

## 1. REQUEST

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| <b>Enquiry title: *</b>  | Harmonised structure for the AsBo report when the applicant appoints a single AsBo for the independent assessment of the applicant's requirement capture process required in Article 13 of Regulation 2018/545 (including the safety requirements) |
| <p><b>Enquiry description: *</b></p> <ol style="list-style-type: none"> <li>The purpose of this AsBo-RFU is to detail and harmonise the structure of a single AsBo report to document the independent assessment activities of the applicant's requirement capture process required in Article 13 of Regulation 2018/545, including all sections of Article 13.</li> <li>The structure of this AsBo-RFU is based on and mirrors the one of recommendation for use 02. Thereby, it is also based on the structure in Annex III of Regulation 402/2013.</li> <li>This AsBo-RFU is addressed to AsBos accredited/recognised for at least the rolling stock scope according to the requirements defined in the recommendation for use 03. It is expected to be used only when the applicant appoints a single AsBo for the independent assessment of the applicant's compliance with all parts in Article 13 of Regulation 2018/545 (including the safety requirements).</li> <li>The advantage of having a standardised layout of the AsBo independent assessment report is to enable any interested stakeholder to easily find out the necessary information in exactly the same sections, when the report complies with this AsBo-RFU. An easy access to all relevant information, needed for the mutual recognition of the applicant's results from the requirement capture process, reduces the authorising entity demands for additional information to the applicant, and/or additional checks and verifications. It shortens thus the time for the issuing of vehicle authorisations.</li> <li>The project-specific content of each section of the AsBo report is dependent on the nature and complexity of the project (project context, assumptions, sub-systems and stakeholders involved, etc.).</li> <li>Where the applicant appoints the AsBo only for the independent assessment of the requirement capture part defined in Article 13(3) of Regulation 2018/545 (i.e. for assessing the use of the risk management process in Annex I of the CSM RA), the AsBo shall use the report structure of the recommendation for use 02.</li> <li>The structure of the present recommendation for use is not foreseen to be used for the following cases: <ol style="list-style-type: none"> <li>When the applicant appoints the AsBo only for the independent assessment of the applicant's requirement capture process of requirements other than safety and safe integration. Then, the AsBo must adapt the structure of this recommendation for use to the right scope of independent assessment. <p><i>Note 1: appointment of different AsBos for the different parts of Article 13 of Regulation 2018/545 (e.g. one AsBo for the requirement capture process of "safety" related requirements, and another one for requirements "other than safety") unavoidably induces a duplication of independent assessment activities by the different AsBos involved in the same project.</i></p> <p><i>Note 2: the independent assessments of the requirement capture process for the individual essential requirements are closely linked to each other in terms of both:</i></p> <ul style="list-style-type: none"> <li>the assessment of the process and procedures applied by the applicant, and;</li> <li>the content of independent assessment activities, knowing that the assessment of technical compatibility, safety and safe integration are inseparable from each other.</li> </ul> <p><i>Trying to separate the independent assessments of the different sections of Article 13 of Regulation 2018/545 would therefore lead to many unnecessary interfaces in assessments. To avoid misunderstandings by the involved stakeholders, and the Authorising Entities requesting additional explanations that induce substantial additional delays, costs and risks to projects, it is neither advisable to separate the independent assessments between different AsBos, nor to document those assessment activities in separate reports of the single AsBo.</i></p> </li> <li>When the applicant appoints the same company for fulfilling several roles on the same project, for example where the same company is accredited/recognised as AsBo, NoBo and DeBo. Such a company shall not use the present AsBo-RFU for documenting their conformity assessment activities under their</li> </ol> </li> </ol> |  |

NoBo and DeBo roles. For the NoBo role, the appointed company shall use the relevant NB Rail recommendations for use; for the DeBo role, it shall use the relevant national prescriptions (if any).

8. Finally, as this recommendation for use relates to the implementation of Regulation 2018/545 on vehicle authorisations, it uses the terminology “applicant” instead of “proposer”, although in terms of risk management both terminologies can interchangeably be used; they have the same meaning.

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| <b>Date of submission:</b>  | 07/06/2023     |
| <b>Related documents:</b><br>{Ref. 1} Regulation (EU) 2018/545 (PA VA)<br>{Ref. 2} Regulation (EU) 402/2013 (CSM RA)<br>{Ref. 3} ISO/IEC 17020:2012 and its subsequent amendments<br>The recommendations for use are available on the Agency web page under the following link<br><a href="https://www.era.europa.eu/domains/common-safety-methods/risk-evaluation-assessment-csm_en">https://www.era.europa.eu/domains/common-safety-methods/risk-evaluation-assessment-csm_en</a> |                |

## 2. TRACEABILITY

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| <b>RFU number:</b>      | 04  |
| <b>Version number:</b>  | 1.0                                       |
| <b>Version comment:</b> | First version, voted by the plenary group |

