with the concerned AsBo(s), is free to decide which option is more suitable.

2.5.5 When I don´t use the methodology of Annex I of CSM RA for requirements capture, which sort of evidence is required for applying for authorisation through the OSS?

For the essential requirement safety, and the safe integration between subsystems, the application of the methodology of Annex I of CSM RA (which also requires the involvement of an AsBo for performing an independent assessment of the risk management process) is mandatory. For other essential requirements, the applicant or the entity managing the change is allowed to use other methodologies. However, the legal text requires that they provide a similar level of assurance to that of using the key principles of the methodology in Annex I of CSM RA.

When another methodology is used, the evidence that needs to be submitted through the OSS should be enough to demonstrate that it provides the same level of assurance as the principles in the methodology of Annex I of CSM RA. The declaration referred to in point 18.10 of Annex I of Regulation (EU) 2018/545 is not part of the evidence to be submitted in this case.

The required evidence can consist of a specific document describing the process in a detailed way, procedures, work instructions, templates, checklists, application guides, other documentation of processes already in place, an independent assessment report (where applicable), etc. In the end, everything that is needed to allow the authorising entity to assess whether the process respects the main principles of points 6 and 7 of Annex I of Regulation (EU) 2018/545 or not:

- Degree of independent assessment applied
- System definition
- For essential requirement safety and safe integration between subsystems:
  - Hazard identification, classification and management (hazard log, hazard record)
  - Risk acceptance principles
  - Risk evaluation
- For all other essential requirements, appropriate centralised tool (table, spreadsheet, database, register, etc.) for the identification and management of requirements.

In addition to this, it is necessary to include in the file accompanying application all the documentary evidence generated as a result of the application of the methodology (reports, logs, records, printouts of IT tools, lists, etc.). This is because when an unknown methodology is used, and in particular where no or poor independent assessment takes place, the authorising entity needs to do a similar work as the AsBo for the requirements capture of essential requirement safety, including checking that the process implemented provides the same level of assurance as the principles in the methodology of Annex I of CSM RA, performing spot-checks (sampling, vertical slice assessments, etc). to understand how requirements are managed from beginning to end.

2.5.6 What will the authorising entity and the NSAs for the area of use check on the documentation for requirements capture that I will submit through the OSS?

It is necessary to make a distinction concerning whether the key principles of the methodology in Annex I of the CSM RA are used for all essential requirements or not:

- If the methodology in Annex I of CSM RA is used for all essential requirements, the supporting evidence consists of the declaration(s) referred to in Article 16 of CSM RA (points 18.10 and 18.12 of Regulation (EU) 2018/545) and the assessment report referred to in Article 15 of CSM RA (points 18.8 and 18.11 of Regulation (EU) 2018/545).

  The assessment to be performed by the authorising entity and the NSAs for the area of use will be focused on the independent assessment report issued by the AsBo and on the declaration to be issued by the applicant.

  Annex II of the Regulation (EU) 2018/545 summarizes the checks to be performed by the Authorising entity; with regards to the requirements capture process, the following aspects will be evaluated:

  - General consistency and coherence of the evidence provided
  - AsBo accreditation/recognition and classification in section 5 of ERADIS
  - Scope of the independent assessment (system under assessment, essential requirements covered), in particular how outcomes from other assessment bodies are considered
  - Clear statements concerning the results of the independent assessment concerning:
    - Compliance with the requirements of Annex I of CSM RA
    - For essential requirement safety and safe integration between subsystems, hazards and associated risks controlled to an acceptable level
    - Whole life cycle for requirements covered (from identification to validation)

        - All applicable requirements necessary to ensure that all the essential requirements are covered, and not only the mandatory rules (TSIs, national rules and other EU law).
    - Evidence used by the AsBo for the independent assessment
    - Scope of the declaration by the applicant and consistency with the independent assessment
    - Non-conformities raised by the AsBo (either closed or open, including history of the closed non-conformities)

  The evidence describing the details of the process and the evidence produced by the applicant as a result of the application of the requirements capture process (which should be the basis of the independent assessment performed by the AsBo) will normally be out of the scope of the assessment by the authorising entity. Should there be any justified doubt or need for further clarification, the necessary documentation can be provided by the applicant upon request of the authorising entity

› If another methodology is used for essential requirements other than safety, the authorising entity will check that it provides the same level of assurance as the methodology of Annex I of CSM RA. The supporting evidence to perform the assessment will cover not only the independent assessment report (if any), but also the description of methodology, the description of the requirements capture process, the evidence of the application of the process etc. The following aspects will be evaluated:

  - Degree of independent assessment and scope (complete V-Cycle)
  - Competences and independency of the independent assessor
  - Assessment report from the independent assessor
  - Aspects covered by the methodology:
    - System definition
    - Identification of requirements
    - Validation of requirements
    - Structured management of requirements in a centralised repository
    - Evidence to be produced
  - Methodology for requirements capture (standardised / widely accepted, intended and suitable for the essential requirements covered)
  - Implementation of the methodology in the requirements capture process
  - General consistency and coherence of all the evidence provided

  In the end, the authorising entity needs to do a similar work as the AsBo for the requirements capture of essential requirement safety, including checking that the process implemented provides the same level of assurance as the principles in the methodology of Annex I of CSM RA, performing spot-checks (sampling, vertical slice assessments, etc). to understand how requirements are managed from beginning to end. The more standardized is the process (closer to the key principles of Annex I of CSM RA, e.g. EN 50126-1), the fewer issues will be raised by the authorising entity during the assessment of the evidence of the requirements capture process.

  When the methodology does not include an independent assessment, the demonstration that it provides the same level of assurance will face many challenges. Even if the authorising entity and the NSAs for the area of use will perform a detailed assessment of both the methodology and the results of its application (likewise an independent assessor), it cannot properly cover the whole life cycle of the vehicle and/or vehicle type (at this point, the vehicle and/or vehicle is already designed, manufactured and tested). In addition, solving eventual non-compliances found at this late stage of the process may be difficult, time consuming and in some cases not feasible without an important delay in the authorisation process and/or additional costs.

The assessment to be performed by the NSAs for the area of use should be focused on the evidence of the application of the methodology concerning the requirements related to national rules, following the same principles described above (not an exhaustive check, but an assessment of the suitability of the process put in place by the applicant to manage the concerned requirements and risks); the assessment of the methodology is in the scope of the authorising entity. The assessments to be performed by the NSAs for the area of use are summarized in Annex III of the Regulation (EU) 2018/545.

It should be noted that the authorising entity and/ or the concerned NSAs for the area of use should not check if the conditions for use and other restrictions (including exported constraints) are reasonable from an economic point of view (e.g., risk not meeting the contractual obligations of the manufacturer with the railway undertaking by imposing conditions for use and other restrictions that may render the operation of the vehicle unfeasible), as long as they do not impact the fulfilment of the essential requirements (e.g. do not create a safety risk). The scope of the assessment should be limited to the consistency, completeness and relevance (including the cross-check by the concerned assessment bodies) of the set of conditions for use and other restrictions.

3. Legal background

3.1. Directive (EU) 2016/797 (as amended)

› Article 2 Definitions

- *"(9) 'essential requirements' means all the conditions set out in Annex III which must be met by the Union rail system, the subsystems, and the interoperability constituents, including interfaces;"*
- *"(22) 'applicant' means a natural or legal person requesting an authorisation, be it a railway undertaking, an infrastructure manager or any other person or legal entity, such as a manufacturer, an owner or a keeper; for the purpose of Article 15, the 'applicant' means a contracting entity or a manufacturer, or its authorised representatives; for the purpose of Article 19, the 'applicant' means a natural or legal person requesting the Agency's decision for the approval of the technical solutions envisaged for the ERTMS track-side equipment projects;"*
- *"(35) 'placing on the market' means the first making available on the Union's market of an interoperability constituent, subsystem or vehicle ready to function in its design operating state;"*

› Article 3 Essential requirements

"*1. The Union rail system, subsystems and interoperability constituents including interfaces shall meet the relevant essential requirements.*

[…]"

› Article 4 Content of TSIs

"[…]

2. […] Vehicles shall comply with TSIs and national rules in force at the time of the request for authorisation of placing on the market in accordance with this Directive and without prejudice to point (f) of paragraph 3.

[…]"

› Article 13 Conformity with TSIs and national rules

"*1. The Agency and the national safety authorities shall consider as meeting the essential requirements, those structural subsystems constituting the rail system which are covered, as appropriate, by the 'EC' declaration of verification established by reference to TSIs, in accordance with Article 15, or the declaration of verification established by reference to national rules in accordance with Article 15(8), or both.*

[…]"

› Article 15 Procedure for establishing the 'EC' declaration of verification

"[…]

2. The applicant shall establish the 'EC' declaration of verification of a subsystem. The applicant shall declare on his sole responsibility that the subsystem concerned has been subject to the relevant verification procedures and that it satisfies the requirements of relevant Union law and any relevant national rule. The 'EC' declaration of verification and the accompanying documents shall be dated and signed by the applicant.

