1. REQUEST

Enquiry title:	**Working method of the Assessment Body**
Enquiry description: 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 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. • 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). • 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. 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.	
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Related documents:	Regulation 402/2013, Article 6 Explanatory Note on the roles and responsibilities of the AsBo

2. TRACEABILITY

RFU number:	1
Version number:	1.1
Version comment:	Traceability column added (from former RFU 4.1) and use of the new template of RFUs

3. SOLUTION

Proposal for the working method of the Assessment Body (AsBo)	Cross reference in Regulation 402/2013 or in ISO/IEC 17020:2012 standard
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 evidence, of the suitability of the system…* " under assessment *"… to fulfil its safety requirements*". The AsBo working method needs thus to give the assurance that the proposer's organisation and processes for the risk management are effective in capturing (i.e. identifying) all reasonably foreseeable hazards arising from the significant change, registering them in the hazard record/log, understanding the hazards and the associated risks, analysing them and mitigating them to an acceptable level.	Art. 3(14) Art. 6(1) Art. 16 § 2.2.4, § 4.1.2 in Ax I
2. Having regard to the requirements contained in Article 6(2)[(1)] of Regulation 402/2013 and in section § 7.1[(2)] of the ISO/IEC 17020:2012 standard referred to in Annex II of that Regulation, to give this assurance the AsBo working method needs to include the following :	Art. 6(2) ISO/IEC 17020:2012
(a) the understanding of the change and of the proposer's organisation for the change management and risk management;	Art. 6(2)(a), § 1.1.1, § 1.1.4, § 1.1.6, § 2.1.1 & § 5.2(a) in Ax I
(b) the planning and prioritisation of the AsBo independent safety assessment activities;	Points (b), (c), (e) in Ax III, § 7.1.2 in ISO/IEC 17020:2012
(c) 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;	Art. 6(1), Point (d) in Ax III, § 7.3, § 7.4.2(f) & § 7.4 in ISO/IEC 17020:2012
(d) the delivery of the independent safety assessment conclusions and report.	Ax III, Point (e) in Ax III, § 7.4, § 7.4.2(f) in ISO/IEC 17020:2012
3. <u>Understand the change and proposer's organisation for the change management and risk management</u>	Art. 6(2)(a), § 5.2(a) in Ax I
(a) based on documentation provided by the proposer, the AsBo must get a clear and thorough understanding of the following :	Art. 6(2)(a)
(1) the scope and context of the significant change under assessment for planning the intensity of the independent safety assessment and the particular areas for in-depth assessments;	Art. 6(2)(a) § 7.1.2 in ISO/IEC 17020:2012
(2) the proposer's plans and organisation for the management of the change;	Art. 6(2)(b), § 1.1.1, § 2.1.1, § 1.1.4, § 1.1.6 & § 5.2(a) in Ax I
(b) to do that, the AsBo usually needs the following information :	Art. 6(2)(a)

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

(2) *Section § 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.*

(1) the complete system definition of the change as required in paragraph § 2.1.2 in Annex I of Regulation 402/2013, including the interfaces with other sub-systems and 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
(2) 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
(3) the description of the organisation[3], 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 impacted through the interfaces [see section § 3(b)(1) above]) and of the competencies of the experts appointed for carrying out the risk management process for the change.	Art. 6(2)(b), § 1.1.6, § 1.1.2, § 1.2.3, § 1.2.4, & § 5.2(a) in Ax I
4. **Plan and prioritise the AsBo independent safety assessment activities**	§ 7.1 in ISO/IEC 17020:2012
(a) 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.	(b) in Ax III § 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
(b) Considering that independent safety assessment is an inspection activity within the framework of Article 6(2) of Regulation 402/2013 and section § 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 by the AsBo. In order to provide the assurance described in section § 1 above, the AsBo independent safety assessment strategy must :	(b) in Ax III, § 7.1.2 in ISO/IEC 17020:2012
(1) cover all steps of the risk management process, and assess the correct application of the risk management process and the	Art. 6(1), Art. 6(2)(c), § 1.1.7, § 2.2.2, § 2.3.8(d) in Ax I