## 3. SOLUTION

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| <b>I Introduction</b>   | <b>Legal basis</b>  |
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| <p>1. Article 13 of Regulation 2018/545 on vehicle authorisations requires the applicant to have a requirement capture process which shall ensure that the requirements applicable to the vehicle are:</p> <ul style="list-style-type: none"> <li>(a) identified;</li> <li>(b) assigned to functions/sub-systems, or are addressed through conditions for use or other restrictions;</li> <li>(c) implemented and validated, or;</li> <li>(d) addressed through clear conditions for use or other restrictions.</li> </ul> <p>with the objective of managing and mitigating the identified risks to an acceptable level</p> | <p><b>Article 2(11) and Article 13(1) of Regulation 2018/545</b></p>  |
| <p>2. Article 13(2) of Regulation 2018/545 emphasises that the applicant's requirement capture process of Article 13(1) shall cover:</p> <ul style="list-style-type: none"> <li>(a) the essential requirements for sub-systems referred to in Article 3 and specified in Annex III to Directive (EU) 2016/797;</li> <li>(b) technical compatibility of the sub-systems within the vehicle;</li> <li>(c) safe integration of the sub-systems within the vehicle;</li> <li>(d) technical compatibility of the vehicle with the network in the area of use.</li> </ul>   | <p><b>Article 13(2) of Regulation 2018/545</b></p>  |
| <p>3. Article 13(3) of Regulation 2018/545 does not add more requirements other than:</p>   | <p><b>Article 13(3) of Regulation 2018/545</b></p>  |
| <ul style="list-style-type: none"> <li>(a) the use by the applicant of the risk management process in Annex I of the CSM RA as methodology for the requirement capture as regards the essential requirements 'safety' related to the vehicle and sub-systems as well as safe integration between sub-systems for aspects not covered by the TSIs and the national rules.</li> <li>(b) through point 1.1.2 of Annex I of the CSM RA, the obligation for the applicant to appoint an AsBo for the independent assessment of that process and requirements.</li> </ul>   | <p><b>Article 13(3) of Regulation 2018/545</b><br/><b>Point 1.1.2 of Annex I of Regulation 402/2013</b></p> |
| <p>4. <b>IMPORTANT</b>: users of Regulation 2018/545 shall not reduce the reading of words "requirements capture" to the sole identification of requirements applicable to the design of the vehicle. It must include also all other stages reminded in section 1 just above, equally important for a proper management of the implementation of all relevant requirements.</p>   | <p><b>Article 2(11) and Article 13 of Regulation 2018/545</b></p>   |
| <p>5. When the applicant appoints an AsBo for the independent assessment of its requirement capture process of essential requirements other than safety, the AsBo has to produce an assessment report.</p>  | <p><b>Point 18.1 in Annex I of Regulation 2018/545</b></p>  |
| <p>6. Independently of the applicant's decision in section 5 just above, the applicant shall appoint an AsBo to assess the correct application of Annex I of the CSM RA for the requirement capture of the essential requirements 'safety' related to the vehicle and subsystems, and of the safe integration between subsystems for aspects not covered by the TSIs and the national rules.</p>  | <p><b>Article 13(3) of Regulation 2018/545 and Point 1.1.2 in Annex I of Regulation 402/2013</b></p>        |

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| 7.   | In relation to section 6 just above, the AsBo has to formally document the independent assessment activities, the associated results and the applicable limitations (if any) in a safety assessment report.  | <b>Article 6(2), Article 15(1),<br/>Point 5.3 in Ax I, Ax III of<br/>Reg. 402/2013<br/>Clause 7.4 of ISO/IEC 17020<br/>Ax B(d) of ISO/IEC 17020</b> |
| 8.   | The applicant is required to take into account the conclusions of the AsBo independent assessment report for the acceptance of the outcomes of its requirement capture process of the vehicle.   | <b>Points 18.1, 18.7 and 18.8<br/>of Annex I of Reg. 2018/545<br/>Articles 15(1) and 16<br/>of Reg. 402/2013</b>                                    |
| <b>II Legal basis</b>  |  |   |
| 1.   | The legal bases are given in the previous chapter. They are not duplicated.  |   |
| <b>III General information regarding the structure of the AsBo assessment report</b> |  |   |
| 1.   | This structure of the AsBo assessment report mirrors the structure of the general recommendation for use 02 on the AsBo safety assessment, applicable to all other occurrences of use of the risk management process in Annex I of the CSM RA.   |   |
| 2.   | The structure recommended in this document follows thus the same chapter and section numbering as the recommendation for use 02. It includes in a single document the results of the AsBo independent assessments of the applicant's requirement capture process required in Article 13 of Regulation 2018/545, including both the safety and non-safety requirements. Thereby, when the AsBo complies with the present recommendation for use, it is not requested to also comply with the recommendation for use 02. |   |
| 3.   | The content and structure/format presented below is essential, to avoid the accepting entities asking for additional information to the applicant, or having to carry out additional checks and verifications.   |   |
|  | <u>Note:</u>   |   |
|  | (a) By virtue of Clause 7.4.5 of the ISO/IEC 17020:2012 standard, in specific and justified cases, to avoid unnecessary administrative burden, a shorter AsBo report, with an adjusted structure, can be accepted, provided it complements, and explicitly refers to, an existing report produced by the same AsBo, which is fully compliant with the structure presented below.   |   |
|  | (b) Typical examples are changes to non-safety relevant components (e.g. replacement of a GSM-R sub-system of an onboard ETCS sub-system), or bug-fixing by a manufacturer for a vehicle that was already assessed and covered by an AsBo assessment report.   |   |
|  | (c) In those specific cases, the AsBo report can be limited to the independent assessment, and to the follow up, of the correct implementation and management by the applicant of the considered change/ corrections and to the assessment that the change does not adversely impact the non-modified parts of the vehicle.  |   |
|  | (d) Nonetheless, in case a shorter AsBo report is produced, for the mutual recognition of the applicant's requirement capture process, the AsBo shall provide both the short version of the independent assessment report, and the long version on which it is based.  |   |
| 4.   | To ensure a correct and proper traceability and control of the document, the AsBo assessment report shall fulfil all requirements in Clause 7.4 of the ISO/IEC 17020:2012 standard and shall include:  |   |
|  | (a) a cover page with a title of the change under independent assessment;  |   |
|  | (b) a unique document identification or reference, and date of issue, as foreseen through the AsBo documentation management system;  |   |
|  | (c) a version control (including a short description of changes in the respective versions of the same report);  |   |
|  | (d) signature or other indication of approval, by authorised personnel, as foreseen through the AsBo documentation management system;  |   |
|  | (e) a table of contents compliant with the structure requested in section 3 of point IV below;   |   |

