

1. REQUEST

Enquiry title:	Working method of the Assessment Body
Enquiry description:	
<p>1. The railway stakeholders across the EU, or even within the same company, have a different understanding of the requirements contained in Articles 3(14), 6(1) and 6(2) of Regulation 402/2013 and of those defined in the ISO/IEC 17020:2012 standard, concerning the CSM assessment body (AsBo). That creates confusion on the actual roles, responsibilities, and in particular the working method the assessment body should apply to perform the independent safety assessment requested in Article 6 of Regulation 402/2013 and the inspections required by the mandatory compliance with the ISO/IEC 17020 standard referred to in Annex II of Regulation 402/2013.</p> <p>(a) Some stakeholders and AsBos have a proper understanding of the requirements in Regulation 402/2013 and ISO/IEC 17020 standard concerning their roles, responsibilities, the extent and the depth of the independent safety assessment and of the inspection methods (sampling and vertical slice-analysis principles based on risk) to apply in order “to arrive at the expert judgement on the correctness of the application of the risk management process of the CSM RA and of the suitability or appropriateness of the results from the risk management to permit the system under assessment to fulfil safely the intended objectives”. The mutual recognition of the independent safety assessment report of such AsBos is possible without any additional checks by the accepting entity (e.g. an NSA or another AsBo).</p> <p>(b) Other stakeholders and some AsBos consider that the AsBos have rather a superficial role in checking just that the different steps of the risk management process of the CSM are gone through but without the necessity to carry out any detailed assessment of any part of the proposer’s risk management. Any deeper technical safety assessment is expected to be done by an ISA, i.e. a stakeholder who (with the exception of the CCS TSI) does not exist in the EU railway legislation. On one hand, the mutual recognition of the independent safety assessment report of such AsBos referred to in Article 15(5) of the CSM is not possible without additional checks. On the other hand, by virtue of the CSM RA, the responsibility to demonstrate the gaps of the ISA assessment with the requirements of the CSM RA and ISO/IEC 17020 is wrongly set up on the accepting entity (e.g. NSA or another AsBo) which has to accept in its decision the report of such AsBos.</p> <p>2. In order to permit the mutual recognition, it is necessary to avoid any wrong interpretation of the requirements in Regulation 402/2013 and ISO/IEC 17020 standard concerning the AsBo roles, responsibilities and the extent and depth of the assessment and inspection methods. It is therefore of common interest to further harmonise and better detail the different steps of the independent safety assessment work of the AsBo.</p>	
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Related documents:	
<p>{Ref. 1} Regulation 402/2013, Article 6</p> <p>{Ref. 2} Explanatory Note on the roles and responsibilities of the AsBo</p> <p>{Ref. 3} Recommendation for use 02 on a harmonised template for the AsBo safety assessment report</p> <p>{Ref. 4} Recommendation for use 03 on the AsBo technical knowledge and competence requirements for the different areas</p> <p>{Ref. 5} Recommendation for use 04 on a harmonised structure for the independent assessment report of the applicant’s requirement capture process, when the applicant appoints the same AsBo for assessing all scopes of Article 13 of Regulation 2018/545. RFU 04 is not published at the time of adoption of the present RFU.</p> <p>{Ref. 6} Recommendation for use 08 on the use by the AsBo of external experts and sub-contractors – Mutual recognition of reports from other conformity assessment bodies</p>	

{Ref. 7} [Recommendation for use 11 on Tracking \(identification, recording and closing\) of issues and non-compliances by the AsBo](#)

Those recommendations for use (RFUs), other RFUs still to be developed, and the Agency notes are available on the Agency web page under the following link https://www.era.europa.eu/common_safety_methods_for_risk_evaluation_and_assessment, in case the hyperlinks do not work.

2. TRACEABILITY

RFU number:	01
Version number:	2.0
Version comment:	Improvements to the RFU structure and clarifications to prevent potential misunderstanding, or misuses, of the recommended methodology.

3. SOLUTION

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Proposal for the working method of the Assessment Body (AsBo)	Cross reference in Reg. 402/2013, ISO/IEC 17020:2012 standard or another EU laws
0. Requirements for having a process for independent assessment	Art. 3(14), 6(2), & 15(1)
0.A. Prerequisites	
1. To implement the present recommendation for use 01, the AsBo must :	Art. 7, Ax II
(a) have the technical knowledge, and fulfil the competency requirements defined in the recommendation for use 03 for the scope(s) of its accreditation, or recognition.	§ 2 in Ax II Clause 6.1 in ISO/IEC 17020:2012

<p>For most of projects, especially for complex projects or for the independent assessment of the applicant's requirement capture process defined in Article 2(11) and Article 13 of (EU) Regulation 2018/545, that requirement cannot be fulfilled by a "one-person AsBo team"⁽¹⁾. An effective independent assessment of the correct application of the risk management process in Annex I of the CSM RA, and expert judgement of the appropriateness of the results from that process, will usually require the establishment of a multidisciplinary team with several people, with different and complementary competencies, including any relevant technical expertise as described later in this document.</p>	
<p>(b) track (identification, recording and closing) of issues and non-compliances it identifies according to the recommendation for use 11:</p>	<p>Bullet point (d)(ii) in Ax III</p>
<p>(c) comply with recommendation for use 08, in case of hiring in external experts, sub-contracting parts of its work, or accepting reports from other conformity assessment bodies;</p>	<p>Clauses 6.1 and 6.3 in ISO/IEC 17020:2012</p>
<p>(d) document its independent safety assessment activities, results and conclusions according to the recommendation for use 02.</p>	<p>Art. 15(1), Ax III</p>
<p>2. The independent assessment by an AsBo that the CSM RA requires can never be reduced to the sole assessment of the application of a risk management process by the proposer. Articles 3(14) and 6 of the CSM RA, as well as the ISO/IEC 17020:2012 standard referenced in Annex II of that CSM, also explicitly and above all require an expert judgment by the AsBo of whether the application of the process produces correct results (i.e. systematic hazard and risk identification and adequate control of the risks) to allow the system under assessment to fulfil safely the intended objectives.</p>	<p>Art. 3(14), Art. 6(1) Clause 6.1.2 in ISO/IEC 17020:2012</p>
<p>3. This RFU specifies the minimum acceptable framework for building such an expert judgement, based on traceable, transparent and verifiable evidence of the assessments carried out by the AsBo.</p>	<p>Art. 6(2), Art. 15(1), Art. 15(5) § 5.3 in Ax I</p>
<p>0.B. Requirements from the definition in Article 3(14)</p>	
<p>1. According to the definition of the assessment body in Article 3(14) of Regulation 402/2013, the independent safety assessment by an AsBo is about undertaking investigation "... to provide a judgement, based on evidence, of the suitability of the system..." under assessment "... to fulfil its safety requirements". The AsBo working method for this <u>investigation</u> needs thus to be structured to give the assurance that the proposer's organisation and processes for the risk management are effective in:</p> <p>(a) capturing (i.e. identifying) all reasonably foreseeable hazards arising from the significant change;</p> <p>(b) registering them in the hazard record/log;</p> <p>(c) understanding the hazards and the associated risks;</p> <p>(d) analysing those hazards, and the associated risks;</p> <p>(e) mitigating the risks to an acceptable level through appropriate safety requirements (risk control measures);</p> <p>(f) demonstrating the correct and effective management and implementation of the safety requirements identified by the risk</p>	<p>Art. 3(14) Art. 6(1) Art. 16 § 2.2.4, § 4.1.2 in Ax I</p>