[…]

› Article 20 Placing on the market of mobile subsystems

"*1. Mobile subsystems shall be placed on the market by the applicant only if they are designed, constructed and installed in such a way as to meet the essential requirements.*

[…]"

› Article 21 Vehicle authorisation for placing on the market

"[…]

3. The application for a vehicle authorisation for placing on the market shall be accompanied by a file concerning the vehicle or vehicle type and including documentary evidence of:

(a) the placing on the market of the mobile subsystems of which the vehicle is composed in accordance with Article 20, on the basis of the 'EC' declaration of verification;

(b) the technical compatibility of the subsystems referred to in point (a) within the vehicle, established on the basis of the relevant TSIs, and where applicable, national rules;

(c) the safe integration of the subsystems referred to in point (a) within the vehicle, established on the basis of the relevant TSIs, and where applicable, national rules, and the CSMs referred to in Article 6 of Directive (EU) 2016/798;

(d) the technical compatibility of the vehicle with the network in the area of use referred to in paragraph 2, established on the basis of the relevant TSIs and, where applicable, national rules, registers of infrastructure and the CSM on risk assessment referred to in Article 6 of Directive (EU) 2016/798.

[…]"

› Annex IV 2.4. Technical file accompanying the 'EC' declaration of verification

"*The technical file accompanying the 'EC' declaration of verification shall be assembled by the applicant and must contain the following:*

[…]

(d) certificates of verification issued in accordance with other legal acts of the Union;

(e) *when verification of safe integration is required pursuant to in point (c) of Article 18(4) and in point (c) of Article 21(3), the relevant technical file shall include the assessors' report(s) on the CSMs on risk assessment referred to in Article 6(3) of Directive.*"

3.2. Regulation (EU) 2018/545 (as amended)

› *Article 2* Definitions

- *"(11) 'requirements capture' means the process of identification, assignment, implementation and validation of requirements performed by the applicant in order to ensure that relevant Union and national requirements are complied with. Requirements capture may be integrated in the product development processes;"*
- "*2(12) 'safe integration' means the fulfilment of the essential requirement on safety as specified in Annex III of Directive (EU) 2016/797 when combining parts into its integral whole, such as a vehicle or a subsystem as well as between the vehicle and the network, with regards to the technical compatibility;*"
- *"(16) 'vehicle type authorisation' means the decision issued by the authorising entity based on reasonable assurance that the applicant and the entities involved in the design, manufacture, verification and validation of the vehicle type have fulfilled their obligations and responsibilities in order to ensure conformity with the essential requirements of the applicable legislation enabling that a vehicle manufactured according to this design may be placed on the market and may be used safely in the area of use of the vehicle type according to the conditions for use of the vehicle and other restrictions, when applicable, specified in the vehicle type authorisation and to be applied to all vehicle authorised in conformity to this type;"*

› Article 3 Responsibilities of the applicant

"The applicant shall submit its application for vehicle type authorisation and/or vehicle authorisation for placing on the market in accordance with the provisions of this Regulation.

It is the responsibility of the applicant to ensure that the relevant requirements from applicable legislation are identified and met when submitting its application for vehicle type authorisation and/or vehicle authorisation for placing on the market."

› Article 13 Requirements capture

"1. In accordance with the overall objective of managing and mitigating identified risks to an acceptable level, the applicant shall, before submitting an application, undertake a requirements capture process which shall ensure that all the necessary requirements covering the design of the vehicle for its life cycle have been:

(a) identified properly;
(b) assigned to functions or subsystems or are addressed through conditions for use or other restrictions; and
(c) implemented and validated.

2. The requirements capture performed by the applicant shall in particular cover the following requirements:

(a) essential requirements for subsystems referred to in Article 3 and specified in Annex III to Directive (EU) 2016/797;
(b) technical compatibility of the subsystems within the vehicle;
(c) safe integration of the subsystems within the vehicle; and
(d) technical compatibility of the vehicle with the network in the area of use.

3. The risk management process set out in Annex I to Commission Implementing Regulation (EU) No 402/2013 (1) shall be used by the applicant as the methodology for requirements capture as regards the essential requirements 'safety' related to the vehicle and subsystems as well as safe integration between subsystems for aspects not covered by the TSIs and the national rules."

› Article 17 Identification of the rules including non-application of TSIs

"1. Based on the choice of the authorisation case in accordance with Article 14 and the requirements capture set out in Article 13 the applicant shall identify all applicable rules, in particular the TSIs and national rules.
[…]"

› Article 26 Perform verifications and establish evidence

"*1. The applicant shall, as applicable per authorisation case, perform the necessary checks in order to establish the evidence referred to in Annex I.*

[…]"

› Article 38 Assessment of the application

"The assessment of the application shall be carried out by the authorising entity and the concerned NSAs for the area of use to establish a reasonable assurance that the applicant and the actors supporting the applicant have fulfilled their obligations and responsibilities in the design, manufacture, verification and validation stages of the vehicle and/or vehicle type in order to ensure conformity with the essential requirements of the applicable legislation so that it may be placed on the market and may be used safely in the area of use of the vehicle type according to the conditions of use and other restrictions specified within the application."

› Article 39 The assessment of the application by the authorising entity

"1. The authorising entity shall assess the aspects specified in Annex II.

[…]

3. When a non-standardised methodology for the requirements capture has been used by the applicant, the authorising entity shall assess the methodology applying the criteria laid down in Annex II.

4. The authorising entity shall check the completeness, relevance and consistency of the evidence from the applied methodology for requirements capture irrespective of the method used. For a new authorisation as specified in Article 14(1)(d) the assessment performed by the authorising entity shall be limited to the parts of the vehicle that are changed and their impacts on the unchanged parts of the vehicle. The checks to be performed by the authorising entity for an 'extended area of use' authorisation

as specified in Article 14(1)(c) shall be limited to the applicable national rules and to the technical compatibility between the vehicle and the network for the extended area of use. Checks already carried out at the previous authorisation shall not be repeated by the authorising entity.

[…]"

› Article 40 The assessment of the application by the concerned NSAs for the area of use

"[…]

2. In the assessment of the requirements capture, the NSAs for the area of use shall check the completeness, relevance and consistency of the evidence produced by the applicant from the applied methodology for requirements capture.

[…]"

› Article 48 The information in the issued vehicle type authorisation

"*The vehicle type authorisation issued by the authorising entity shall contain the following information:*

[…]

c) an identification of the basic design characteristics of the vehicle type:

i. stated in the type and/or design examination certificates;

ii. the area of use of the vehicle;

iii. the conditions for use of the vehicle and other restrictions;

iv. the reference, pursuant to the provisions of Article 16 of Regulation (EU) No 402/2013, including the document identification and the version, to the written declaration by the proposer referred to in Article 3(11) of Regulation (EU) No 402/2013, covering the vehicle type

[…]

f) reference to other Union or national law with which the vehicle type is compliant;

[…]"

› Annex I Content of the application

- *"18.1 The supporting evidence for the requirements capture in accordance with Article 13(1).*

  If the applicant uses the methodology set out in Annex I of Regulation (EU) No 402/2013, the supporting evidence consists of the declaration by the proposer referred to in Article 16 of Regulation (EU) No 402/2013 and the safety assessment report referred to in Article 15 of Regulation (EU) No 402/2013.

  If another methodology is used, the evidence required is that necessary to demonstrate that it provides the same level of assurance as the methodology set out in Annex I of Regulation (EU) No 402/2013"

- "18.7 *Specification of and where applicable (non standardised methodology) a description of the methodology used for the requirements capture for the:*

  (a) essential requirements for subsystems as specified in Article 3 and Annex III of Directive (EU) 2016/797;

  (b) technical compatibility of the subsystems within the vehicle;

  (c) safe integration of the subsystems within the vehicle; and

  (d) technical compatibility of the vehicle with the network in the area of use."

- *"18.8 CSM on risk assessment, safety assessment report (Article 15 Regulation (EU) No 402/2013) covering the requirements capture for the essential requirements 'safety' for the subsystems and safe integration between subsystems."*

- *"18.10 Risk declaration (Article 16 Regulation (EU) No 402/2013) covering the requirements capture for the essential requirements 'safety' for the subsystems and safe integration between subsystems for aspects not covered by the TSIs and the national rules."*

- *"18.11 CSM on risk assessment, safety assessment report (Article 15 Regulation (EU) No 402/2013) covering the potential modification of the overall safety level for the vehicle."*
- *"18.12 Risk declaration (Article 16 Regulation (EU) No 402/2013) covering the potential modification of the overall safety level for the vehicle."*

› Annex II Aspects for assessment by the authorising entity

- *"6.1. Is the applied methodology used for the requirements capture fit for purpose concerning the following aspects:*
  (a) Has a standardised/accepted methodology been used?; and
  (b) Is the method intended for and suitable for the essential requirements it covers?"
- *"6.2. When the methodology applied is not standardised or covers other essential requirements than it is intended for, the following aspects shall be checked to evaluate if they are sufficiently considered and covered by the methodology:*
  (a) Degree of independent assessment applied
  (b) System definition
  (c) Hazard identification and classification
  (d) Risk acceptance principles
  (e) Risk evaluation
  (f) Requirements established
  (g) Demonstration of compliance with the requirements
  (h) Hazard management (log)"
- "7. *Sufficient evidence from the methodology used for the requirements capture:*
  - *7.1. When the risk management process set out in Annex I of Regulation (EU) No 402/2013, has been used as the methodology for requirements capture the following shall be checked:*
    (a) CSM on risk assessment, declaration by the proposer (Article 16 Regulation (EU) No 402/2013) is signed by the proposer and supports that all identified hazards and associated risks are controlled to an acceptable level.
    (b) CSM on risk assessment, safety assessment report (Article 15 Regulation (EU) No 402/2013) supports the declaration by the proposer for the specified scope according to Article 13 and at least the essential requirement safety for subsystems and safe integration between subsystems within the vehicle
  - *7.2. When another methodology than the risk management process set out in Annex I of Regulation (EU) No 402/2013, has been used as the methodology for requirements capture the following shall be checked:*
    (a) System definition is complete and consistent with the design of the vehicle?
    (b) Hazard identification and classification is consistent and plausible?
    (c) All risks have been properly managed and mitigated?
    (d) Requirements derived from the risk management are properly traced to the risk and to the evidence of compliance with the requirement?
    (e) Structured and consistent management of the hazards throughout the process?
    (f) Is there a positive opinion from the independent assessment?"
- "14. *CSM on risk assessment, safety assessment report (Article 15 Regulation (EU) No 402/2013) covering the requirements capture for the essential requirements 'safety' for the subsystems and safe integration between subsystems positive opinion"*
- "15. *CSM on risk assessment, safety assessment report (Article 15 Regulation (EU) No 402/2013) covering the potential modification of the overall safety level for the vehicle (significant change) positive opinion"*
- "16. *Changes as compared to the authorised vehicle type are sufficiently described and match the CSM on risk assessment, safety assessment report (Article 15 Regulation (EU) No 402/2013)"*