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|  | <p>(f) optional: (if available) symbol of accreditation, or recognition, to be used in compliance with the applicable rules of the accreditation<sup>(1)</sup> (respectively recognition) body.</p> <p>5. The AsBo assessment report shall also number every page of the report, using the “Page Number format “Page n/nn or Page n out of nn”, where ‘nn’ designates the total number of pages of the report. That allows a quick verification of completeness of the report.</p> <p>6. In case a project does not need/use a specific section, the section number should be kept and marked as “not used” (or similar text). It is essential to keep the recommended section numbering identical across all AsBo assessment reports to facilitate finding easily and quickly the information necessary for the mutual recognition of the AsBo report, in particular when the project language is different from English.</p> <p>7. For every heading/sub-heading, the AsBo shall provide an overall summary permitting to understand its independent assessment activities. The AsBo report should be as much self-explanatory as possible, to limit the reader’s requests for additional details. Nevertheless, where convenient, the AsBo may reference separate/external documents of either the AsBo’s documentation, or evidence provided by the applicant, or other conformity assessment bodies (e.g. NoBo, DeBo, other AsBos, in case of onboard CCS sub-system) for further details on a sub-heading.</p> <p>Where necessary (e.g. complex projects with multiple suppliers), it is allowed to add sub-headings underneath the mandatory headings/sub-headings in order to describe separately the roles of, and interfaces with, all relevant sub-suppliers.</p>   |
|  | <p><b>IV Harmonised structure of the AsBo assessment report</b></p> <p>1. The numbers and titles of the headings below <u>shall be respected</u> in the report for the reasons explained in section 6 of chapter III. Where needed for the project, the AsBo may use another official language of the European Union, as defined by the applicant.</p> <p>2. Where the title of the heading is not explicit enough:</p> <p>(a) <i>the text below, written in italic blue colour formatting (as the present one)</i>, describes the information the AsBo is expected to document formally in the report. The <i>italic blue colour text and associated paragraph italic blue numbers</i> are not a mandatory sub-title; the italic text has to be replaced by the project specific information and evidence related to the outcomes of the independent assessment activities;</p> <p>(b) if despite that explanatory text in italic, the expected content of the heading is not understandable, the reader can find more details on the expected inputs in Annex A below.</p> <p><b>3. <u>Headings and sub-headings of the AsBo independent assessment report:</u></b></p> <p><i>The title of the AsBo report shall be explicit enough regarding its scope. It can be for example:</i></p> <p>AsBo independent assessment report of the applicant’s process for the requirements and risk management as required in Article 13 of Regulation 2018/545 for <i>[write the name of the project]</i></p> <p><b>Abstract (Optional)</b></p> <p><i>An abstract is always appreciated. However, when the project language is different from English, a short presentation of the report in English, with the points below, is more than helpful for mutual recognition:</i></p> <ul style="list-style-type: none"> <li>• <i>Project name and identification of the vehicle under assessment assigned to the AsBo;</i></li> <li>• <i>An overall summary of the project objectives and organisation;</i></li> <li>• <i>A clear statement on whether the AsBo confirms that:</i></li> </ul> |

<sup>(1)</sup> The “EA conditions for the use of Accreditation Symbols, Logos and other claims of accreditation and reference to the EA MLA Signatory status” are defined in the European Co-operation for Accreditation document EA-3/01 M: 2021.

- ✎ *the applicant has a requirement capture process that fulfils all 4 steps (identification, assignment, implementation and validation) in Articles 13(1) and 13(2) of Regulation 2018/545;*
- ✎ *the applicant uses correctly and effectively the risk management process set out in Annex I of the CSM-RA, as required in Article 13(3) of Regulation 2018/545, for the requirement capture of the essential requirements 'safety' related to the vehicle and sub-systems as well as for the safe integration between sub-systems for aspects not covered by the TSIs and the national rules. The results from that risk management enable the vehicle to fulfil the intended objectives safely;*

- *If the AsBo statement is conditional, refer to the section of the report with the conditions that must be complied with for a safe use and maintenance of the vehicle and/or vehicle type.*

## 1 Identification information

### 1.1 Identification of the assessment body (AsBo)

1.1.1 *The AsBo is expected to include here the information on the AsBo contained in the ERADIS database.*

### 1.2 Identification of the applicant

### 1.3 Identification of the vehicle/ vehicle type under assessment

1.3.1 *For consistency with the title of the chapter, the AsBo shall <write the name of the project> and the identification of the vehicle/vehicle type. The following information is expected:*

- (a) *project name, including where applicable a version or configuration version (if any);*
- (b) *vehicle/type manufacturer name.*

1.3.2 *For further details about the project and its organisation, refer to heading 3 below.*

## 2 Legislation, standards and guidance material

2.0 *This chapter lists the references against which the applicant's organisation and requirement capture process will be independently assessed by the AsBo. It shall not list the reference requirements against which the AsBo is accredited/recognised.*

### 2.1 Mandatory European regulations and standards

The legislation and standards applicable to the independent assessment of the applicant's requirement capture process are:

- Article 13 of Regulation 2018/545, considering the full definition of the terminology "requirement capture process" in Article 2(11) and;
- the risk management process in Annex I of Regulation 402/2013, for the management of safety related requirements and safe integration.

### 2.2 Optional reference documents/material

2.2.1 *If the AsBo wishes, they can include additional references, they consider relevant or necessary.*

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

### 3.1 Description of the context and background of the project (change under assessment)

3.1.1 *Explain what the project, or the change, is about and give a short summary, including in particular the intended areas of use of the vehicle, to enable to understand the context of the project/change and the acceptability of the conditions and limits for the use of the vehicle and/or vehicle type. For more details, reference can be made to applicant's documentation.*

3.1.2 *The AsBo report is not expected to summarise the applicant's safety files (e.g. Safety Case); this remains the responsibility of the applicant.*

### 3.2 Applicant's organisation of the project under assessment

3.2.1 *The AsBo is expected to provide a summary of the organisation of the project/change and a description of the roles of all actors involved, including the various conformity assessment bodies, e.g. for vehicles fitted with an on-board CCS sub-system. If possible, an organisational flowchart or organigram would be appreciated.*

3.2.2 *For further details, the AsBo can refer to an applicant's document.*

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

3.3.1 *Describe the services the applicant assigned to the AsBo regarding the independent assessment of:*

- (a) *the requirement capture process the applicant puts in place to address Article 13 of Regulation 2018/545, including;*
- (b) *the requirement capture process regarding the essential requirements 'safety' related to the vehicle and sub-systems as well as safe integration between sub-systems for aspects not covered by the TSIs and the national rules.*