(1) A one-person team is a team that has only one person as member of the team.

assessment, during the entire development and implementation ⁽²⁾ process of the change under assessment.	
0.C. Limits of the AsBo scope of work vs. the development process (design to implementation phases) of a change	
1. For specific projects ⁽³⁾ , it can happen that the design and implementation phases of the project take many years and are therefore assigned to different AsBos. In such cases, the AsBo assigned for the independent assessment of the design phase is not able to verify the correctness of the proposer's demonstration of compliance with the safety requirements.	§ 2.1.2(g), § 5.2(d) in Ax I Bullet point (c) in Ax III
2. The compliance with explicit safety ⁽⁴⁾ , and technical requirements ⁽⁵⁾ , defined in some TSIs requires also an independent assessment of the proposer's demonstration of compliance with those specific requirements. When the proposer appoints an AsBo only for those checks, the AsBo scope of work is limited. The AsBo is not able to verify the correctness of the other phases of the proposer's development process of the system under assessment.	Clause 6.2.3.5 in LOC & PAS TSI, Clause 6.2.6(c) in safety in railway tunnels (SRT) TSI Clause 7.1.4 in LOC&PAS TSI, Clause 7.2.2.4 in WAG TSI
3. For such specific cases, the AsBo shall clearly describe the boundaries of its independent assessment activities in its safety assessment report:	Bullet point (c) in Ax III
(a) What are the exact scope (e.g. the design phase) and limitations to the assessment of the proposer's demonstration of correct identification and management of the safety (or technical) requirements for the scope for which the AsBo has been contracted?	Bullet point (c) in Ax III § 2.1.2(g), § 5.2(d) in Ax I
(b) Which phase(s) of the development process (e.g. the implementation phase) is(are) not in the scope?	Bullet point (c) in Ax III § 2.1.2(g), § 5.2(d) in Ax I
(c) What are the limits, including the acceptability of any assumptions to be checked by the AsBo of the next phase of the project (e.g. at implementation phase)?	Bullet points (c), (d)(ii) and (e) in Ax III § 2.1.2(g), § 5.2(d) in Ax I
0.D. Requirements from Articles 6(2) and Article 15(1)	N/A
1. Human behaviour and human performance play a central role in the safe and efficient design, risk assessment, risk management, and where relevant, manufacturing, installation, operation and maintenance of the railway system.	§ 1.1.2, § 2.1.2(b)&(c), § 2.2.1 in Ax I § 2, § 3(a) in Ax II
2. Regulation 402/2013, and the ISO/IEC 17020:2012 standard referenced therein, do neither require, nor forbid the AsBo to perform a complete and thorough review of all details and outcomes of the proposer's (and of its sub-contractors) risk management activities. Nonetheless, as represented in Figure 1 below, focussing on a thorough review of 100% of outcomes of the	Art. 6(2) (b) and (c), § 1(a)&(c) in Ax I Clauses 6.1.2 and 7.1.2 in ISO/IEC 17020:2012

⁽²⁾ This includes the identification of the safety related application conditions (SRACs) for the safe integration and use of the change under assessment within the environmental, operational and maintenance context of the overall system. Usually, the next step of the proper consideration of those SRACs (e.g. with the SMS of a railway undertaking) is in the scope of another risk management that is independently assessed by another AsBo.

⁽³⁾ This can happen on large infrastructure projects spread over many years. As considerable time can elapse between the "design and implementation" phases of the project, the infrastructure manager might assign another AsBo for the implementation phase of the change. The AsBo assessing the design phase will thus not be able to verify the correctness and effectiveness of the proposer's management and implementation of safety requirements during the implementation phase of the change under assessment.

⁽⁴⁾ This concerns Clause 6.2.3.5 of the LOC & PAS TSI and Clause 6.2.6(c) of the safety in railway tunnels TSI.

⁽⁵⁾ This concerns Clause 7.1.4 of the LOC&PAS TSI, and Clause 7.2.2.4 of WAG TSI.

<p>proposer’s risk management activities is not the best, most effective and proportionate use of the AsBo time and resources available for carrying out the independent assessment activities. Such an AsBo working method :</p>	
<p>(a) does not give the assurance that the independent assessment will identify all non-compliances in the risk management outcomes, as this latter might fail to generate relevant outputs;</p>	<p>§ 2.2.1 in Ax I § 2, § 3(a) in Ax II</p>
<p>(b) does not enable the AsBo to identify the actual issues within the proposer’s organisation, safety and quality processes, project management, and any other deficiencies that can result in inappropriate, or absence of, outputs. All those elements (staff competencies, appropriate processes and correct application of those processes by the staff) are key for a correct application by the proposer of its risk management process and for deriving correct outputs, and;</p>	<p>Art. 6(2) (b) and (c) § 2, § 3(a) in Ax II</p>
<p>(c) does not enable to detect the variability of human performance, and the influence of human and organisational factors at all stages of the development and implementation process of the change under assessment.</p>	<p>Art. 6(2) (b) and (c) § 2, § 3(a) in Ax II</p>
<div style="text-align: center;"> <p>The diagram shows an iceberg floating in water. The tip of the iceberg, which is above the water surface, is labeled '[O] OUTCOMES' and 'Visible issues'. The much larger part of the iceberg is submerged below the water surface and is labeled '[P] PROCESSES' and '[S] STRUCTURE [STAFF / RESOURCES]' and 'Under the surface (hidden issues)'. To the left of the iceberg, there are two horizontal double-headed arrows: one labeled 'Available outcomes' pointing towards the tip, and another labeled 'Organisation in place for producing the outcomes' pointing towards the submerged part. Vertical double-headed arrows connect the tip to the submerged part, and the submerged part to the water surface. The entire diagram is enclosed in a dashed blue border.</p> </div> <p>Figure 1: SPO or risk-based independent assessment process.</p>	<p>Art. 6(2) (b) and (c), § 1(a)&(c) in Ax I Clauses 6.1.2 and 7.1.2 in ISO/IEC 17020:2012</p>
<p>3. Thereby, it is essential that the independent assessment aims to identify the hidden root causes that can result in producing inappropriate outcomes by the proposer’s risk management, including those arising from human and organisational factors. The AsBo working method shall thus assess all following three aspects of the proposer’s arrangements for the change management and risk management activities :</p>	<p>Art. 6(2) (b) and (c) § 1.1.2, § 2.1.2(b)&(c), § 2.2.1 in Ax I § 2, § 3(a) in Ax II</p>
<p>(a) the Structure/Staff, i.e. the competencies of the involved staff/resource;</p>	<p>§ 1.1.2</p>
<p>(b) the supporting safety and quality Processes;</p>	<p>Art. 6(2) (b) and (c) § 1(a)&(c) in Ax I</p>
<p>(c) (finally) the Outcomes, i.e. method and results of the risk assessment.</p>	<p>Art. 3(14), Art. 6(1), § 5.1 in Ax I, Clauses 6.1.2 and 7.1.2 in ISO/IEC 17020:2012</p>
<p>Note : as represented visually in Figure 1 above, although this structured way of proceeding is used in the healthcare domain, under the terminology [S P O approach, standing for Structure/Staff-Processes-Outcomes], it represents perfectly the three core aspects the AsBo independent assessment shall cover.</p>	<p>N/A</p>