› Annex III Aspects for assessment by the concerned NSAs for the area of use

- *"5. Sufficient evidence from the methodology used for the requirements capture only for the national rules for the concerned area of use:*
  - *5.1. When another methodology than the risk management process set out in Annex I of Regulation (EU) No 402/2013, has been used as the methodology for requirements capture the following shall be checked:*
    - *(a) System definition is complete and consistent with the design of the vehicle?*
    - *(b) Hazard identification and classification is consistent and plausible?*
    - *(c) All risks have been properly managed and mitigated?*
    - *(d) Requirements derived from the risk management are properly traced to the risk and to the evidence of compliance with the requirement?"*
- *"9. CSM on risk assessment, safety assessment report (Article 15 Regulation (EU) No 402/2013) covering the requirements capture for the essential requirements 'safety' for the subsystems and safe integration between subsystems positive opinion"*
- *"10. CSM on risk assessment, safety assessment report (Article 15 Regulation (EU) No 402/2013) covering the potential modification of the overall safety level for the vehicle (significant change) positive opinion"*
- *"11. Changes as compared to the authorised vehicle type are sufficiently described and match the CSM on risk assessment, safety assessment report (Article 15 Regulation (EU) No 402/2013)"*

3.3 Regulation (EU) 402/2013

› Article 15 Safety assessment reports

"1. The assessment body shall provide the proposer with a safety assessment report in accordance with the requirements set out in Annex III. The proposer shall be responsible for determining if and how to take into account the conclusions of the safety assessment report for the safety acceptance of the assessed change. The proposer shall justify and document the part of the safety assessment report for which the proposer eventually disagrees.

[…]

5. When a system or part of a system has already been accepted following the risk management process specified in this Regulation, the resulting safety assessment report shall not be called into question by any other assessment body in charge of performing a new assessment for the same system.

Mutual recognition shall be conditional upon demonstration that the system will be used under the same functional, operational and environmental conditions as the already accepted system, and that equivalent risk acceptance criteria have been applied."

› Article 16 Declaration by the proposer

"Based on the results of the application of this Regulation and on the safety assessment report provided by the assessment body, the proposer shall produce a written declaration that all identified hazards and associated risks are controlled to an acceptable level."

› Annex I

"1. GENERAL PRINCIPLES APPLICABLE TO THE RISK MANAGEMENT PROCESS

1.1. General principles and obligations

1.1.1. The risk management process shall start from a definition of the system under assessment and comprise the following activities:

(a) the risk assessment process, which shall identify the hazards, the risks, the associated safety measures and the resulting safety requirements to be fulfilled by the system under assessment;
(b) demonstration of the compliance of the system with the identified safety requirements; and
(c) management of all identified hazards and the associated safety measures.

This risk management process is iterative and is depicted in the diagram of the Appendix. The process ends when compliance of the system with all the safety requirements necessary to accept the risks linked to the identified hazards is demonstrated.

[…]

1.1.3. The proposer in charge of the risk management process shall maintain a hazard record in accordance with point 4.

[…]

1.1.7. Evaluation of the correct application of the risk management process falls within the responsibility of the assessment body.

[…]

2. DESCRIPTION OF THE RISK ASSESSMENT PROCESS

[…]

2.2. Hazard identification

2.2.1. The proposer shall systematically identify, using wide-ranging expertise from a competent team, all reasonably foreseeable hazards for the whole system under assessment, its functions where appropriate and its interfaces. All identified hazards shall be registered in the hazard record in accordance with point 4.

4. HAZARD MANAGEMENT

4.1. Hazard management process

4.1.1. Hazard record(s) shall be created or updated (where they already exist) by the proposer during design and implementation until acceptance of the change or delivery of the safety assessment report. A hazard record shall track the progress in monitoring risks associated with the identified hazards. Once the system has been accepted and is in operation, the hazard record shall be further maintained by the infrastructure manager or the railway undertaking in charge of the operation of the system under assessment as an integrated part of its safety management system.

[…]

5. EVIDENCE FROM THE APPLICATION OF THE RISK MANAGEMENT PROCESS

5.1. The risk management process used to assess the safety levels and compliance with safety requirements shall be documented by the proposer in such a way that all the necessary evidence showing the suitability of both the application of the risk management process and of its results are accessible to an assessment body.

[…]

5.3. The assessment body shall establish its conclusion in a safety assessment report as defined in Annex III"

› Annex III Safety assessment report of the assessment body

"The safety assessment report of the assessment body shall contain at least the following information:

- *(a) identification of the assessment body;*
- *(b) the independent assessment plan;*
- *(c) the definition of the scope of the independent assessment as well as its limitations;*
- *(d) the results of the independent assessment including in particular:*
  - *i. detailed information on the independent assessment activities for checking the compliance with the provisions of this Regulation;*
  - *ii. (ii) any identified cases of non-compliances with the provisions of this Regulation and the assessment body's recommendations;*
- *(e) the conclusions of the independent assessment"*

3.4. Regulation (EU) 2019/250 (as amended)

› Article 5 'EC' declaration of verification

"1. An 'EC' declaration of verification shall be based on the information resulting from the verification procedures for subsystems set out in Article 15 of Directive (EU) 2016/797 and Annex IV to that Directive. One 'EC' declaration of verification shall comprise the verification in respect with Union law and, where appropriate, national rules.

[…]"

4. Annexes

4.1. Requirements management matrix

Below, an illustrative example of the main elements that the tool to manage the requirements should cover can be found. This does not mean that the table presented should be used as it is presented; its purpose is to illustrate and give example of the granularity that is considered necessary to provide proper evidence of the requirements capture process applied to the AsBo and to the authorising entity.

In terms of requirements capture, the requirements should be broken down to the smallest possible requirement from a given source that can be:

- Identified;
- Assigned;
- Implemented, and
- Validated.

From this point of view, one single source (e.g., a TSI) can result in many detailed requirements. And then, such low level requirements can result in many different requirements to be managed independently, either because there are different requirements or because they are to be assigned to different component/systems/functions or validated in a different way.

Managing all detailed (low level) requirements into a single “master list” of requirements is not necessary. E.g., source requirements can be broken down to single functions/elements/systems to which they need to be assigned. Then, for each function/element/system, the exercise should be repeated until the necessary level of granularity is achieved. However, it´s paramount that the traceability is kept in all steps, so that at any given moment it should be possible to trace back detailed requirements to the source requirements.

In the example presented in the tables, the Regulation (EU) 2014/1302 (TSI LOC&PAS) requires that vehicles are fitted with two white headlamps, in order to give visibility to the driver (in addition, the headlamps allow others to identify the train). From this particular clause of the TSI, two other requirements can be derived:

- There shall be two lamps, and
- The lamps shall be white.

The way to manage each of those requirements can be different, and impact different other elements of the vehicle:

- The structure and outer shell of the car/locomotive should have space to accommodate the lights
- The lamps themselves should be white

Of course, there are many other detailed requirements that the vehicle type shall fulfil:

- The electrical system should provide electricity to the lights (normally through the auxiliary system, and/or the battery);
- The train control system should be able to control the lights;
- There should be an adequate way to turn on / off / dim the lights in the drivers desk
- The lights should have the right colourimetry and project a beam with the right direction, shape and intensity, etc.

However, these aspects are also covered by other TSI requirements as well and will be addressed by other requirements.