3.3.2 *Where for whatever reasons the AsBo sub-contracts any part of its independent assessment activities, the AsBo shall clearly describe which part(s) is(are) sub-contracted, and who is the sub-contractor, as this is requested by Clauses 6.3.2 and 7.4.4 of the ISO/IEC 17020:2012 standard.*

3.3.3 *Report in particular the stage of the project when the applicant contracted the AsBo, and when the AsBo started the inspection activities (early on the project, or if much later, the precise moment when the AsBo started the assessment of the project).*

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

### 3.4 Limitations of the scope and assumptions of the independent assessment

3.4.1 *List transparently and clearly the exclusions to the scope/elements outside of the boundaries of the system under assessment, or contractual restrictions for the inspection activities.*

3.4.2 *This is of prime importance when for example the applicant contractually and explicitly requests the AsBo to limit its assessments only to the identification step of Article 13 of Regulation 2018/545. Referring to section 4 in chapter I above, in practice the applicants shall never make the mistake to exclude the remaining three key steps of the requirement capture process. Nonetheless, if it happens, the AsBo report shall clearly state that:*

- (a) *the applicant does not want the AsBo to independently assess the assignment, implementation and validation steps of the requirement capture process requested in clauses (b) and (c) of Article 13 of Regulation 2018/545, and thereby;*
- (b) *the AsBo did not assess the applicant's requirement capture process but only the identification of requirements applicable to the design of the vehicle and/or the vehicle type;*
- (c) *it is necessary that another entity independently assesses the other three key steps of the applicant's requirement capture process (e.g. the authorising entity).*

### 3.5 Relationships with the assessment activities carried out by other bodies

3.5.1 *Considering that the independent assessment of the applicant's requirement capture process shall not duplicate the checks carried out by other parties involved, it is essential to describe the organisational interfaces, and the roles of all other involved conformity assessment bodies (NoBos, DeBos, other AsBos – if any, applicant's in-house assessments, and the own role of the AsBo drafting the present report).*

3.5.2 *This section is expected to describe how those other checks/assessments affect or interface with the AsBo independent assessment of the applicant's requirement capture process. This is of prime importance, knowing that, in principle, the applicant will use the NoBo and DeBo reports to demonstrate compliance with relevant European, national and legal requirements. As this might overlap with the independent assessment plan, the AsBo can cross-references the relevant sub-sections in section 4 below, where this is described.*

3.5.3 *Further details should be included in chapter 4 on the AsBo independent assessment plan and strategy.*

## 4 Independent assessment plan

4.0 *Introductory explanations for the understanding, not to be present in the AsBo report (including the present “4.0 heading”)*

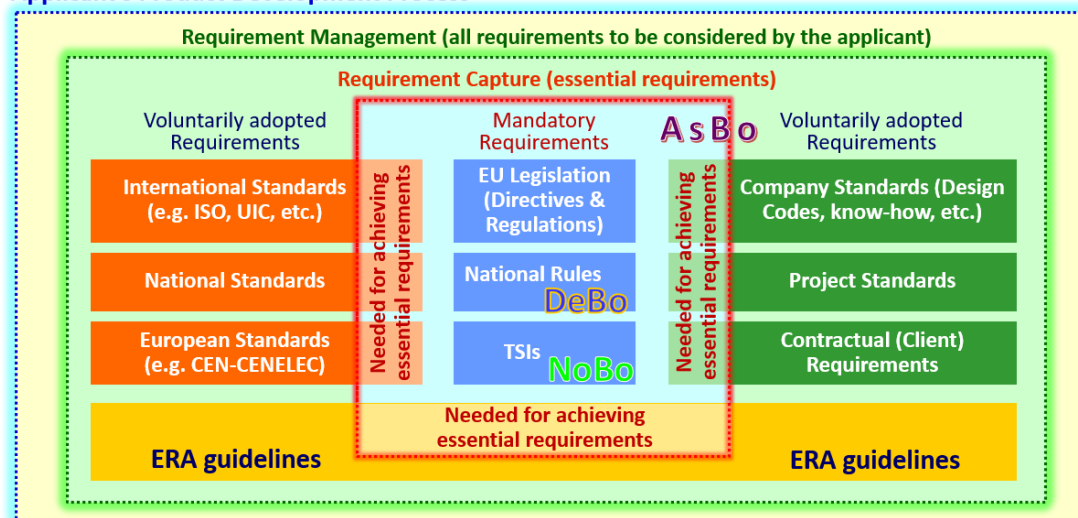
4.0.1 *This part of the report shall outline the main principles/steps of the independent assessment plan<sup>(2)</sup> (roadmap/overview) of the AsBo for building the AsBo expert judgement on the extent to which the applicant’s requirement capture process meets “all requirements” in Article 13 of Regulation 2018/545. This chapter shall contain the following two sub-heading:*

- (a) *independent assessment plan of the applicant’s requirement capture process [Articles 13(1) and 13(2) of Regulation 2018/545];*
- (b) *independent assessment plan of the applicant’s risk management process [Article 13(3) of Regulation 2018/545].*

4.0.2 **Important:** *the AsBo independent assessment plan is dependent on the applicant’s project organisation and evidence the applicant uses for demonstrating compliance with Article 13 of Regulation 2018/545. Regarding the independent assessment activities, it is likely to be different depending on whether the applicant uses, or does not use, inputs from other conformity assessment reports” (e.g. from NoBos, DeBos and other AsBos, where relevant) to support the demonstration of the correct implementation of its requirement capture process (refer to sections 3.5.1 and 3.5.2 above).*

4.0.3 **Reminder:** *as described in the ERA guide for the practical arrangements for the vehicle authorisation process (Ref. ERA1209-200), and in the ERA clarification note on requirement capture (Ref. ERA1209-146), “all requirements” in Article 13 of Regulation 2018/545 include the following categories of requirements, as represented in the figure below:*