<p>4. Having regard to the requirements contained in Article 6(2)⁽⁶⁾ and point 1.1.2⁽⁷⁾ in Annex I of Regulation 402/2013, and in Clause 7.1⁽⁸⁾ of the ISO/IEC 17020:2012 standard referred to in Annex II of that Regulation, the following can be concluded.</p> <p>To give the assurance that the proposer’s organisation and processes for the risk management are effective (see section 0.B. above), as represented in Figure 1 above, the AsBo working method shall be a four-step approach or process, which includes the SPO elements described in section 0.D.-3 above. The AsBo independent assessment process shall include the following four complementary steps (or key pillars) :</p>	<p>Art. 6(2), § 1.1.2 in Ax I ISO/IEC 17020:2012</p>
<p>(a) 1st step: the understanding of the change and of the proposer’s organisation (supporting safety and quality processes and staff in charge of risk assessment) for the change management and risk management. This shall be based on proposer’s documentation;</p>	<p>Art. 6(2)(a), § 1.1.1, § 1.1.4, § 1.1.6, § 2.1.1 & § 5.2(a) in Ax I</p>
<p>(b) 2nd step: the planning and prioritisation of the AsBo independent safety assessment activities, where necessary, revised/readjusted based on the findings identified during the independent assessment activities;</p>	<p>Points (b), (c), I in Ax III, Clause 7.1.2 in ISO/IEC 17020:2012</p>
<p>(c) 3rd step: the independent safety assessment of the correct application of the risk management process and of the suitability of the results from the risk management. This includes the gathering and reporting of the documented evidence of the identified non-compliances and the follow up of their management by the proposer;</p>	<p>Art. 6(1), Point (d) in Ax III, § 7.3, § 7.4.2(f) & Clause 7.4 in ISO/IEC 17020:2012</p>
<p>(d) 4th step: the delivery of the independent safety assessment conclusions and report to the proposer.</p>	<p>Art. 15(1), Ax III, Bullet point (e) in Ax III, § 7.4, Clause 7.4.2(f) in ISO/IEC 17020:2012</p>
<p>0.E. Usability of this RFU for the independent assessment by the AsBo of the applicant’s requirements capture process of a railway vehicle</p>	<p>Regulation 2018/545</p>
<p>1. As described in section IV.E-6 of the recommendation for use 03, an AsBo accredited or recognised for the rolling stock area in compliance with the requirements and criteria specified in RFU 03 has the necessary competency for carrying out the independent assessment of the proposer’s ⁽⁹⁾ requirement capture process defined in the (EU) Regulation 2018/545 on railway vehicle authorisations.</p>	<p>N/A</p>
<p>2. The working method described in this RFU allows the AsBo to carry out during the same independent assessment activities the checks of both :</p>	<p>N/A</p>
<p>(a) the applicant’s compliance with the CSM RA for the purposes of either the CSM RA, or Article 13(3) of (EU) Regulation 2018/545, and:</p>	<p>Art. 13(3) of Regulation 2018/545</p>

⁽⁶⁾ Article 6(2) of Regulation 402/2013 specifies the main steps of the independent safety assessment activities, without imposing any specific working method.

⁽⁷⁾ Point 1.1.2 in Annex I of Regulation 402/2013 requires that “the risk management process shall include appropriate quality assurance activities **and be carried out by competent staff**”.

⁽⁸⁾ Clause 7.1 of the ISO/IEC 17020:2012 standard referred to in Annex II of Regulation 402/2013 specifies that “the AsBo has and uses adequate documented instructions on « inspection planning » and on « sampling and inspection techniques » in order “to ensure ... the correct processing and interpretation of results” from the independent safety assessment activities.

⁽⁹⁾ When dealing with the authorisation of a railway vehicle, the term “proposer” of (EU) Regulation 402/2013 on the CSM RA corresponds to the term “applicant” of (EU) Regulation 2018/545 on railway vehicle authorisations.

(b) the existence and effective use of an applicant's process for the systematic capture and management of all requirements necessary for the design of the vehicle under assessment.	§ 18 in Ax I of Regulation 2018/545
3. Regarding the applicant's requirement capture process, this RFU does not, and shall not, require the AsBo to take over any extra responsibility to the ones already defined in the (EU) Regulation 2018/545 :	§ 18 in Ax I of Regulation 2018/545
(a) the applicant is the sole responsible for identifying, managing and demonstrating the implementation and validation of all requirements relevant for the vehicle (i.e. right ones and all necessary ones);	Art. 4 of Safety Directive 2016/798, Recital (5), Art. 50(1), (3) in Regulation 2018/545
(b) when the applicant appoints an AsBo for the independent assessment of its requirement capture process, the AsBo is responsible for providing an expert judgement, based on evidence, that:	§ 18(1), § 18(8), § 18(11) in Ax I, § 7, § 14, § 15, § 16 in Ax II, § 9, § 10, § 11 of Reg. 2018/545
(1) the applicant has a systematic process for the identification, management, and demonstration of the implementation and validation of the requirements that the vehicle shall fulfil, and;	§ 18(1), § 18(8), § 18(11) in Ax I, § 7, § 14, § 15, § 16 in Ax II, § 9, § 10, § 11 of Reg. 2018/545
(2) any requirements that the applicant's requirement capture process identifies is traced down through the development process of the vehicle life-cycle.	§ 18(1), § 18(8), § 18(11) in Ax I, § 7, § 14, § 15, § 16 in Ax II, § 9, § 10, § 11 of Reg. 2018/545
To fulfil this responsibility, compliance with Article 6(3) of the CSM RA requests the AsBo to avoid any unnecessary duplication of conformity assessments with those already carried out by a NoBo, a DeBo or an AsBo which independently assessed just the compliance with Article 13(3) of the (EU) Regulation 2018/545 or the risk management process in Annex I of the CSM RA.	Art. 6(3) (of CSM RA)
(c) as the (EU) Regulation 2018/545 " <u>does not contain</u> " any legal requirement regarding the following points, it shall be understood that :	N/A
(1) the AsBo is neither responsible for judging the adequacy (i.e. the correctness of the requirements) and the completeness (i.e. that the identification is complete), nor for validating the requirements identified by the applicant;	No explicit legal basis for such an AsBo role in Reg. 2018/545
(2) the AsBo is not responsible for the approval of the NoBo and DeBo conformity assessments, who are fully responsible for the correctness and conclusions of their conformity assessments with the applicable TSIs and national rules;	No explicit legal bases for such an AsBo role in Safety Dir. 2016/798, Interop. Dir. 2016/797 and in Reg. 2018/545
(3) the AsBo is not responsible for the closing by the applicant of any non-compliances with the applicable TSIs and national rules reported by the NoBo and the DeBo.	No explicit legal bases for such an AsBo role in Safety Dir. 2016/798, Interop. Dir. 2016/797 and in Reg. 2018/545
The AsBo is not responsible for allowing the applicant to deviate from the applicable TSIs or national rules. Instead, the AsBo is expected, if so requested by the applicant, to independently assess the applicant's demonstration for the safe use of the vehicle, with clearly identified safety-related conditions, despite the identified non-compliances with the applicable TSIs or national rules.	No explicit legal bases for such an AsBo role in Safety Dir. 2016/798, Interop. Dir. 2016/797 and in Reg. 2018/545