Sources of requirements

Requirement source	Essential requirement	Breakdown in requirements matrix needed?	Conformity assessment needed?
Reference for the sources of requirements, including reference document (with date and/or version). List all sources from which requirements necessary to meet essential requirements of Annex III of Directive (EU) 2016/797 derive (Directives, Decisions, Regulations, EN standards, UIC standards, other international standards, guidelines, customer specifications, in-house guidelines, in-house design codes etc.).	Describe the essential requirements of Annex III of Directive (EU) 2016/797 linked to the requirement: -Safety -Health -Reliability and availability -Environmental protection -Technical compatibility -Accessibility	Indicate whether there is a need to break down the detailed requirements within the source (typically, in case of complex sources containing many heterogeneous requirements).	Indicate whether the source of requirements envisages a conformity assessment (e.g., verification by a NoBo) .
Regulation (EU) 2014/1302, as amended by Regulations (EU) 2016/919, 2018/868, 2019/776 and 2020/387 (TSI LOC&PAS)	*-Safety* *-Health* *-Reliability and availability* *-Environmental protection* *-Technical compatibility* *-Accessibility*	*Yes. Breakdown of requirements in the TSI necessary.*	*Yes. NoBo certificates and accompanying report.*
Regulation no 1907/2006 Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), with all amendments and corrigendums until 2021/01/25 (Regulation (EU) 2021/57)	-Environmental protection	*No. List of materials installed in the vehicle compliant with REACH regulation is considered enough.*	*No.*

Requirements matrix

Article 13(1)(a) Identification					Article 13(1)(b) Assignment			Article 13(1)(c) implementation	
Unique ID	**Requirement source**	**Requirement**	**Applicability**	**Applicability justification**	**Subsystem**	**Allocation**	**Responsible**	**Vehicle / subsystems specification(s)**	
Unique identification of the requirement	Source of the requirement, including reference document (with date and/or version) and section within the document.	Description of the requirement. It doesn´t have to be the text of the requirement in full, a meaningful summary is acceptable.	Indicate if the requirement is considered to be applicable or not to the project (Applicable/Not applicable)	Justification about why the requirements is considered to be not applicable.	Indicate to which subsystem the requirement applies: -Rolling stock (RS) -Control-command and signalling (CCS) -Vehicle (RS & CCS)	Indication to which functions/products the requirement is allocated to. The proposals in EN 15380 can be used; other project breakdown structure used by the applicant should be acceptable too.	Responsible person and/or team in charge of managing the requirement.	Reference to the vehicle specification(s), including date and/or version, and specific clauses where this requirement is assigned.	Short description of the document scope.
R00001	§4.2.7.1.1 of Regulation (EU) 2014/1302, as amended by Regulations (EU) 2016/919, 2018/868, 2019/776 and 2020/387	Two headlamps shall be provided at the front end of the train in order to give visibility for the train driver.	Applicable	Not applicable	RS	BE - Driver´s cab metal panelling BE - Frame of driver´s cab BE - Thermoplastic head	Structures - Mr John Doe	TD-1523 2022/01/12 §3.4.2	Technical specification of the vehicle.
R00002	§4.2.7.1.1 of Regulation (EU) 2014/1302, as amended by Regulations (EU) 2016/919, 2018/868, 2019/776 and 2020/387	The headlamps that shall be provided at the front end of the train shall be white.	Applicable	Not applicable	RS	KB - Train headlights	Systems engineering - Ms Jane Doe	PRC1234-1234 rev.2, §5.2.1.3	Purchase specification of the headlights.

Requirements matrix (cont.)

Article 13(1)(c) validation (design type)							Article 13(1)(b) conditions for use	Article 13(1) validation		
Design evidence		Type test evidence		Conformity assessment			Conditions for use and other restrictions	Status		
Reference to the evidence, including date and/or version), and specific clause(s) which demonstrates compliance with the requirement.	Short description of the document scope. If not self explanatory, please briefly describe how the evidence contributes to the demonstration of compliance.	Reference to type test evidence, including date and/or version), and specific clause(s) which demonstrates compliance with the requirement. If none, state 'Not Applicable'.	Short description of the document scope. If not self explanatory, please briefly describe how the evidence contributes to the demonstration of compliance.	Reference to validation evidence (including date and/or version) which demonstrates that the requirement has been met. State "Not applicable" if none.	Short description of the document scope: -NoBo report -DeBo report -AsBo report -Inspection body report -Certificate -Self declaration -etc.	Clear status of the conclusion of the validation activities: -Compliant -Compliant with CfU and restrictions -Not compliant	Describe which are the conditions for use and/or other restrictions that arise from this particular requirement and/or as a result of the management of the requirement. A reference to another document is also allowed if there are many conditions for use (including date and/or version, and reference within the document). If none, state "Not applicable".	Describe the status of the requirement: -Open -Closed -Closed (trasferred) -Closed (cancelled)	Short description of the status of the requirement, in particular where it has been cancelled or transferred (exported). When transferred or exported, please describe the receiving party: -Operation -Maintenance -Infrastructure -etc. If none, state 'Not Applicable'.	Reference to the evidence of the transfer, including date and/or version, and specific clause(s). If none, state 'Not Applicable'. When the evidence of the transfer is already referenced in column S, state "See column S".
DRWABCDEF-1234 rev.2	End cars drawings.	Not applicable	Not applicable	256/1563-0000 rev.3, §5.4	NoBo report	Compliant	Not applicable	Closed	Not applicable	Not applicable
CCA4589340000 rev.0, §2.2.1	Technical specification of the headlight.	Not applicable	Not applicable	256/1563-0000 rev.3, §5.4	NoBo report	Compliant	Not applicable	Closed	Not applicable	Not applicable

4.2. Assessment report by the AsBo concerning the requirements capture process

REPORT ON THE INDEPENDENT ASSESSMENT OF THE APPLICANT'S REQUIREMENT CAPTURE PROCESS ACCORDING TO ARTICLE 13 OF REGULATION (EU) 2018/545 FOR [PROJECT NAME]

<This proposal of structure for the independent assessment report addresses the most frequent and general case that the Agency has faced when acting as authorising entity. Usually, the applicant appoints a single AsBo for the independent assessment of the applicant's capture and management of all essential requirements, including those related to safety (Article 13(3) of Regulation (EU) 2018/545), the identification and management of all risks arising from design choices of the Vehicle (e.g., risk assessment at the level of whole vehicle in case of changes to an already authorised vehicle and/or vehicle type), and the safe integration within the vehicle.

Another potential case is that the applicant appoints the AsBo only for the independent assessment of the requirements capture of the essential requirement related to safety, of the safe integration between subsystems (mandatory by Regulation (EU) 2018/545), and of the identification and management of all risks arising from design choices of the Vehicle (e.g., risk assessment at the level of whole vehicle for the changes) according to the CSM RA. However, the Agency has not yet received such type of application

There could be other cases though and more difficult to manage, where the applicant appoints several AsBos: 1°) one AsBo for the independent assessment of the requirements capture of the essential requirement related to safety and the safety integration between subsystems, 2°) one AsBo for the independent assessment of the identification and management of all risks arising from design choices of the Vehicle according to the CSM-RA (e.g., risk assessment at the level of whole vehicle for the changes), and 3°) another AsBo for the independent assessment of the requirement capture of all other essential requirements. In this complex project organisation, each AsBo will produce a separate report to be consolidated with the other ones. The present proposal of structure does not explicitly cover this scenario. The proposed structure would need to be adapted, e.g., remove mentions to requirement capture of essential requirement related to safety, hazards, risks arising from design choices (e.g., risk assessment at the level of whole vehicle) etc., so that the report would only cover the essential requirements other than safety and safety integration).

The proposed structure below can be adapted to the AsBo documentation management system, provided that the template used by the AsBo contains all the necessary information and the document meets the usual requirements concerning quality and traceability (unique reference of the document, date of issuing, version/issue, history of changes etc.).

The AsBo which does not agree with some parts, is free to amend, or delete, them provided it reliably and unambiguously reports on how they actually performed the independent assessment, and what are all limits and conclusions of the independent assessment of the requirement capture. >

Executive summary (Abstract)

[A 1.] This independent assessment report has been produced by [LEGAL DENOMINATION OF THE ASBO]. The purpose of this report is to provide an independent opinion on the extent to which the applicant [LEGAL DENOMINATION OF THE APPLICANT] has met the requirements in Article 13 of the Implementing Regulation (EU) 2018/545 concerning the requirements capture process applied to [PROJECT NAME]. It presents the results and conclusions of the independent assessment of the:

- effectiveness of the applicant's process for the capture and management of all applicable requirements relevant for the design/upgrade of the vehicle and/or vehicle type referenced in this report;
- applicant's correct, consistent and systematic implementation and application of that process throughout the entire development process of the vehicle and/or vehicle type, and
- suitability of the object of assessment to meet the essential requirements of Annex III of Directive (EU) 2016/797 as a result of the application of the requirements capture process

[A 3.] The present report [does not cover / covers] the independent safety assessment, referenced through Article 13(3) of Regulation (EU) 2018/545, concerning the check of compliance of the "applicant's process for the risk management of essential requirements related to safety and of the safe integration between sub-systems" with the process in Annex I of Regulation (EU) 402/2013. *<If covered, delete next sentence>* That specific activity is subject of a separate report [REFERENCE OF THE SAFETY ASSESSMENT REPORT FOR THE ESSENTIAL REQUIREMENT SAFETY AND THE SAFE INTEGRATION BETWEEN SUBSYSTEMS, where applicable].

[A 4.] The present report [does not cover / covers] the independent safety assessment, referenced through Article 13(3) of Regulation (EU) 2018/545, concerning the check of compliance of the requirements capture process for essential requirements other than safety: reliability and availability, health, environmental protection, technical compatibility and accessibility. *<If covered, delete next sentence>* That specific activity is subject of a separate report [REFERENCE OF THE SAFETY ASSESSMENT REPORT FOR THE REQUIREMENTS CAPTURE RELATED TO ESSENTIAL REQUIREMENTS OTHER THAN SAFETY, where applicable].

[A 6.] The present report [does not cover / covers] the independent safety assessment, referenced through Article 13(3) of Regulation (EU) 2018/545, concerning the check of compliance of the identification and management of all risks arising from design choices of the vehicle with the process in Annex I of Regulation (EU) 402/2013. *<Delete next sentence when the report covers the application of CSM RA to the whole vehicle>* That specific activity is subject of a separate report [REFERENCE OF THE SAFETY ASSESSMENT REPORT FOR THE RISK ASESSMENT AT THE LEVEL OF THE WHOLE VEHICLE, where applicable].