**Applicant’s Product Development Process**



**Figure 1: Requirements to be covered by the applicant’s requirement capture process.**

- (a) 1<sup>st</sup> category: *all applicable European and national legislation including:*
  - (1) *TSIs and notified national rules (NRs) for vehicle authorisation, the conformity of which is to be assessed respectively by the NoBo and by the DeBo;*
  - (2) *any additional requirements from applicable European and national legislation other than TSIs or notified national rules for vehicle authorisation.*

<sup>(2)</sup> *If necessary for the mutual recognition of the AsBo independent assessment report, on demand the complete independent assessment plan shall be made available to an authorising entity, or to another conformity assessment body, with the prior permission of the applicant (refer to the confidentiality clause in section 4.2 of the ISO/IEC 17020:2012 standard).*

*Note 1: this 1<sup>st</sup> category contains the essential requirements ‘safety’ related to the vehicle and sub-systems explicitly specified in the applicable European and national legislation. Those are a part of safety related requirements. Compliance with Article 13(3) of Regulation 2018/545 will systematically identify all safety requirements necessary to enable the vehicle to fulfil the intended objectives safely.*

*Note 2: [this hyper link provides further information on other applicable EU legislation](#)*

*Examples of such additional applicable requirements (non-exhaustive list) the applicant’s requirement capture process has to consider:*

- (i) Directive 2014/30/EU on electromagnetic compatibility;*
  - (ii) Directive 2010/35/EU on transportable pressure equipment;*
  - (iii) Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment;*
  - (iv) Directive 2014/68/EU making available on the market of pressure equipment);*
  - (v) etc.*
- (b) 2<sup>nd</sup> category: any relevant standards, codes of practice and guidelines applicable to the project, which are necessary to address the essential requirements;*
- (c) 3<sup>rd</sup> category: any other safety requirements (i.e. additional safety related requirements to be identified when complying with Article 13(3) of Regulation 2018/545), not specified in the applicable European and national legislation, but which are crucial for either:*
- (1) the safe integration between the vehicle sub-systems, as well as of the vehicle within its operational, maintenance and environmental contexts of the railway system;*
  - (2) the control of all risks arising from the design/upgrade choices related to the vehicle and/or vehicle type.*

*4.0.4 When the applicant appoints a single AsBo for the independent assessment of the entire requirement capture process defined in Article 13 of Regulation 2018/545 (case covered by the present RFU), the AsBo independent assessment activities are expected to cover:*

- (a) the applicant’s process for the capture and management of all requirements necessary to achieve the essential requirements, regardless of the category of those requirements;*
- (b) regarding the essential requirements related to safety and safe integration:*
  - (1) the correct implementation by the applicant of the risk management process set out in Annex I of the CSM RA as requirement capture methodology, and;*
  - (2) the suitability of the results from that risk management process to enable the vehicle and/or vehicle type to fulfil the intended objectives safely.*

*4.0.5 The overview of the AsBo independent assessment plan shall thus enable the authorising entity to understand, without requesting additional explanations to the applicant, how the AsBo builds its expert judgement regarding the compliance with the entire Article 13 of Regulation 2018/545.*

*4.0.6 The assessment plan summarised in this chapter does not relate to other contractual agreements that can exist between the AsBo and the applicant concerning for example the coordination and management of the independent assessment activities during the project. If needed, other specific documents should address separately such contractual arrangements. They do not need to be documented in the present report.*

*4.0.7 Note: it is also normal practice that both the assessment plan and detailed assessment activities are updated in the course of assessment, e.g. based on the identified issues, during in-depth assessments of the selected highest risk areas.*

**4.1 Overall strategy and methodology for the independent assessment of the applicant’s requirement capture process [Articles 13(1) and 13(2) of Regulation 2018/545]**

**4.1.1 This part of the report is expected to summarise the AsBo plans for:**

- (a) the assessment of whether the applicant has a systematic process that fully covers Article 13(1) of Regulation 2018/545, i.e. the identification, management, and demonstration of the implementation and validation of the requirements the vehicle shall fulfil.*

- (b) *the assessment of the effectiveness of the applicant's process to capture and manage all applicable requirements, and of whether any identified requirement is effectively considered down through the entire development process.*
- (c) *the assessment of whether the applicant has adequate documentary evidence for demonstrating the compliance with all steps of its requirement capture process, including the validation of the correct implementation of all requirements, and;*
- (d) *the expert judgement of the suitability of the applicant's requirement capture process, and of its results, to enable the fulfilment by the vehicle and/or the vehicle type of all the necessary requirements applicable to its design (see Article 13(1) and Article 13(2) of Regulation 2018/545).*

4.1.2 When the applicant uses inputs/evidence from other conformity assessment reports (e.g. from NoBos, DeBos and other AsBos, where relevant) to support the requirement capture process for any category of requirements in section 4.0.3 above (e.g. to demonstrate the implementation of TSIs and notified national rules for vehicle authorisation), the AsBo independent assessment plan shall describe:

- (a) *how the AsBo plans to consider, mutually accept, and incorporate the results of the assessment reports produced by those other bodies, to avoid duplicating the assessments already carried out by those other bodies;*
- (b) *using the working method described in the recommendation for use N° 01, whether the AsBo intends to carry out additional sample checks, and for which parts of the applicant's requirement capture process (i.e. for bullet (a)(2) and (b) in section 4.0.3 above and);*
- (c) *etc.*

4.1.3 **Important note:** *the description on how the AsBo considers the results from other conformity assessment bodies 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 or AsBo on the same project). The selected company shall comply with the respective requirements regarding the relevant documentary evidence (files, certificates or reports) in compliance with the prescriptions of every one of those roles.*

4.2 Overall strategy and methodology for the independent assessment plan of the applicant's risk management process [Article 13(3) of Regulation 2018/545]

4.2.1 This part of the report is expected to summarise the AsBo plan for the assessment of both:

- (a) *the correct application of the risk management process in Annex I of the CSM RA (Article 13(3) of Regulation 2018/545), and*
- (b) *the suitability of the results from the applicant's risk management process to enable the vehicle and/or vehicle type to fulfil the intended objectives safely.*