In case of non-compliances, the Authorising Entity remains the sole responsible for not issuing, or for issuing with or without restrictions, the authorisation for placing the vehicle on the market, based on the results of the conformity assessments carried out by the NoBo, DeBo and AsBo. The (EU) Regulation 2018/545 does not lay that responsibility down on the AsBo.	Interoperability Directive 2016/797 and Reg. 2018/545
4. Regarding the terminology used in this RFU, for the independent assessment of the applicant's requirement capture process, the AsBo shall have in mind that :	N/A
(a) the term "proposer" shall be understood as "applicant";	N/A
(b) "independent assessment of safety" shall be understood as "independent assessment of the requirement capture";	N/A
(c) "risk management process in Annex I of the CSM RA" shall be understood as "requirement capture process" the applicant puts in place for complying with the requirements in Article 13(1) of Regulation 2018/545.	N/A
I 1st step : understand the change and the proposer's organisation for the change management and risk management	Art. 6(2)(a), § 5.2(a) in Ax I
1. Based on documentation provided by the proposer, the AsBo must get a clear and thorough understanding of the following :	Art. 6(2)(a)
(a) the scope and context of the significant change under assessment;	Art. 6(2)(a)
(b) the proposer's plans and organisation for the management of the change and of the risk management activities.	Art. 6(2)(b), § 1.1.1, § 2.1.1, § 1.1.4, § 1.1.6 & § 5.2(a) in Ax I
This is essential for planning proportionately the intensity of the independent safety assessment activities and to determine the particular areas where in-depth assessments are to be carried out.	Clause 7.1.2 in ISO/IEC 17020:2012
2. To do that, the AsBo usually needs the following information :	Art. 6(2)(a)
(a) the complete system definition of the change as required in point 2.1.2 in Annex I of Regulation 402/2013, including the interfaces and interactions with both the other parts of the railway system and human operators, and with other actors impacted by the change through those interfaces;	Art. 6(2)(a), § 1.1.6, § 1.2.1 & § 2.1.2 in Ax I
(b) the description of the proposer's (and sub-contractor's, if any) safety and quality processes in place for managing the change, including in particular their risk assessment and risk management planning;	Art. 6(2)(b), § 1.1.6 & § 1.1.2 in Ax I
(c) the description of the organisation ⁽¹⁰⁾ , the project management and the risk management. This requires the proposer's description of the roles of all involved actors (including the sub-contractors [if any] and those	Art. 6(2)(b), § 1.1.6, § 1.1.2, § 1.2.3, § 1.2.4, & § 5.2(a) in Ax I

⁽¹⁰⁾ The term organisation refers here to the proposer's (project) organisation, including the safety and quality processes and assigned resources and responsibilities, actually put in place by the proposer for managing the development, the risk assessment and risk management of the significant change under assessment. It does not refer to the overall organisation of the proposer's company. Where the CENELEC 50126, 50128, 50657 and 50129 standards are used as Codes of Practice for controlling the identified hazards, the project organisation is expected to describe how the compliance with the CENELEC Safety Integrity Levels, and the associated levels of independency of project development activities, is achieved for the hazards and risks arising from the change under assessment. By virtue of point 3.3 in Annex I of Regulation 402/2013, the

impacted through the interfaces [see section I-2(a) above]) and of the competencies of the experts appointed for carrying out the risk management process for the change.	
II 2nd step : plan and prioritise the AsBo independent safety assessment activities	Clause 7.1 in ISO/IEC 17020:2012
1. The aim of the independent safety assessment plan is to highlight the key milestones of the independent safety assessments necessary for ensuring a thorough assessment of the change, of the results of every step of the risk management process in Annex I of the CSM and the completion of the project on time, having in mind the potential hidden root causes that can threaten the success of the risk management (see the previous two chapters).	Point (b) in Ax III Clause 7.1.2 in ISO/IEC 17020:2012
Note: the AsBo strategy for the independent safety assessment activities does not need to be communicated to the proposer in detail to avoid that the proposer's risk management activities are focussed to the areas of high interest for the AsBo. It does not cover the contractual agreements that can exist between the AsBo and the proposer for coordinating the management of the independent safety assessment. Specific documents should address such contractual arrangements separately.	N/A
2. Considering that independent safety assessment is an inspection activity within the framework of Article 6(2) of Regulation 402/2013 and Clause 7 of the ISO/IEC 17020:2012 standard, it is to be based on the AsBo perception of the risks arising from the change and thus on risk prioritisation and professional judgement ⁽¹¹⁾ by the AsBo, independently on the proposer's risk classification. It is thus possible, that the perception of risks by the AsBo differs from the proposer's one. In order to provide the assurance described in section O.B. above, the AsBo independent safety assessment strategy must :	Point (b) in Ax III, Clause 7.1.2 in ISO/IEC 17020:2012
(a) cover all steps of the risk management process, and assess the correct application of the risk management process and the suitability of the results from the application of that process, but also;	Art. 6(1), Art. 6(2)(c), § 1.1.7, § 2.2.2, § 2.3.8(d) in Ax I
(b) cover all phases and activities of the proposer's organisation and management of the change (i.e. applying the SPO approach described in section O.D. above), as well as the proposer's demonstration of the control of all risks to an acceptable level.	Art. 6(2)(c), § 1.1.7, § 3.3 in Ax I § 2.3 when CoP used § 2.4 when Ref. Syst. used § 2.5 when explicit estim.
3. In practice, the planning of the AsBo independent safety assessment activities is done as an integrated part of the assessments done in section III.A below. Before starting the independent safety assessment, the AsBo has to review beforehand and to understand thoroughly all the inputs listed in section I above. Based on that documentary review, the AsBo has to produce the "independent safety assessment" plan ⁽¹²⁾ that will drive its activities.	Art. 6(2)(a), § 1.1.6, § 1.1.2 & § 5.2(a) in Ax I, (b) in Ax III, Clause 7.1.2 in ISO/IEC 17020:2012

AsBo is required to independently assess whether the project organisation matches with the applicable Safety Integrity Levels.