Nevertheless, "safety", being one of the essential requirements in Annex III of the Directive (EU) 2016/797 and a sub-set of all requirements, is covered in the present report. The references to the conclusions and safety related application conditions (SRACs) raised by the separate independent safety assessment activities at the level of the risk assessment for the whole vehicle are considered in the framework of this report.

[A 7.] <The executive summary is the last part of the report to be written. It shall provide a brief overview of the report and enable to get a quick overview of its content. It shall present the key points necessary to support the conclusions, including in particular the stage of the project when the independent assessment started. It shall permit the reader to understand those main points and to make an informed decision on whether they need, or wish, to read in detail some sections, or the whole report.>

[A 8.] <The executive summary shall provide the answers to the following questions :>

- *What is the purpose of the independent assessment?*
- *At what stage of the vehicle development process was the AsBo contracted?*
- *What methods did the AsBo use to perform the independent assessment of the requirement capture process?*
  - *Which non-compliances did the AsBo find and the applicant close successfully, before the closure of the project (reference to a summary table in an annex is allowed)?*
  - *Does the independent assessment lead to any recommendations for future actions?*
  - *What are the main findings and conclusions reached as a result of the independent assessment?*
  - *Does the requirements capture process and its application meet the requirements of Article 13 of Regulation (EU) 2018/545?:*
    - *"[…] overall objective of managing and mitigating identified risks to an acceptable level […]*
    - *"[…] ensure that all the necessary requirements covering the design of the vehicle for its life cycle have been:*
      - *identified properly;*

- *assigned to functions or subsystems or are addressed through conditions for use or other restrictions; and*
- *implemented and validated."*

- *"The risk management process set out in Annex I to Regulation (EU) 402/20131 shall be used by the applicant as the methodology for requirements capture as regards the essential requirements "safety" related to the vehicle and subsystems as well as safe integration between subsystems"*

Please ensure that the answers to the questions above (moment of project when AsBo got involved, methodology, history of non-compliances, any recommendations, main findings, and conclusions) are included in the executive summary>

Table of contents

<Please include a table of contents>

0. Introduction

0.1. Objectives of the report

[L 1.] This Independent Assessment Report has been produced by [LEGAL DENOMINATION OF THE ASBO] to report on the extent to which [LEGAL DENOMINATION OF THE APPLICANT] has met the requirements of Article 13 of Regulation (EU) 2018/545, concerning the requirements capture process applied to [PROJECT NAME].

[L 2.] It is structured to permit the reader to have a clear view of the:

- context of the project, and the scope and objectives of the independent assessment;
- information about the applicant, and the vehicle and/or vehicle type under assessment;
- information about the AsBo and the team in charge of independent assessment;
- strategy for the independent assessment activities;
- independent assessment, the identified findings (non-compliances) and the recommendations (if any) for future actions by the applicant;
- conclusions of the independent assessment in terms of fulfilling the requirements of Article 13 of the Regulation (EU) 2018/545, and
- list of documents used for the independent assessment, and a summary of the history of main non-compliances, with corrective actions implemented by the applicant.

0.2. "Requirement capture" terminology and its scope

[L 1.] The "requirement capture" terminology in Article 13 of Regulation (EU) 2018/545 integrates all steps of the development process (CENELEC V-Cycle from steps 1 to 10) of the design of the vehicle. Thereby, it does not just refer to the identification (i.e., capture) of the applicable requirements. On the contrary, it must be understood as an integrated process which aims to systematically :

- identify all requirements (all essential requirements, including those related to safety, European and national legislation, customer's requirements, etc.) applicable to the design of a vehicle;
- include those requirements in the design specifications of the vehicle;
- register all identified requirements into an appropriate centralised tool (repository). That can be either a physical tool or an IT tool (table, database, register, etc.) subject to proper configuration management;
- allocate those requirements down to the areas of expertise and/or subsystems of the breakdown structure of the vehicle architecture, or export any necessary conditions for use or other restrictions;

› manage, trace, and demonstrate the correct implementation, verification and validation of all requirements through every step of the development process of the vehicle (CENELEC V-Cycle from steps 1 to 10);

› provide documentary evidence of compliance with every step of that development process.

[L 2.] In order to keep consistent with the terminology used in the Implementing Regulation (EU) 2018/545, as well as for the simplicity of reading of this report, the rest of the document will only use the terminology "requirement capture", having clearly in mind that in practice it includes all the steps/activities above.

[L 3.] The independent assessment of the applicant's process for the requirement capture also covers all those steps/activities of the development process (CENELEC V-Cycle from steps 1 to 10) of the design of the vehicle. It is not limited to the inspection/review of the process for the identification of the applicable requirements.

1. Identification information

1.1. Identification of the assessment body (AsBo)

[L 1.] [ASBO´S NAME]

[L 2.] [LEGAL DENOMINATION OF THE ASBO]

[L 3.] [ACRONYM OF THE ASBO]

[L 4.] [ASBO´S ID IN ERADIS]

[L 5.] [DATE OF VALIDITY OF ACCREDITATION/RECOGNITION]

[L 6.] [AREAS OF COMPETENCE COVERED BY THE ACCREDITATION/RECOGNITION (classification in section 5 of ERADIS)]

[L 7.] [COMPLETE POSTAL ADDRESS OF THE ASBO]

[L 8.] [FIRST NAME, SURNAME, TITLE OR FUNCTION OF ASBO´S CONTACT PERSON]

[L 9.] [ADDITIONAL INFORMATION ABOUT THE ASBO, when applicable]

1.2. Identification of the applicant

[L 1.] [APPLICANT´S NAME]

[L 2.] [LEGAL DENOMINATION OF THE APPLICANT]

[L 3.] [ACRONYM OF THE APPLICANT]

[L 4.] [COMPLETE POSTAL ADDRESS OF THE APPLICANT]

[L 5.] [FIRST NAME, SURNAME, TITLE OR FUNCTION OF APPLICANT´S CONTACT PERSON]

1.3. Identification of the vehicle/vehicle type under assessment

[L 1.] [PROJECT NAME]

[L 2.] [VEHICLE/TYPE MANUFACTURER NAME]

[L 3.] [TYPE NAME, when applicable]

[L 4.] [TYPE ID IN ERATV, when applicable]

[L 5.] [CATEGORY AND SUBCATEGORY OF THE VEHICLE/TYPE]

[L 6.] [PARENT TYPE/VARIANT TYPE ID IN ERATV, when applicable]

[L 7.] [AUTHORISATION CASE, ARTICLE 14 OF REGULATION (EU) 2018/545, when applicable]

[L 8.] [CATEGORY OF THE CHANGE, ARTICLE 15/16 OF REGULATION (EU) 2018/545, when applicable]

2. Legislation, standards and guidance material applicable to the AsBo for the independent assessment activities of the applicant's requirement capture

3.1. Mandatory European regulations and standards

[L 1.] The legislation and standards applicable to the independent assessment of the applicant's requirement capture process are :

- Article 13 and Annexes I, II and III of the Implementing Regulation (EU) 2018/545, and
- Regulation (EU) 402/2013, in particular Annex I.

2.2. National regulation (where relevant)

[L 1.] <Introduce any other legislation (e.g., national legislation) or standard used or considered for the independent assessment of the requirements capture process>

2.3 Applicable codes of practice and standards

[L 1.] <This section shall list the codes of practice and standards (if any) against which the applicant's organisation and work will be independently assessed.>

2.4 European guidance material and non-legislative acts non-legally binding

[L 1.] In addition to this legal basis, the clarification note ERA1209/146 about requirements capture, available at ERA website, is considered as a reference document to perform the independent assessment activities that are the subject of this report.

3. Definition of the project and scope of the independent assessment

3.1 Description of the context and background of the project (vehicle subject to authorisation)

[L 1.] <Explain what the project is about and give a short summary, including the intended areas of use of the vehicle, to enable to understand the context of the project. For more details, reference can be made to applicant's documentation.>

3.2. Applicant´s organisation of the project under assessment

[L 1.] <Describe the organisation of the project under assessment, with all involved actors and who is in charge of which activities. If possible, an organisational flowchart or organigram would be appreciated.>

[L 2.] <For more details, the AsBo can reference any relevant applicant's documentation on the project background, the project organisation, and the description of the different parties involved and their respective roles and responsibilities.>

3.3. Scope and objectives of the independent assessment and of the present report

[L 1.] This section describes the context and background of the independent assessment for the requirement capture.