4.2.2 This part is expected to include the plans for:

- (a) *the assessment of the applicant's compliance with the quality and safety management processes used for carrying out the risk management activities;*
- (b) *the assessment of competence of the applicant's staff in charge of the risk management activities;*
- (c) *where the applicant reuses the results of assessment reports produced by other bodies (NoBo, DeBo or other AsBos, e.g. on-board CCS sub-system), to avoid the duplication of assessments already carried out by those other bodies, describe how the AsBo takes into account those results in its independent assessment;*
- (d) *the use of judgement-based sampling and vertical slice-assessment techniques, as well as the methodology and criteria applied for selecting the key areas/highest risks for in-depth assessments, or another approach for assessing the applicant's compliance with the risk management process;*
- (e) *the combined use of inspections of documents, complemented by audits or interviews;*
- (f) *if the independent assessment activities are limited to inspections of documents, the reasons for not cross-checking the actual application of the processes by competent staff, e.g. through audits/interviews with the applicant's staff;*
- (g) *the ways to report to the applicant the issues identified along the project (e.g. verbally, via telephone, using e-mails, etc.) to enable the applicant to take timely any necessary remedial actions, without prejudice for the obligation of a written and formal AsBo report, and;*

- (h) *the way to assess and follow-up the adequacy of the applicant's remedial actions for addressing those issues.*
- (i) *finally, the expert judgement of whether the vehicle and/or the vehicle type can be used safely within its operational, maintenance and environmental context.*

#### 4.3 Independent assessment team

4.3.1 *List the personnel involved in the assessment activities and their respective roles in the AsBo team*

## 5 Evidence of independent assessment activities

5.0 *Introductory explanations for the understanding, not to be present in the AsBo report (including the present "5.0 heading")*

5.0.1 *This chapter shall give the evidence and the overview of the actual activities the AsBo carried out for implementing the independent assessment plan summarised in chapter 4 above. It shall reflect the results of the assessment of the applicant's project organisation, and of the implementation of its safety and quality processes for the management of the design of the vehicle/vehicle type. The chapter shall provide clearly the evidence of the independent assessment activities for all categories of requirements presented in bullet points (a), (b) and (c) in section 4.0.3 above of the report.*

5.0.2 *According to the AsBo independent assessment plan to be summarised in chapter 4 above, this chapter shall contain the following two separate parts:*

- (a) *evidence of independent assessment of the applicant's requirement capture process [Articles 13(1) and 13(2) of Regulation 2018/545];*
- (b) *evidence of independent assessment of the applicant's risk management process [Article 13(3) of Regulation 2018/545].*

5.1 *Evidence of independent assessment activities of the applicant's requirement capture process [Articles 13(1) and 13(2) of Regulation 2018/545]*

5.1.1 *Considering point 18.1 in Annex I of Regulation 2018/545, the evidence of the independent assessment of the applicant's requirement capture process by the AsBo is expected to address at least the following points of Regulation 2018/545:*

- (a) **Article 13(1)(a):** *evidence of the identification by the applicant of all requirements (European and national legislation, national standards, company standards, etc.) applicable to the design of the vehicle and/or the vehicle type for meeting the essential requirements. This includes the evidence of checks of:*
  - (1) *the incorporation by the applicant of all identified requirements into the specifications of the vehicle (System Definition);*
  - (2) *the registration of all those identified requirements into an appropriate centralised tool (repository), either a physical tool (e.g. paper or electronic documentation) or any IT tool that the applicant judges appropriate (e.g. table, database, register, etc.) subject to proper configuration management. Where the applicant uses databases and IT tools as part of its requirement capture process, the AsBo shall have evidence of the assessment of the relevance of those tools to fulfil the requirements in Article 13(1) of Regulation 2018/545 [e.g. a documented description – preferably by the applicant – of the interactions between those tools to fulfil Article 13(1) and their assessment by the AsBo];*
- (b) **Article 13(1)(b):** *evidence of the assignment by the applicant of those requirements down to functions, subsystems, equipment of the breakdown structure of the vehicle architecture, or export any necessary conditions for use or other restrictions;*
- (c) **Article 13(1)(c):** *evidence of the correct implementation by the applicant of all identified requirements through all of the four key steps of the development process of the vehicle, as listed in Article 13(1) of Regulation 2018/545.*
- (d) **Article 13(1)(c):** *evidence of the verification and validation by the applicant of the implementation of all requirements, implying that the applicant has documentary evidence available regarding:*

- (1) *the compliance with every step of the development process of the vehicle, as listed in Article 13(1) of Regulation 2018/545;*
- (2) *the vehicle compliance with the related essential requirements.*

5.1.2 *Regarding the requirements of category (a)(1) in section 4.0.3 above, it is likely that the applicant will refer to the conformity assessments carried out by the NoBo for the compliance with the applicable TSIs, and by the DeBo for the compliance with the applicable notified national rules for vehicle authorisation. In that case, the AsBo is expected to refer to the conformity assessment reports of those two bodies that it mutually accepts.*

5.1.3 *Regarding the requirement capture of the additional European and national legislation requirements not covered by the NoBo and the DeBo conformity assessments (i.e. categories in bullet points (a)(2) and (b) in section 4.0.3 above), the AsBo shall provide the evidence of independent assessment vs. the four steps of Article 13(1) of the Regulation 2018/545. It shall describe the sample checks it performed to build the expert judgement that those categories of requirements are also effectively processed using the same applicant's requirement capture process as the one used for the category in bullet point (a)(1) in section 4.0.3 above.*

## 5.2 Evidence of independent assessment activities of the applicant's risk management process [Article 13(3) of Regulation 2018/545]

5.2.1 *This part shall provide the evidence of independent assessment of the applicant's process for the capture and managements of requirements in bullet point (c) in section 4.0.3 above). The AsBo shall:*

- (a) *list and justify the key areas and samples the AsBo selected for in-depth assessment and verification of both the correct application of the risk management process in Annex I of the CSM-RA by the applicant, and the suitability of the results from the risk assessment;*
- (b) *indicate the date(s) of the independent assessment activities, as required in Clause 7.4.2(c) of the ISO/IEC 17020:2012 standard.*