⁽¹¹⁾ "Professional judgement" refers to the knowledge, competence, skills and experience of the AsBo in the fields of risk assessment and risk management needed to arrive at a judgement, based on evidence, of the suitability of the system under assessment to fulfil its safety requirements.

⁽¹²⁾ Depending on the identified issues and non-compliances, the AsBo might decide to update and re-plan the priorities for the independent safety assessment activities initially planned as described in sections II-4, II-5, II-6 and II-7.

<p>Although the assessment plan has to cover and to include the assessment of every step of the risk management process of Regulation 402/2013 and of its flowchart, it shall not be limited to that. In practice, as explained in sections O.D. and I above, the setting up of the plan for the independent safety assessment will permit the AsBo to achieve all the following :</p>	
(a) a thorough understanding of the significant change.	Art. 6(2)(a)
<p><i>Although it is not to be part of the AsBo assessment, any available information that the proposer agrees to share with the AsBo about its decision on the significance of the change can help the AsBo to better understand the change;</i></p>	N/A
(b) the understanding of the proposer’s organisation (staff competencies and supporting safety and quality processes) for the management of the change and of the risk management;	Art. 6(2)(b), § 1.1.6, § 1.1.2 & § 5.2(a) in Ax I
(c) description of the AsBo methodology for assessing the correct application and correct management of the risk management by the proposer, in accordance with both the requirements of Regulation 402/2013 and the proposer’s supporting safety and quality processes. This includes the description of :	Points (b) & (d) in Ax III, Clause 7.1.2 in ISO/IEC 17020:2012
(1) the assessment of the correct application of the proposer’s risk management process and of the suitability of the results from that process;	Art. 6(1), § 2.3 when CoP used, § 2.4 when Ref. Syst. used, § 2.5 when explicit estim.
(2) the gathering and reporting of documented evidence of the identified non-compliances with respect to both Regulation 402/2013 and the proposer’s safety and quality processes, and then;	Art. 6(2)(c), (d) in Ax III, Clause 7.3 in ISO/IEC 17020:2012
(3) the follow up of the proper management by the proposer of those non-compliances, or in case the proposer does not accept some non-compliances, a clear identification of the open issues in the AsBo final safety assessment report;	Art. 15(1), (d)&(e) in Ax III,
(d) have a clear view on the set of activities to be completed for the delivery of the independent safety assessment conclusions and report.	Art. 6(1), Art. 6(2)(b) & (c), (b) in Ax III, (d) in Ax III, Clause 7.1.2 in ISO/IEC 17020:2012
<p>4. As mentioned above, independently of the proposer’s risk classification, the areas the AsBo considers as highest or most critical risks should undergo thorough independent safety assessment.</p> <p>Inspection activities as meant by Clause 7.1.2 of the ISO/IEC 17020:2012 standard and Article 6(2) of Regulation 402/2013 require the AsBo to exercise professional judgement and a risk-based approach to determine (i.e. to select) the areas of highest or most critical risk(s) from its perspective. This is known as “judgement-based sampling⁽¹³⁾ technique” in standards on inspections. The AsBo shall then carry out on those “samples” an in-depth independent assessment to determine whether the perceived risks are adequately addressed by the proposer’s processes and by their application of those processes.</p>	Art. 3(14), § 2.2.3, (b) in Ax III, “Introduction” & Clause 7.1.2 in ISO/IEC 17020:2012

⁽¹³⁾ According to point A.6.2. of the ISO 19011:2018 standard, providing guidelines for auditing management systems, “judgement-based sampling” relies on the competence and experience of the audit team.

<p>IMPORTANT :</p> <p>“Judgment based sampling”, “sample checks” or “independent assessment of selected samples” result therefore from the AsBo professional judgement and a risk-based selection of the most representative areas, testifying the correct application and effectiveness of the proposer’s risk management process.</p> <p>“Judgment based sampling” <u>shall not be understood as pure “spot/random-checking”</u>, or for checking quickly for problems by randomly looking just at “a few things”, papers or outcomes of the proposer’s risk management activities.</p> <p>On the contrary, “sample checks” refers to the need for a systematic and in-depth assessment, through every step of the proposer’s risk management process, of the correct assessment of functions and risks of the system under assessment, and the acceptable control of associated risks that could potentially result in collisions, derailments or other types of well-known railway accidents (see below the selection technique of “samples”).</p>	<p>Art. 3(14), “Introduction” & Clause 7.1.2 in ISO/IEC 17020:2012</p>
<p>5. The selection, actual extent and level of detail of the independent safety assessment of all risks the AsBo considers necessary to assess is at the sole discretion and expert judgement of the AsBo. It is thus possible, that the perception of risks by the AsBo differs from the proposer’s one. This is important for the AsBo in order to check also the correct identification and the proper control of such risks by the proposer.</p>	<p>Art. 3(14), Art. 6(2) Clauses 6.1.2 and 7.1.2 in ISO/IEC 17020:2012</p>
<p>6. In practice, for selecting the areas or samples for in-depth independent assessment, the AsBo will consider the following risks :</p>	<p>Art. 3(14), Art. 6(2) Clauses 6.1.2 and 7.1.2 in ISO/IEC 17020:2012</p>
<p>(a) risks related to the organisation (including staff competencies), application and effectiveness of the safety and quality processes for managing the change;</p>	<p>Art. 6(2)l, § 1.1.5, § 1.2.7, § 1.2.1, § 5.2(a) in Ax I</p>
<p>(b) risks related to an incorrect application of the risk management process of the CSM;</p>	<p>Art. 6(1), § 1.1.7 in Ax I</p>
<p>(c) all risks arising from the change which could potentially result in collisions⁽¹⁴⁾, derailments⁽¹⁵⁾ or other types⁽¹⁶⁾ of well-known railway accidents and with catastrophic or critical consequences, if those risks are not properly identified and managed by the proposer.</p>	<p>Art. 3(14), § 2.2.3, (b) in Ax III, “Introduction” & Clause 7.1.2 in ISO/IEC 17020:2012</p>
<p>(d) other categories of risks having less serious consequences shall not be disregarded. Those risks may also warrant independent safety assessment; usually a lower level of detail in their assessment is acceptable.</p>	<p>Art. 3(14), § 2.2.3, (b) in Ax III, “Introduction” & Clause 7.1.2 in ISO/IEC 17020:2012</p>
<p>Remark: the risks in bullet points (a) and (b) can also result in the accidents listed in point (c). It is thus important they are also independently assessed, applying the SPO approach described in section 0.D. above).</p>	<p>Art. 3(14), (b) in Ax III, “Introduction” & § 7.1.2 in ISO/IEC 17020:2012</p>

⁽¹⁴⁾ *Types of collisions : head on collisions, rear collisions, slanting/ lateral collisions, collisions with buffer stops, collisions with obstructions/ obstacles on the track (which may also cause derailment).*

⁽¹⁵⁾ *Types of derailments : plain track, curves, junctions.*

⁽¹⁶⁾ *Other types of railway accidents : level crossings, fires, explosions and releases of dangerous chemicals (when operating dangerous goods), people falling from trains, collisions with people on the tracks, etc.*