[L 2.] <In particular, clearly indicate the stage of the vehicle development process when you (the AsBo) were contracted (early on the project, or if much later, the precise moment when you started the assessment of the project.>

[L 3.] <Add a reference to the Assessment Plan and/or Scope Definition as necessary>

[L 4.] *<For vehicles fitted with on-board CCS equipment, it is important to describe whether the AsBo responsible for requirements capture is also responsible for its assessment according to the CCS TSI or, on the contrary, it has used the outcomes of the assessments performed by another AsBo. In both cases, the AsBo for requirements capture is the sole responsible for the independent assessment for the whole vehicle and/or vehicle type.>*

[L 5.] *<For more details, the AsBo can reference any relevant applicant's documentation on the project background information>*

[L 6.] The purpose of this report is to provide an independent opinion on the extent to which the applicant has met the requirements in Article 13 of the Implementing Regulation (EU) 2018/545. It presents the results and conclusions of the independent assessment of the:

- effectiveness of the applicant's process for the capture and management of all requirements relevant for the design/upgrade of the vehicle and/or vehicle type referenced in this report. It includes the verification of whether the applicant has identified the European and national legislation, standards, codes of practice and guidelines applicable to the project, which are necessary to address the essential requirements;
- applicant's correct, consistent and systematic implementation of that process throughout the entire development process (CENELEC V-Cycle from steps 1 to 10) of the vehicle and/or the vehicle type for demonstrating that those requirements are captured and actually implemented, verified and validated in the design and manufacturing;
- applicant's documentary evidence of demonstration of validation of the implementation of all those requirements, and
- suitability of the object of assessment to meet the essential requirements of Annex III of Directive (EU) 2016/797 as a result of the application of the requirements capture process

[L 7.] *The AsBo shall precise the scope of the report concerning the independent assessment of the essential requirement safety. It should also precise whether the report covers the most common case (all essential requirements) or not (a report may cover all other essential requirements though). The following paragraphs are proposed to describe the scope of the independent assessment as precisely as possible. Where possible, references to other related independent assessment reports for the other scopes should be provided.>*

[L 8.] *<Depending on the scope of the independent assessment and of the report, some of the paragraphs L8, L9 and/or L10 may need to be removed (eliminate paragraphs for aspects that are not covered). In such case, section 3.4 should be amended accordingly, to have a consistent information on what is covered and what is not covered>.*

[L 9.] The present report covers the independent safety assessment, referenced through Article 13(3) of Regulation (EU) 2018/545, concerning the check of compliance of the "applicant's process for the risk management of essential requirements related to safety and of the safe integration between sub-systems" with the process in Annex I of Regulation (EU) 402/2013.

[L 10.] The present report covers the independent safety assessment, referenced through Article 13(3) of Regulation (EU) 2018/545, concerning the check of compliance of the requirements capture process for essential requirements other than safety: reliability and availability, health, environmental protection, technical compatibility and accessibility.

[L 11.] *The AsBo shall precise the scope of the assessment report concerning the independent assessment of the identification and management of all risks arising from design choices of the Vehicle (e.g., risk assessment at the level of whole vehicle following a change to an existing vehicle and/or vehicle type). The AsBo should precise whether the report covers this or not; that may be the subject of another report)>*

[L 12.] The present report covers the independent safety assessment, referenced through Article 13(3) of Regulation (EU) 2018/545, concerning the check of compliance of the identification and management of all risks arising from design choices of the vehicle with the process in Annex I of Regulation (EU) 402/2013.

<When the report does not cover the application of CSM RA to the whole vehicle following changes to an existing vehicle and/or vehicle type, but it covers the independent assessment of the requirements capture for the essential requirement safety and safe integration of the subsystems: >

Nevertheless, "safety", being one of the essential requirements in Annex III of the Directive (EU) 2016/797 and a sub-set of all requirements, is covered in the present report. The references to the conclusions and safety related application conditions (SRACs) raised by the separate independent safety assessment activities at the level of the risk assessment for the whole vehicle are considered in the framework of this report.

3.4 Limitations of the scope and assumptions of the independent assessment

[L 1.] *<Explain the aim, the specific objectives, the limitations, and assumptions (if any) of your independent assessment>*

[L 2.] *<Identify any exclusions to the scope of the independent assessment in terms of elements outside the system boundary, details not considered and/or out of scope of the AsBo contract with the applicant, interfaces which are out of scope, extent to which operational and maintenance details are in the scope of the independent assessment and how they relate to the independent safety assessment report, etc.>*

[L 3.] *<Remove paragraphs L4, L5 and/or L6 in order the make this section 3.4 coherent with section 3.3 and paragraphs L8, L9 and/or L10, to have consistent information on aspects covered and not covered by the independent assessment and by the report>*

[L 4.] The present report [does not cover] the independent safety assessment, referenced through Article 13(3) of Regulation (EU) 2018/545, concerning the check of compliance of the "applicant's process for the risk management of essential requirements related to safety and of the safe integration between sub-systems" with the process in Annex I of Regulation (EU) 402/2013. That specific activity is subject of a separate report [REFERENCE OF THE SAFETY ASSESSMENT REPORT FOR THE ESSENTIAL REQUIREMENT SAFETY AND THE SAFE INTEGRATION BETWEEN SUBSYSTEMS, where applicable].

[L 5.] The present report [does not cover] the independent safety assessment, referenced through Article 13(3) of Regulation (EU) 2018/545, concerning the check of compliance of the requirements capture process for essential requirements other than safety: reliability and availability, health, environmental protection, technical compatibility and accessibility. That specific activity is subject of a separate report [REFERENCE OF THE SAFETY ASSESSMENT REPORT FOR THE REQUIREMENTS CAPTURE RELATED TO ESSENTIAL REQUIREMENTS OTHER THAN SAFETY, where applicable].

[L 6.] The present report [does not cover] the independent safety assessment, referenced through Article 13(3) of Regulation (EU) 2018/545, concerning the check of compliance of the identification and management of all risks arising from design choices of the vehicle with the process in Annex I of Regulation (EU) 402/2013. That specific activity is subject of a separate report [REFERENCE OF THE SAFETY ASSESSMENT REPORT FOR THE RISK ASESSMENT AT THE LEVEL OF THE WHOLE VEHICLE, where applicable].

3.5 Relationships with the assessment activities carried out by other bodies

[L 1.] *<Considering that the independent assessment of the requirement capture process shall not duplicate the checks carried out by other parties involved, it is essential to describe the interfaces, and the approval roles of all other involved conformity assessment bodies (NoBos, DeBos, other AsBos – if any, applicant's in-house assessment, and your own role).*

Describe how those other checks/assessments affect or interface with your independent assessment work. This is of prime importance, knowing that, in principle, the applicant will use their reports to demonstrate compliance with relevant European, national and legal requirements. Further details should be included in section 4, independent assessment strategy.>

3. Independent assessment plan of the AsBo

4.1. Overall strategy and methodology for the independent assessment

[L 1.] The details about the independent assessment activities of the applicant's requirement capture process are described in the assessment plan, [REFERENCE OF THE ASSESSMENT PLAN].

[L 2.] *< The concept of independent assessment always includes at least the following core elements :*

- *the use of a "pair of eyes" independent of the team dealing with the project;*
- *the systematic assessment of the applicant's :*
  - *structure/organisation of the project, including the competencies of the project team;*
  - *processes and procedures in place for driving the project, and;*
  - *outcomes from the implementation of those processes and procedures by the project organisation.*

  This is known in literature as the "SPO approach", where S- stands for structure or organisation, P- stands for processes and procedures, and O- stands for outcomes;
- *building an expert judgement on the correctness of the outcomes from the applicant's processes, based on the use of sample checks and vertical slice assessment techniques on a selected number of requirements the independent assessor judges representative.>*

[L 3.] The methodology for the independent assessment of the applicant's requirement capture process is similar to the one used for fulfilling the requirements in Article 6(2) of Regulation (EU) 402/2013.

[L 4.] This independent assessment of the requirement capture process applies the core principles described in the recommendation for use N°01 on the working method of the CSM assessment body. When reading this recommendation for use it is necessary to:

- replace "proposer" by "applicant";
- replace "independent assessment of safety", by "independent assessment of the requirement capture";
- replace "risk management process" by "requirement capture process".

[L 5.] *<Without the need to repeat fully the contents of the recommendation for use no.1, it is important to stress that the strategy for the independent assessment of the applicant's requirements capture process is a four step approach:*

1. *based on applicant's documentation :*

   (i) get a clear and thorough understanding of the scope and context of the project/vehicle. This enable to plan the intensity of independent assessment activities, and the particular areas where in-depth assessments are needed;

   (ii) get a clear and thorough understanding of the applicant's plans, project organisation, and safety and quality processes in place for the design of the vehicle that support the requirement capture process in Article 13 of Regulation (EJU) 2018/545;

2. *plan and prioritise the independent assessment activities necessary to check the effectiveness of the project organisation and of those processes supporting the applicant's requirement capture process;*

3. *following the SPO approach described here above, carry out the independent assessment of :*

   (i) the correct implementation by the applicant of the requirement capture process, and;

   (ii) the suitability of the results/outcomes from that process.

   This includes the gathering and reporting to the applicant of documented evidence of all identified non-compliances, and of the follow up of their management by the applicant;

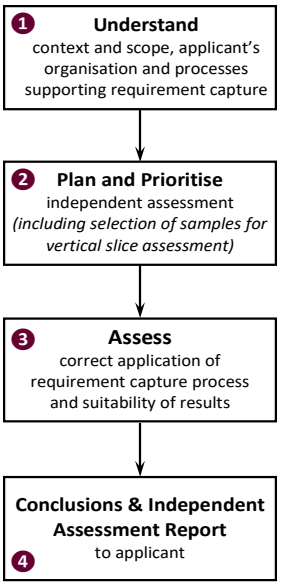


Figure 6: Independent assessment based on a 4 step SPO approach, with sample checks and vertical slice assessments.