5.2.2 *Regarding the identified issues, they are to be reported in chapter 6.*

5.2.3 *This RFU does not impose any mandatory sub-structure for providing the evidence that the independent assessment verifies the compliance of the applicant's risk management with the requirements of Annex I of the CSM-RA. This can be achieved in different ways, following for example every step of the risk management process in Annex I of the CSM-RA, or using any other equivalent structure (e.g. mapping the independent assessment activities onto the structure of the applicant's safety case specified in the CENELEC 50129 standard).*

5.2.4 *Whatever sub-structure the AsBo uses, it shall include a mapping/traceability table that provides the evidence of coverage (i.e. of an independent assessment) of every step of the risk management process in Annex I of the CSM-RA process:*

- (a) *system definition;*
- (b) *the applicant has quality and safety management processes in place for supporting the risk management activities;*
- (c) *the applicant assigns competent resources to the risk management;*
- (d) *management of interfaces and joint identification and control of risks across interfaces shared between sub-systems and/or other actors;*
- (e) *systematic and exhaustive hazard identification and, where applicable, classification into broadly, or non-broadly, acceptable risks;*
- (f) *registration of all identified hazards in a Hazard Record/Log;*
- (g) *choice of risk acceptance principle and risk evaluation:*
  - (1) *use of Codes of practice (CoP);*
  - (2) *comparison to similar Reference Systems;*
  - (3) *explicit risk estimation;*
- (h) *comparison with risk acceptance criteria (risk evaluation step);*
- (i) *setting of safety requirements to be implemented;*
- (j) *hazard Management through a Hazard Record/Log;*
- (k) *demonstration of compliance with the safety requirements;*
- (l) *check of overall risk management process and of the safe integration;*

## 6 Results from the independent assessment

6.0 *Introductory explanations for the understanding, not to be present in the AsBo report (including the present “6.0 heading”)*

6.0.1 *This chapter shall provide a list of all issues and AsBo observations regarding:*

- (a) *the overall applicant’s requirement capture process of the vehicle and/or the vehicle type [Articles 13(1) and 13(2) of Regulation 2018/545];*
- (b) *the applicant’s risk management process of the vehicle and/or the vehicle type [Article 13(3) of Regulation 2018/545]*

6.0.2 *This RFU does not impose any mandatory sub-structure for providing the results of the independent assessment of those two processes, as long as the identified issues are clearly separated between those two processes in all sections below. An acceptable option (not mandatory) is the use of separate sub-headings for each process [respectively on one hand for Articles 13(1) and 13(2), and on the other hand for Article 13(3) of Regulation 2018/545] in every part of chapter 6.*

6.0.3 *Depending on the project organisation described in section 3.2 above (see also section 4.0.2 above), sections below might need to reference the results of assessments carried out by other bodies, where those later ones interact with the AsBo independent assessment activities.*

6.1. *If relevant, issues from the AsBo independent assessment activities*

6.1.1 *There is no obligation to include by default the detailed history of issues that the AsBo identified, and the applicant successfully closed<sup>(3)</sup>, at the moment of delivering the AsBo report. Nevertheless, transparency is essential to build trust. So, the AsBo is requested to provide an overall statement and description of the main issues the independent assessment found out, and the applicant successfully addressed.*

6.1.2 *If any, detail the issues still open and the applicant’s plans for closing them, etc.*

6.1.3 *Using its own terminology, the AsBo shall categorise those open issues into either “blocking” ones, that prevent, or “non-blocking” ones, that do not prevent, the delivery of a positive assessment report. The AsBo shall justify why an issue is non-blocking.*

6.1.4 *Where for whatever reasons the AsBo sub-contracts any part of its independent assessment activities, according to Clause 7.4.4 of the ISO/IEC 17020:2012 standard, the AsBo shall clearly identify the results that are supplied by the sub-contractor(s).*

6.2 *If relevant, results from the assessments carried out by other conformity assessment bodies, or other parties*

6.2.1 *Based on the project organisation in chapter 3 above, where the AsBo uses results of conformity assessments carried out by other bodies, the AsBo shall justify the reasoning for using them. For example, when accepting results from:*

- (a) *other AsBos (e.g. in case of involvement by the applicant, or by its suppliers, of several AsBos on the same project, e.g. on-board CCS sub-system), but that are not sub-contractors of the AsBo which produces the present report;*
- (b) *the <NoBo ‘EC’ verification of conformity>;*
- (c) *the <DeBo verification of conformity vs. the applicable national rules>.*

6.3 *Non-blocking issues (if any) for the current project in future phases*

6.3.1 *Referring to section 6.1.3 above, and the terminology the AsBo uses for categorising the issues, the AsBo can adapt the title of this heading to its own terminology.*

<sup>(3)</sup> *If necessary for the mutual recognition of the AsBo independent assessment report, on demand the history log of identified and closed issues shall be made available to an authorising entity, or to another conformity assessment body, with the prior permission of the applicant (refer to the confidentiality clause in section 4.2 of the ISO/IEC 17020:2012 standard).*

6.4 Non-blocking issues (if any) for further improvements of quality, safety, requirement capture and risk management processes of the applicant for future projects (not in scope of current project)

6.4.1 *Referring to section 6.1.3 above, and the terminology the AsBo uses for categorising the issues, the AsBo can adapt the title of this heading to its own terminology.*

## 7 Conditions and limits for use

7.1 If relevant, conditions and limits for use from the AsBo independent assessment activities

- (a) *List, or where relevant provide the reference to, the safety related application conditions, limits of use of the independent safety assessment, the implications, etc. This shall include, where relevant, the conditions and limits for use transferred by the applicant, and not covered by the other conformity assessment bodies, or other parties. To avoid duplication of guidance text, please refer also to section 7.2.2 below;*
- (b) *These conditions and limits are the outcomes of the AsBo assessments covered by the present report. Where relevant, they shall include (e.g. a reference to) the limitations of the scope and assumptions of the AsBo independent assessment described in sub-heading 3.4 of the AsBo report;*
- (c) *State the timescales for the resolution of conditions and limits of use (if necessary).*