7. The use of a risk-based strategy and professional judgement for setting up the priorities for the independent safety assessment activities enables the AsBo :	Art. 3(14), (b) in Ax III, "Introduction" & Clause 7.1.2 in ISO/IEC 17020:2012
(a) to focus the thorough assessment efforts on the areas the AsBo considers to be the highest or most critical risks, and;	Art. 3(14), (b) in Ax III, "Introduction" & Clause 7.1.2 in ISO/IEC 17020:2012
(b) to ensure that the level of the independent safety assessment activity is proportionate to the level of : (1) the risks arising from the change; (2) the risks arising from the management and the organisation of the change by the proposer;	Art. 3(14), (b) in Ax III, "Introduction" & Clause 7.1.2 in ISO/IEC 17020:2012,
(3) the risks arising from the interfaces and the interactions of the change under assessment with both the other parts of the railway system, human operators, and with other actors impacted by the change through those interfaces.	§ 1.1.5, § 1.1.6, § 1.2.1, § 1.2.3, § 1.2.4 & § 1.2.7 in Ax I
8. To make possible the mutual recognition of the AsBo independent safety assessment report, according to the recommendation for use 02 (RFU 02), the final report shall include a summary of the independent safety assessment plan built in section II above, a description of what was actually assessed and the reference of the complete independent safety assessment plan ⁽¹⁷⁾ . For more details, see the RFU 02.	(b) in Ax III
III 3rd step : carry out the independent safety assessment, gather evidence and follow up the proposer's action plan(s)	
III.A Execution of the assessment plan and strategy	
1. Once the AsBo has understood the significant change, and the proposer's organisation for the change management and risk management, the AsBo must implement the independent safety assessment strategy set out in its plan in section II-3 above. This implies that the AsBo has to carry out all activities below.	Art. 6(2)(b) and (c) Art. 6(2)(a), § 1.1.6, § 5.2(a) in Ax I
III.B Independent assessment of the proposer's plans and organisation for managing the change	
1. If the safety and quality processes are not already certified by a relevant conformity assessment body, the AsBo has to conduct an assessment of the proposer's organisation, safety and quality processes in place (i.e. the inputs provided to the AsBo in section I above) the proposer intends to use for managing the design and the implementation of the significant change. <i>In practice the AsBo will carry out those assessments during the setting out of the independent safety assessment plan and strategy in sections I and II above.</i>	Art. 6(2)(b), § 1.1.6 in Ax I

⁽¹⁷⁾ *If necessary for the mutual recognition of the AsBo independent safety assessment report, on demand the complete independent safety assessment plan shall be made available to an authorising entity, or to another conformity assessment body, with the prior permission of the proposer (refer to the confidentiality clause in Clause 4.2 of the ISO/IEC 17020:2012 standard).*

<p>2. If the proposer's organisation and safety and quality processes are already certified by a relevant conformity assessment body (e.g. an RU/IM safety management system certified by either the national safety authority, or ERA), the AsBo shall not reassess them but anyway must understand thoroughly the organisation and those processes in order to carry out the assessments in section III.C-2 below.</p> <p>Note: The proposer's demonstration of the correct application of those safety and quality processes for the change under assessment remains an essential part of the independent safety assessment by the AsBo (see section III.C below and section O.D.-3 above).</p>	§ 1.1.4, § 5.2(a) in Ax I
<p>3. It is to note that if the proposer sub-contracts the risk management or a part of it, the sub-contractors are considered being part of the "proposer's organisation" regarding the AsBo assessment. So, the proposer remains responsible for ensuring that the sub-contractors perform the risk management according to the proposer's safety and quality management systems. The AsBo will have to assess its correct fulfilment by the sub-contractors.</p>	Art. 5(2), § 3.1, § 3.2 & § 3.3 in Ax I
<p>III.C Independent assessment of the actual implementation and management of the change</p>	Art. 6(2)(c), § 5.2(a) in Ax I
<p>1. This consists in conducting an assessment⁽¹⁸⁾ of the actual organisation and actual management of the significant change by the proposer, using the supporting proposer's safety and quality processes. It includes the assessment of the correct application of the provisions and requirements of Regulation 402/2013 for every step of the risk management process in Annex I of the Regulation. In order to do so, the AsBo shall carry out the tasks below.</p>	Art. 6(2)(c), § 1.1.6, § 5.2(a) in Ax I
<p>2. The AsBo shall conduct a thorough vertical slice assessment⁽¹⁹⁾, based on its experts judgement ("judgement-based sampling"), at least on the areas the AsBo considers to be of highest or most critical risks⁽²⁰⁾, independently on the proposer's risk classification, as well as on the risk areas having less serious consequences, the AsBo considers necessary in its assessment strategy in section II-4 above. The vertical slice assessment is necessary in order to :</p>	Art. 3(14), (b) in Ax III, "Introduction" & Clause 7.1.2 in ISO/IEC 17020:2012
<p>(a) check whether the proposer applies correctly the requirements for every step of the risk management process specified in Annex I of Regulation 402/2013.</p>	Art. 6(1), § 2.1.2, § 2.1.3, § 2.1.4, § 2.1.5, § 2.1.6, § 2.1.7 in Ax I
<p>The AsBo has to pay particular attention to :</p>	N/A
<p>(1) the methods the proposer applies for the hazard identification phase and whether the used methods ensure that <u>all reasonably foreseeable hazards</u> are systematically identified for the whole</p>	§ 1.1.5, § 1.2.1, § 1.2.7, § 2.2.1, § 2.2.3, § 2.2.5, § 2.2.6, § 3.4 in Ax I § 2.3 when CoP used

⁽¹⁸⁾ For information, this is the same principle as the ones of modules CH1 and SH1 from Commission Decision 2010/713 to be used by a notified body in the EU for the assessment of conformity and suitability for use of the interoperability constituents and for the EC verification of subsystems.

⁽¹⁹⁾ The terms "**vertical slice assessment**" refer to a thorough end-to-end review of the application of the risk management process contained in the Appendix to Annex I of the CSM for risk assessment at least for the areas of highest or most critical risk(s) of the change under assessment. The purpose is to check **a representative cross-sectional slice of the results** from the risk management and to cover all the steps of the risk management process of Regulation 402/2013 to testify its effectiveness.