4. *deliver the independent assessment conclusions, and the present report, to the applicant.>*

[L 6.] *<The objective of this four step approach, combined with the SPO approach described above, is to :*

- *identify systematically, and proactively, the root causes in either the applicant's requirement capture process, or in the way the process is implemented by the applicant's project team, and which result in a failure to meet the objectives, and;*
- *enable the applicant to take any necessary corrective actions before submitting the application for authorisation.>*

[L 7.] *<The AsBo can add any other key areas of focus for the independent assessments that are performed and give the reasons why they are performed>*

[L 8.] *<When the applicant uses inputs from other assessment reports (e.g., from NoBos, DeBos and other AsBos, where relevant) to support the requirement capture process (e.g., to demonstrate the implementation of European or national requirements), describe :*

- *how you consider, or mutually accept, the assessment reports from those other bodies*
- *whether you make sampling and spot checks of process output evidence*
- *etc.*

[L 9.] *<Describe how the independent assessment will integrate the outcomes or results from the conformity assessment activities carried out by other conformity assessment bodies, when this is necessary (e.g., report from NoBos for the validation of requirements that are linked to the applicable TSIs), in order to avoid duplication of work due to assessments performed by the different conformity assessment bodies involved>.*

[L 10.] *<The description on how outcomes or results from other conformity assessment bodies is considered in the independent assessment remains necessary even when the same company fulfils several roles on the same project (e.g., the same company is acting as NoBo, DeBo, , AsBo for the independent assessment of the requirement capture, and AsBo for the independent assessment of the identification and management of all risks arising from design choices of the Vehicle (i.e. risk assessment at the level of whole vehicle following a change)>*

[L 11.] <The AsBo can provide the reference to its management system concerning the internal procedures that are relevant for the independent assessment. Those documents do neither need to be included nor summarised in the present report.>

Table 1: References to applicable documents from the AsBo management system.

ID	Title	Document reference	Version / date
1	*<Insert as many lines as necessary>*		
2			
3			

4.2. Independent assessment Team

[L 1.] *<List all personnel involved in the independent assessment of the requirement capture and their respective roles>*

[L 2.] *<Give a statement of competency of the team, and of specific individuals (e.g., the lead assessor, etc.)>*

[L 3.] *<Give a statement of independence of the assessment team members with respect to the "design, risk assessment, risk management, manufacture, supply, installation, operation/use, servicing and maintenance" of the vehicle under assessment. Include any issues that arise on the independence and how these have been managed.>*

5. Evidence of independent assessment activities of the requirements capture

[L 1.] *<The applicant shall be able to provide to the AsBo the list of documentary evidence for the different steps of the requirement capture process in order to enable the AsBo to perform the independent assessment activities. In the absence of sufficient physical, or database, evidence, the AsBo is entitled to raise non-compliances for the relevant points.>*

[L 2.] *<The AsBo should describe the independent assessment activities/tasks it carried out and the documents it assessed for every key step of the requirement capture process. When the AsBo mutually accepts "assessment reports/records" from other conformity assessment bodies, or parties, it should reference those reports.>*

Table 2: Index of the independent assessment activities/tasks for the requirements capture process .

Applicant's activity in the requirement capture	Independent assessment activities performed
1. Identification of all requirements (European and national legislation, customer's requirements, etc.) applicable to the design of a vehicle that are needed to meet essential requirements	*<Document the independent assessment carried out for verifying this requirement>*
2. Integration of all identified requirements into the specifications of the vehicle (System Definition)	*<Document the independent assessment carried out for verifying this requirement>*
3. Registration of all identified requirements into an appropriate centralised tool (repository), either a physical tool or an IT tool (table, database, register, etc.) subject to proper configuration management	*<Document the independent assessment carried out for verifying this requirement>*
4. Allocation of those requirements down to the areas of expertise and/or subsystems of the breakdown structure of the vehicle architecture, or export any necessary conditions for use or other restrictions	*<Document the independent assessment carried out for verifying this requirement>*
5. Management, traceability, and demonstration of the correct implementation of all requirements through every step of the development process of the vehicle (CENELEC V-Cycle from steps 1 to 10)	*<Document the independent assessment carried out for verifying this requirement>*
6. Availability of documentary evidence of compliance with every step of the development process of the vehicle (CENELEC V-Cycle from steps 1 to 10).	*<Document the independent assessment carried out for verifying this requirement>*
<Insert as many lines as necessary>	

[L 3.] *<The AsBo shall describe how it assessed those main steps of the applicant's requirement capture process throughout the whole development process (steps 1 to 10 of the CENELEC V-Cycle) of the vehicle. >.*

6. Results from the independent assessment

6.1. Project organisation and relationships with the assessments carried out by other bodies

[L 1.] Based on the organisation of the project presented in chapter 3 above, and the need to avoid a duplication of assessments between different conformity assessment bodies involved in the project, the independent assessment of the [PROJECT NAME] does not redo the work of those other bodies.

[L 2.] However, in order to state on the appropriateness of the applicant's requirement capture process with Article 13 of Regulation 2018/545, this report integrates also the outcomes or results from the conformity assessment activities carried out by the other conformity assessment bodies referenced in section § 3.2 above (i.e. NoBos, DeBos, other relevant assessment parties, and other AsBos – where relevant [e.g. for the on-board CCS sub-system]).

[L 3.] *<This separation remains necessary even when the same company fulfils several roles on the same project (e.g. the same company is acting as NoBo, DeBo, AsBo for the independent safety assessment of the application of the process in Annex I of Regulation (EU) 402/2013, and for example AsBo for the independent assessment of the requirement capture for a Vehicle Authorisation). If the same company fulfils more than one role, there shall be a separate section/chapter for every of the roles the AsBo fulfils.>*

6.2. Issues/non-compliances from the independent assessment activities

[L 1.] This section lists the findings, or non-compliances, still open at the time of issuing of the present report, related to the independent assessment of the requirements capture process as applied to the project.

<Describe the findings from the independent assessment of the requirements capture process as applied to the project.>

[L 2.] Annex 3 below gives a summary of the history of main findings, or non-compliances, that the independent assessment raised during the project development, but the applicant successfully addressed and closed, prior to the release of this report. The reader can get there an overview of the main project achievements in terms of requirement capture.

[L 3.] At the time of release of this report, the following findings, or non-compliances, are still open:

<If all findings, non-compliances, are closed, the paragraph shall be adapted accordingly>

- *<describe in detail the main (most critical) non-compliances or findings identified by the independent assessment activities>;*
- *<indicate the current status (on-going, open)>;*
- *<describe the applicant's plans for closing them>.*

6.3. Results from the assessment carried out by other conformity assessment bodies, or other parties

[L 1.] This section lists the findings, or non-compliances, related to the assessments performed by other conformity assessment bodies involved in the project.

[L 2.] *<Describe the relevant findings from other conformity assessment bodies involved.>*

[L 3.] The other conformity assessment bodies involved in the project, report the following non-closed findings, or non-conformities, that are relevant for the independent assessment of the requirements capture process:

<if there are no open findings, the paragraph shall be amended accordingly>

<The AsBo is not obliged to copy/paste all the open findings, or non-conformities, from those other bodies; it can however list the most relevant ones, if any. It is allowed to provide the reference of the corresponding report, and the accurate section in that report, where those issues can be found>

[L 4.] *<Where relevant, the AsBo shall indicate clearly whether it considered that the findings, or non-conformities, coming from the verification activities carried out by those other conformity assessment bodies, were properly managed by the applicant, in application of its requirements capture process>*

6.4 Non-blocking issues/non-compliances for the current project in future phases

[L 1.] This section lists the observations of the AsBo concerning the improvement of non-blocking points for the current project.

<If the AsBo does not provide any observation, the paragraph shall be adapted accordingly.>

[L 2.] *<Based on the independent assessment activities of the requirement capture process for the current project, the following improvements are recommended to the applicant:>*

- *<for the next steps of the current project, when the applicant took the precautions to appoint the AsBo at the very early stages of the project in order to enable a proactive independent assessment, or>*

[L 3.] *<Provided that those observations do not affect the decision on the compliance of the vehicle with the applicable requirements, there is no obligation for the AsBo to trace here the observations raised by the NoBo, DeBo, or AsBo in charge of the independent safety assessment. The applicant can find them in the respective reports.>*

6.5 Non-blocking issues/non-compliances for further improvements of the applicant's organisation and requirement capture process for future projects (not in scope of current project)

[L 1.] This section lists the observations of the AsBo concerning the improvement of non-blocking points for other projects in future.

<If the AsBo does not provide any observation, the paragraph shall be adapted accordingly.>

[L 2.] *<Based on the independent assessment activities of the requirement capture process for the current project, the following improvements are recommended to the applicant:>*

- *<for next projects, so that the applicant implements better the requirement capture (e.g., improvement of the applicant's organisation and processes supporting the requirement capture process), based on the experience gained with the AsBo independent assessment on the present project. That should enable the applicant to avoid reproducing the same non-conformities.>*

[L 3.] *<Provided that the observations do not affect the decision on the compliance of the vehicle with the applicable requirements, there is no obligation for the AsBo to trace here the recommendations raised by the NoBo, DeBo, or AsBo in charge of the independent safety assessment. The applicant can find them in the respective reports.>*

7. Conditions for the use of the vehicle and other restrictions

7.1 Project organisation and relationships with the assessments carried out by other bodies

[L 1.] Given the organisation of the project, several conformity assessment bodies are involved in the project. The independent assessment of the requirement capture analysed whether the conditions, limits for use for use and other restrictions arising from their respective conformity assessments are properly considered by the requirements capture process applied by the applicant.

<When no other conformity assessment bodies are involved, adapt the paragraph accordingly.>

[L 2.] This chapter lists the conditions for use of the vehicle and other restrictions at the time of release of the present report. They are based on the results of the present independent assessment, but also on the findings/non-conformities presented in sections above.