7.2 If relevant, conditions and limits for use transferred through the conformity assessment activities of other conformity assessment bodies, or other parties

7.2.1 *Based on the project organisation in chapter 3 above, it can happen that either the applicant's documentation, or the assessments carried out by other bodies, identify conditions and limits for use. They can be referenced in:*

- (a) *applicant's documentation;*
- (b) *reports of other AsBos (e.g. in case of involvement of several AsBos on the same project);*
- (c) *files of the <NoBo 'EC' verification of conformity>;*
- (d) *files of the <DeBo verification of conformity vs. the applicable national rules>.*

7.2.2 *The AsBo shall assess that the applicant has demonstrated that the vehicle and/or vehicle type can be used safely, maintained and safely integrated within the intended areas of use, with all those conditions and limits for use.*

7.2.3 *The AsBo independent assessment of the applicant's demonstration in section 7.2.2. shall confirm that the conditions and limits for use:*

- (a) *have an identified receiver (e.g. operator, maintainer, etc.);*
- (b) *are either accepted by the receiver, where the user of the vehicle and/or vehicle type is known during the project, or;*
- (c) *where the user is unknown, are self-evident (i.e. from the AsBo point of view understandable without access to other documents), unambiguous and complete;*
- (d) *do not contain references that their receivers are not able to access;*

7.2.4 *The AsBo shall provide a reference to:*

- (a) *the applicant's documentation which lists all conditions and limits for the safe use of the vehicle and/or vehicle type to be fulfilled by the user;*
- (b) *where relevant, the conditions and limits for use from the AsBo independent assessments in sub-heading 7.1 above, as well as the limitations of the scope and assumptions of the AsBo independent assessment described in sub-heading 3.4 of the AsBo report.*

## 8 Conclusions

8.1 Describe the conclusions from the independent assessment, and give a clear status of the project regarding the existence at the applicant, and the effective use of a systematic process for:

- (a) the requirement capture of the vehicle and/or the vehicle type [Articles 13(1) and 13(2) of Regulation 2018/545];
- (b) that applicant's process embeds the risk management process of Annex I of the CSM RA regarding the risk management of the vehicle and/or the vehicle type [Article 13(3) of Regulation 2018/545].

8.2 This RFU does not impose any mandatory sub-structure for providing the conclusions of the independent assessment regarding those two parts of the applicant's requirement capture processes, as long as the conclusions are clear for every part of Article 13 of Regulation 2018/545. An acceptable option (not mandatory) is the use of separate sub-headings for each process [respectively on one hand for Articles 13(1) and 13(2), and on the other hand for Article 13(3) of Regulation 2018/545].

8.3 For a final report, the AsBo shall:

- (a) give a clear statement on the existence of an applicant's requirement capture process and on its suitability for the vehicle and/or the vehicle type to meet all requirements in Article 13;

To fulfil that, without constraining the way to achieve the following, the AsBo conclusion shall clearly state whether the independent assessment covers all four steps, or just a part, of the applicant's requirement capture process of Article 13(1) of Regulation 2018/545.

That can be achieved for example by graphical means (putting the appropriate cross as proposed here), and then listing explicitly the steps of Article 13(1) of Regulation 2018/545 that the AsBo did not cover.

☐

**YES**, all 4 steps of Article 13(1) of Regulation 2018/545 are covered

☐

**NO**, not all 4 steps of Article 13(1) of Regulation 2018/545 are covered

When the "NO" option is checked, the AsBo is required to list explicitly the parts here below that the independent assessment did not cover.

| Steps of Article 13(1) of Regulation 2018/545   |               | Covered YES/NO |
|---|---------------|----------------|
| Identification  | Article 13(a) | YES/NO         |
| Assigned to functions or sub-systems, or addressed through conditions for use or other restrictions | Article 13(b) | YES/NO         |
| Implementation  | Article 13(c) | YES/NO         |
| Verification and Validation   | Article 13(c) | YES/NO         |

- (b) give a clear statement on both;

- (1) the compliance of the applicant's risk assessment process with the process in Annex I of the CSM RA, and;
- (2) the suitability of the results from that process to enable the vehicle and/or the vehicle type to be used safely within its operational, maintenance and environmental context. This fulfils the requirement in Clause 7.4.2(f) of the ISO/IEC 17020:2012 standard;

- (c) if relevant (most likely often the case), give a clear reference to the information required in section 7.2.4 above.

8.4 For an intermediate report, clearly describe the remaining issues and the outstanding independent assessments still to be carried out.

- |   |   |
|---|---|
| <b>Annex 1</b>  | <b>Abbreviations</b>  |
| <b>Annex 2</b>  | <b>List of applicant's documents used for the independent assessment</b>  |
| <b>Annex 3</b>  | <b>(Optional) Record and traceability of the assessment of applicant's documentation vs. Regulation 2018/545 and the risk assessment process in Annex I of Regulation 402/2013</b><br><i>This would then include the records produced by the AsBo during the independent assessment</i> |
| <b>Annex 4</b>  | <b>(Optional) History of identified issues closed by the applicant</b>  |
| <b>Annex 5</b>  | <b>Optional elements of the assessment report referenced in the informative Annex B of the ISO/IEC 17020:2012 standard</b>  |
| <b>Enclosure 1 (Optional) Independent assessment plan</b> |   |

#### 4. DECISION

|                                 |              |
|---------------------------------|--------------|
| <b>Decision of Cooperation:</b> | Accepted     |
| <b>Plenary meeting number:</b>  | 18           |
| <b>Date of decision:</b>        | 18 June 2024 |

#### 5. ANNEX

|   |  |
|---|--|
| <b>Additional details on the solution:</b><br>No further details needed |  |
| <b>Annex documents:</b>   | Annex A: Example of a detailed structure of the AsBo report in compliance with this AsBo-RFU |

## **Annex A Example of a detailed structure of the AsBo report in compliance with this AsBo-RFU**

See section 4.2 of the [ERA clarification note 1209-146 V1.2 on the requirement capture](#).