⁽²⁰⁾ See also the strategy in section II concerning the assessment of risks having less serious consequences.

system under assessment, its functions and its interfaces. Indeed, hazards can be controlled only if they are identified.	§ 2.4 when Ref. Syst. used § 2.5 when explicit estim.
Given the variability of human performance, and the influence of human and organisational factors on the correct application of safety, quality and risk management processes, it is essential that the AsBo verifies whether the proposer's risk management correctly captures and addresses (i.e. adequately controls) :	§ 1.1.2, § 2.1.2(b)&(c), § 2.2.1 in Ax I § 2, § 3(a) in Ax II
(i) the HOF (Human and Organisational Factors) related risks that can arise during all phases of the development process of the change under assessment, and;	
(ii) the risks that can arise during the operation and maintenance of the system in its environmental context (e.g. tasks to be carried out by human operators, organisational arrangements, human capabilities and limitations, etc.);	
(2) the correct implementation by the proposer of the safety requirements (risk control measures) defined by the risk management, including thus when codes of practice, or similar reference systems, are used the independent safety assessment of their correct application.	§ 3 in Ax I (§ 3.1, § 3.2, § 3.3, § 3.4) § 2.3 when CoP used § 2.4 when Ref. Syst. Used § 2.5 when explicit estim.
(i) The assessment of the correct implementation by the proposer of the safety requirements (i.e. of safety measures) identified by the risk assessment requires sufficient technical knowledge and professional judgment by the AsBo, especially with respect to risks arising from technical design choices.	Art. 3(14), Art. 15(1), §3.3. in Ax I, § 1(b), § 2, § 3 in Ax II, Ax III
(ii) To avoid duplication of assessments by different bodies, where a NoBo, or a DeBo, have already assessed the technical compliance, the highest technical competence for the AsBo is not always needed (e.g. area not selected for thorough independent assessment by "judgement-based sampling"). However:	Art. 3(14), Art. 6(2), Art. 6(3) Clauses 6.1.2 and 7.1.2 in ISO/IEC 17020:2012
↳ when a TSI requires the applicant to use the risk management process in Annex I of the CSM RA for demonstrating the compliance with some specific safety requirements defined in the TSI, and either the TSI requests, or the applicant selects, an AsBo to carry out an independent assessment of that demonstration, the AsBo shall have relevant technical competency in the technical area of those specific safety requirements;	Clause 6.2.3.5 in LOC & PAS TSI, Clause 6.2.6(c) in safety in railway tunnels (SRT) TSI, Clause 4.2.1 of CCS TSI Clause 7.1.4 in LOC&PAS TSI, Clause 7.2.2.4 in WAG TSI
↳ when the system under assessment is non-compliant with either a TSI, or an NNTR, the AsBo team shall have the relevant technical understanding to independently assess the proposer's demonstration of the capability of the system under assessment to be used safely, under conditions for use well defined by the proposer, despite the non-compliance identified by the NoBo/DeBo.	Art. 3(14), Art. 15(1), §3.3. in Ax I, § 1(b), § 2, § 3 in Ax II, Ax III Clause 7.1.4 in LOC&PAS TSI, Clause 7.2.2.4 in WAG TSI
(iii) It is thus of prime importance that the AsBo experts act with due diligence. They shall be self-aware of limits of their personal skills, professional competencies and ability to fully understand the railway technical area under assessment. They shall know when to stop their own assessment and where to	Art. 3(14), Art. 15(1), §3.3. in Ax I, § 1(b), § 2, § 3 in Ax II, Ax III

	involve other technical experts, who are fully qualified to provide them with necessary railway technical expertise and advices on both the appropriateness of design choices and the quality and robustness of the proposer's work.	
	(iv) For example, where they have limited railway technical knowledge, the AsBo experts shall consult their relevant technical experts, with such knowledge, for additional support (e.g. for checking the suitability of Codes of Practice or Similar Reference Systems, the appropriateness of technical measures for controlling the risks arising from proposer's technical design choices, etc).	Art. 3(14), Art. 15(1), §3.3. in Ax I, § 1(b), § 2, § 3 in Ax II, Ax III
	(v) The AsBo experts (including technical experts) shall be free to decide on what is the necessary depth and level of detail of their assessments, or proposer's documentation to assess.	Art. 3(14), Art. 15(1), §3.3. in Ax I, § 1(b), § 2, § 3 in Ax II, Ax III Clauses 6.1.2 and 7.1.2 in ISO/IEC 17020:2012
	(b) check whether the proposer actually applies the safety and quality processes for the design and the implementation of the change;	Art. 6(2)(c), § 1.1.2 in Ax I
	(c) check whether the application of the safety and quality processes is effective and permits the proposer's risk assessment to identify appropriate risk control measures;	Art. 6(1), Art. 3(14), (e) in Ax III, "Introduction" & Clause 7.1.2 in ISO/IEC 17020:2012
	(d) check the absence of non-compliances, including for the sub-contractors, with :	Art. 5(2)
	(1) the provisions of the risk management process in Regulation 402/2013;	Art. 5(2)
	(2) the company (and project) organisation as described in the documentation mentioned in section I-2(c) above;	Art. 6(2)(b), § 1.1.6, § 1.1.2 & § 5.2(a) in Ax I
	(3) the safety or quality processes;	6(2)(c)
	(e) detect any other potential problems such as :	N/A
	(1) any issues with respect to the project management and risk management (e.g. insufficient or not enough qualified resources allocated to the risk assessment and risk management activities);	§ 1.1.2, § 1.1.6, § 5.2(a) in Ax I
	(2) weaknesses in the processes and insufficient documentary evidence of the activities the proposer actually carried out;	Art. 6(1), § 5.1, § 5.2 in Ax I
	(3) etc.	
	(f) be able to arrive at the professional judgement needed in section IV below;	Art. 6(1), Art. 3(14), (e) in Ax III, "Introduction" & Clause 7.1.2 in ISO/IEC 17020:2012
3.	The AsBo shall assess that all hazards identified and registered by the proposer in the hazard record/log are properly managed. This implies to assess that every hazard in the hazard record/log is :	§ 2.2.1, § 2.2.3, § 2.2.4, § 2.2.6, § 3.4, § 4 in Ax I
	(a) assigned to an actor who is in charge of controlling the identified hazard;	§ 1.1.3, § 1.1.5, § 1.1.6, § 1.2.1, § 1.2.7, § 1.2.2, § 4.2 in Ax I
	(b) if the hazard falls under the domain of control of the proposer, it is controlled to an acceptable level by the proposer, or;	§ 1.1.5, § 1.2.5, § 1.2.7, § 3.2 in Ax I