[L 3.] *<The conditions for use and other restrictions below apply to the vehicle and/or vehicle type, based on the independent assessment of the requirements capture process and on the reports from the other conformity assessment bodies involved.>*

<The AsBo is not obliged to copy/paste the restrictions requested by those other bodies. It is allowed to provide the reference of the corresponding report, and the accurate section in that report, where the restrictions can be found>

7.2. Conditions for use from the AsBo for the independent assessment of the requirements capture

[L 1.] *<Describe the limitations for use that you find out as a result of the independent assessment of the requirements capture process;>*

[L 2.] *<Where relevant, the AsBo shall indicate clearly whether it considered that the conditions for use and other restrictions coming from the verification activities carried out by those other conformity assessment bodies, were properly managed by the applicant, in application of its requirements capture process>*

7.3. Conditions for use transferred through the conformity assessment activities of other conformity assessment bodies or other parties

[L 1.] *<In addition to the conditions for use presented in section § 7.2, the following conditions and limits for the safe use and maintenance of the vehicle and/or vehicle type are identified by:>*

<The AsBo is not obliged to copy/paste them in the present report. It can provide the following information:>

- **Other AsBo(s):** *<if relevant, conditions for use from other AsBos (e.g. in case of involvement of several AsBos on the same project):>*

  <Accurate reference to the concerned AsBo report(s) and to the section where the conditions for use and other restrictions can be found>

- **NoBo(s):** *<if relevant, conditions and limits for use from the NoBo 'EC' verification of conformity:>*

  <Accurate reference to the NoBo report(s) and to the section where the conditions and limits for use can be found>

  <Accurate reference to the applicant's technical file(s) accompanying the EC declaration(s) of verification>;

- **DeBo(s):** *<if relevant, conditions and limits for use from the <DeBo verification of conformity vs. the applicable national rules:>*

  <Accurate reference to the DeBo report(s) and to the section where the conditions and limits for use, and other restrictions can be found>

8. Conclusions

[L 1.] *<This section contains the conclusions of the independent assessment of the applicant's requirement capture process, referenced in the scope and objective section.>*

[L 2.] Based on the independent assessment activities, carried out according to the independent assessment plan, it can be concluded that the requirements capture process implemented by [LEGAL DENOMINATION OF THE APPLICANT] for the project [PROJECT NAME]:

<The text below is just a model. It shall be corrected to reflect reliably the precise picture of your specific project, adding complementary information as needed, or removing the statements that do not fully fit>

- is suitable and enables to identify systematically all requirements (including safety requirements derived from the risk analysis in Annex I of CSM RA) relevant for the design/upgrade of the vehicle (including the applicable European and national legislation, standards, guidelines, client's requirements, and internal rules) that are necessary to comply with all essential requirements;
- is suitable for identifying safety risks and allows for an adequate management and control of such risks, following the process of Annex I of Regulation (EU) 402/2013;
- covers the entire development process (CENELEC V-Cycle from steps 1 to 10) of the vehicle, ensuring that the requirements, have been captured (e.g., incorporated into the relevant requirements specifications, documentation specifications, actions lists, repositories, databases, registers) and implemented in the design and manufacturing of the vehicle under assessment;

[L 3.] The conditions for use and other restrictions arising from the conformity assessments performed by other bodies involved (e.g., NoBo(s), DeBo(s), other AsBo(s)) have been properly managed in application of the requirements capture process.

[L 4.] The applicant has produced sufficient documentary evidence to demonstrate the compliance with Article 13 of Regulation (EU) 2018/545, and in particular the validation of the implementation of all the applicable requirements.

[L 5.] As a result of the independent assessment of the requirements capture process, the following conditions for use of the vehicle and other restrictions apply:

<Concerning the list of relevant conditions for use and other restrictions raised by the independent assessment of the requirements capture process, including those arising from the safety analysis which is necessary to meet the essential requirement safety, the AsBo can refer to the respective sections in chapter 7. >

Signature

Date:

Authorised signatory of the AsBo

Annex 1: Abbreviations

[A1.1.] *<This annex shall include the list of all abbreviations used in the document>*

Table 3: Table of abbreviations.

Abbreviation	Meaning
AsBo	CSM Assessment Body as defined in Regulation (EU) 402/2013
CSM	Common Safety Method
DeBo	Designated Body
EU	European Union
NoBo	Notified Body
RFU	Recommendation For Use
SPO	Structure-Processes/Procedures-Outcomes
	<Complete the table, inserting as many lines as necessary>

Annex 2: list of applicant´s documents used for the independent assessment

[A2.1.] *<The AsBo shall list all documents that used for the independent assessment. This is necessary to enable the independent assessment activities to be repeated (if necessary) and to arrive at equivalent conclusions>*

Table 4: References of documents subject to independent assessment

ID	Title	Document reference	Version / date
1	*<Insert as many lines as necessary>*		
2			
3			

Annex 3: (Optional) Documentary evidence from the independent assessment of the applicant's requirement capture process produced by the AsBo

[A3.1.] *<This annex is option. It enables the AsBo to list the outcomes from the independent assessment activities (e.g., minutes of meetings, reports, checklists etc.).>*

Annex 4: History of identified non-compliances closed by the applicant

[A4.1.] *<This annex shall include a summary of :*

- *the identified non-compliances, or findings;*
- *the applicant's corrective actions to manage and close those non-compliances, or findings;*
- *the AsBo independent assessment of those actions>*

[A4.2.] *<This summary shall be completed with a reference to a separate AsBo document, where more details can be found on the history of all identified non-compliances, as well as details about the applicant's corrective actions and the additional independent assessment activities on those actions.>*

Annex 5: Optional elements of the assessment report referenced in the informative Annex B of the ISO/IEC 17020:2012 standard

[A5.1.] *<This annex is optional. The AsBos may use it for documenting any additional and optional elements of the independent assessment activities that the AsBo estimates useful.>*

Annex 6: (Optional) Independent assessment plan

[A6.1.] *<This annex is optional. The AsBos may decide to include the independent assessment plan, referred to in section 3.2 .>*

4.3. Declaration by the applicant concerning the requirements capture process

<Where the declaration covers only the requirements capture process:>

DECLARATION BY THE APPLICANT CONCERNING THE REQUIREMENTS CAPTURE PROCESS

<Where the declaration covers the requirements capture process and the significant change:>

DECLARATION BY THE APPLICANT CONCERNING THE REQUIREMENTS CAPTURE PROCESS AND THE SIGNIFICANT CHANGE

We, Applicant:

[LEGAL DENOMINATION OF THE APPLICANT]
[COMPLETE POSTAL ADDRESS]

<Where the declaration covers only the requirements capture process:>

pursuant to Article 13 and point 18.10 of Annex I of Regulation (EU) 2018/545, declare under our sole responsibility that concerning the vehicle and/ or vehicle type *[NAME/SHORT DESCRIPTION OF THE VEHICLE AND/OR VEHICLE TYPE]:*

<Where the declaration covers the requirements capture process and the significant change:>

pursuant to Article 13 and points 18.10 and 18.12 of Annex I of Regulation (EU) 2018/545, and Article 16 of Regulation (EU) 402/2013, declare under our sole responsibility that concerning the vehicle and/ or vehicle type *[NAME/SHORT DESCRIPTION OF THE VEHICLE AND/OR VEHICLE TYPE]:*

<The identification of the vehicle and/or vehicle type shall enable unique identification and allow for traceability; in addition to project name, or vehicle name, IDs such as (draft) type ID in ERATV, European Vehicle Number EVN etc are recommended>

- we have performed a requirements capture process that fulfils the requirements of Article 13 and Annex I of Regulation (EU) 2018/545;
- all applicable requirements necessary to comply with the essential requirements of Annex III of Directive (EU) 2016/797 have been managed (identified, implemented and validated);
- all identified hazards and associated risks are managed and controlled to an acceptable level;
- the requirements capture process and its application to the vehicle and/or vehicle type have been independently assessed by the following conformity assessment body, *[ACCREDITED OR RECOGNISED]* according to Article 7 of Regulation (EU) 402/2013:

  <Where there may be several AsBos involved, e.g., one covering the essential requirement safety, and another one covering all other essential requirements, therefore two independent assessment reports, duplicate lines below as needed>

  [ASBO´S BUSINESS NAME]
  [ASBO´S ID IN ERADIS]
  [COMPLETE POSTAL ADDRESS OF THE ASBO]

  In accordance with the following independent assessment report:

  [TITLE, REFERENCE, DATE OF ISSUING AND VERSION OF THE INDEPENDENT ASSESSMENT REPORT]

<Where the declaration covers the requirements capture process and the significant change, include the following bullet point:>

- the suitability of both the application of the risk management process as set out in Annex I of Regulation (EU) 402/2013 and of its results concerning the significant change has been independently assessed, pursuant to Article 6 of Regulation (EU) 402/2013, by the following conformity assessment body, *[ACCREDITED OR RECOGNISED]* according to Article 7 of Regulation (EU) 402/2013:

  [ASBO´S BUSINESS NAME]
  [ASBO´S ID IN ERADIS]

[COMPLETE POSTAL ADDRESS OF THE ASBO]

In accordance with the following independent assessment report:

[TITLE, REFERENCE, DATE OF ISSUING AND VERSION OF THE INDEPENDENT ASSESSMENT REPORT]

› The essential requirements covered by the independent assessment are:

- Safety
- Reliability and availability
- Health
- Environmental protection
- Technical compatibility
- Accessibility

<Adapt the list of essential requirements above to those covered by the independent assessment by an AsBo; note that "Safety" can never be removed from the list, as the application of the process in Annex I of Regulation (EU) 2018/545 and the independent assessment by an AsBo is mandatory>

Done on:

[date DD/MM/YYYY]

Signature of Applicant

First Name, Surname