(c) if the hazard falls in the scope of responsibility and the domain of control of another actor, it is transferred to that other actor with its written agreement;	§ 1.1.5, § 1.2.2, § 1.2.3, § 1.2.4, § 1.2.7 & § 4.2 in Ax I
Note : by virtue of point 1.1.5 in Annex I of Regulation 402/2013, the proposer must not assign to an actor safety requirements and hazards that go beyond the scope of responsibility and the domain of control of that actor.	§ 1.1.5 & § 1.2.7 in Ax I
4. As the AsBo usually uses sampling techniques ⁽²¹⁾ (see section II above), the AsBo has to ensure that the independent safety assessment report and the interpretation of the results from the proposer's risk management process are correct and cover all steps, and all results, of the risk management process.	Art. 3(14), (b) in Ax III, "Introduction" & Clause 7.1.2 in ISO/IEC 17020:2012
III.D Gathering of evidence, follow up and assessment of the implementation of proposer's action plan(s) for the identified non-compliances	Art. 6(2), Art. 15(1), Ax III 3rd paragraph in "Introduction", Clause 7.4 and Annex B of ISO/IEC 17020:2012
1. The AsBo shall gather any relevant evidence (i.e. documentary proofs) of the actual deployment of the strategy set out in the assessment plan in section II above;	Art. 6(2), Art. 15(1), Ax III Clause 7.3, Clause 7.4 and Annex B of ISO/IEC 17020:2012
2. The AsBo shall manage the relevant outcomes from the independent safety assessment. This includes :	N/A
(a) a proactive and early identification of (potential) issues;	Art. 6(1)
(b) a regular reporting of the identified issues to the proposer to enable the proposer to take timely remedial actions;	Good practice – No explicit requirement in Reg. 402/2013
(c) keeping the history of the identified non-compliances or raised issues and tracking them either until they are managed and closed by the proposer to a satisfactory solution, or they are documented as open issues in the AsBo final safety report;	Art. 6(2), Art. 15(1), Ax III Clause 7.3, Clause 7.4 and Annex B of ISO/IEC 17020:2012
3. The gathering of evidence (i.e. of documentary proofs) from independent safety assessment is likely to be a combination of audits and inspections including document reviews ⁽²²⁾ , observations, interviews, organisational and personnel competency checks, safety culture and organisation assessment, sampling and vertical slice analyses, use of checklists, etc. The precise scope and level of detail or size of the selected samples or of the vertical slices for the independent safety assessment depend on the complexity of the risk management activities, complexity or novelty of the	Art. 3(14), (b) in Ax III, "Introduction" & Clause 7.1.2 in ISO/IEC 17020:2012

⁽²¹⁾ *The CSM for risk assessment and the ISO/IEC 17020:2012 standard for inspection bodies referenced therein do not oblige the AsBo to perform a complete and thorough independent safety assessment of all outputs of the risk management activities. The AsBo is not obliged to review and check all details and all the results from the proposer's risk management performed.*

Clauses 7.1.1. and 7.1.2 of the ISO/IEC 17020:2012 standard allow the AsBo to use sampling based inspection. Generally, sampling and vertical slice assessments (see also footnote (19)) of the outcomes generated by the proposer's development, risk assessment and risk management activities for the highest or most critical risks is acceptable at an inspection rate lower than 100 % provided the selected sample and vertical slice assessments give confidence to the AsBo in the system being assessed.

⁽²²⁾ *In particular, the review of documentation will include the analysis and evaluation of the quality and consistency of the outputs at every step of the risk management process of the CSM for risk assessment.*

<p>technology, safety culture of the proposer, safety criticality and level of risk introduced by the change;</p>	
<p>4. It is important that the AsBo promptly reports (e.g. verbally, via telephone, using e-mails, etc.) the identified issues and non-compliances, especially on major concerns, to enable the proposer to take timely any necessary remedial actions.</p> <p>5. However, in order to foster the mutual recognition of the AsBo independent assessment activities, it is important that the AsBo formally confirms all issues and non-compliances afterwards in a written form. The history of all identified issues and non-compliances needs also to be systematically and formally recorded as evidence from the independent assessment activities in a history log⁽²³⁾.</p> <p>6. Every issue and non-compliance should have a priority assigned and should be tracked down until a proper resolution by the proposer. This provides a traceable evidence (i.e. documentary proofs) of a proactive involvement of the AsBo in the identification and the assessment of resolution of problems based on the level of risk associated with the change, or on the priority associated with the raised finding.</p> <p>7. The final independent safety assessment report of the AsBo has to clearly document all issues and non-compliances on which according to Article 15(1) of Regulation 402/2013 the proposer disagrees at the end of the independent safety assessment.</p>	<p>Regular reporting is a good practice – There is no explicit requirement in Reg. 402/2013 for that. Reporting of AsBo work specified in Art. 6(2), Art. 15(1), Ax III 3rd paragraph in “Introduction”, Clause 7.4 and Annex B of ISO/IEC 17020:2012</p>
<p>IV 4th step : deliver the independent safety assessment conclusions and report</p>	<p>Art. 15(1), § 5.3 in Ax I</p>
<p>1. The AsBo shall formally document its independent safety assessment activities, results and conclusions according to the actual scope of its work.</p>	<p>Art 3(12), Art. 3(14), Art 6(2), Art. 15(1), § 5.3 in Ax I, Ax III Clause 7.4 of ISO/IEC 17020:2012</p>
<p>2. The structure of the AsBo assessment report depends on whether the proposer contracts the AsBo for the independent assessment of the entire development process of the change (design to implementation phases), or for a limited scope (see section O.C. above:</p>	<p>Bullet point (c) in Ax III § 2.1.2(g), § 5.2(d) in Ax I</p>
<p>(a) When the scope of the independent assessment covers the full development process of the change, the report shall comply with the recommendation for use 02 on the harmonised structure for the AsBo safety assessment report;</p>	<p>Common sense to voluntarily use an RFU adopted at a large majority in the AsBo cooperation, Ax III</p>
<p>(b) When the scope of the independent assessment includes the applicant’s requirement capture process of a vehicle, defined in Article 2(11) and Article 13 of (EU) Regulation 2018/545, the report shall comply with the future recommendation for use 04.</p>	<p>Common sense to voluntarily use an RFU adopted at a large</p>

⁽²³⁾ *If necessary for the mutual recognition of the AsBo independent safety assessment report, on demand the history log shall be made available to an authorising entity, or to another conformity assessment body, with the prior permission of the proposer (refer to the confidentiality clause in Clause 4.2 of the ISO/IEC 17020:2012 standard).*

<p>RFU 04 mirrors the RFU 02. It specifies the harmonised structure of a single AsBo report for documenting the results of the assessment of the applicant's requirement capture process of all essential requirements [Article 13(1) of (EU) Regulation 2018/545], including safety related ones and safe integration [Article 13(1) of (EU) Regulation 2018/545].</p> <p>At the time of adoption and publication of this RFU, RFU 04 is not yet published.</p>	majority in the AsBo cooperation, Ax III
<p>(c) When the scope is limited to some phases of the development process (e.g. design phase), or to the assessment of the proposer's demonstration of compliance with specific safety or technical requirements of applicable TSIs, the report may be adapted to the specificity of the project, according to paragraph 3 in section 0.C. above.</p>	Bullet point (c) in Ax III § 2.1.2(g), § 5.2(d) in Ax I
<p>3. For the points IV-2(a) and IV-2(b) above, an AsBo assessment report which only complies with the Annex III of Regulation 402/2013 is considered unsatisfactory. An AsBo report compliant with Annex III does not contain all necessary information required by RFU 02 and RFU 04. It is thus possible that the accepting entity (e.g. an Authorising Entity – ERA or an NSA, or another AsBo) asks for additional information and/or evidence from either the proposer or the AsBo. The AsBo failure to voluntarily comply with the RFU 02 and RFU 04 can just result in unnecessary delays before the accepting entity is able to mutually recognise a different structure of the AsBo report.</p>	Common sense to voluntarily use an RFU adopted at a large majority in the AsBo cooperation, Ax III

4. DECISION

Cooperation decision:	Accepted
Plenary meeting nr:	Written vote, following the 18 th AsBo Cooperation meeting
Date of decision:	16 April 2024

5. ANNEX

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