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

suitability of the results from the application of that process, but also;	
(2) cover all phases and activities of the proposer's organisation and management of the change, 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 estimation
(c) In practice, the planning of the AsBo independent safety assessment activities is done as an integrated part of the assessments done in section § 5 below. Before starting the independent safety assessment, the AsBo has to review beforehand and to understand thoroughly all the inputs listed in section § 3 above. Based on that documentary review, the AsBo has to produce the "independent safety assessment plan"[(4)] that will drive its activities. 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 § 2 and § 3 above, the setting up of the plan for the independent safety assessment will permit the AsBo to achieve all the following :	Art. 6(2)(a), § 1.1.6, § 1.1.2 & § 5.2(a) in Ax I, (b) in Ax III, § 7.1.2 in ISO/IEC 17020:2012
(1) a thorough understanding of the significant change.	Art. 6(2)(a)
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;	N/A
(2) the understanding of the proposer's organisation 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
(3) description of the methodology for assessing the correct application and correct management of the risk management in accordance with both the requirements of Regulation 402/2013 and the proposer's supporting safety and quality processes. This includes the description of :	(b) in Ax III, (d) in Ax III, § 7.1.2 in ISO/IEC 17020:2012
(i) 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 estimation
(ii) the gathering and reporting of documented evidence of the identified non-compliances with respect to Regulation 402/2013 and the proposer's safety and quality processes, and then;	Art. 6(2)(c), (d) in Ax III, § 7.3 in ISO/IEC 17020:2012
(iii) 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,

(4) *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 in bullet points (d) and (e) here after.*

	(4) 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, § 7.1.2 in ISO/IEC 17020:2012
(d)	Independently of the proposer's risk classification, the areas the AsBo considers as highest or most critical risks should undergo thorough independent safety assessment. Inspection activities as meant by 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 which areas are of highest or most critical risk(s) from the AsBo perspective that should be subject to more in-depth independent safety assessment. In practice, this will be :	Art. 3(14), § 2.2.3, (b) in Ax III, "Introduction" & § 7.1.2 in ISO/IEC 17020:2012
	(1) risks related to the organisation, application and effectiveness of the safety and quality processes for managing the change;	Art. 6(2)(c), § 1.1.5, § 1.2.7, § 1.2.1, § 5.2(a) in Ax I
	(2) risks in the correct application of the risk management process of the CSM;	Art. 6(1), § 1.1.7 in Ax I
	(3) independently of the proposer's risk classification, all risks arising from the change which could potentially result in collisions[(5)], derailments[(6)] or other types[(7)] of well-known railway accidents, if those areas are not properly identified and managed by the proposer. Other categories of risks shall not be disregarded; medium or low risks may also warrant independent safety assessment usually to a lower level of detail. The actual extent and level of detail of the independent safety assessment of low and medium risks is at the sole discretion and expert judgement of the AsBo. This is important in order to check also the correct identification and the proper control of such risks by the proposer.	Art. 3(14), § 2.2.3, (b) in Ax III, "Introduction" & § 7.1.2 in ISO/IEC 17020:2012
	Remark: the risks in bullet points (1) and (2) can also result in the accidents listed in point (3). It is thus important they are also independently assessed.	Art. 3(14), (b) in Ax III, "Introduction" & § 7.1.2 in ISO/IEC 17020:2012
(e)	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" & § 7.1.2 in ISO/IEC 17020:2012
	(1) 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" & § 7.1.2 in ISO/IEC 17020:2012
	(2) to ensure that the level of the independent safety assessment activity is proportionate to the level of the risk arising from the change and from the management and the organisation of the change by the proposer, including the proper management of the interfaces with other sub-systems and other actors impacted by the change.	Art. 3(14), (b) in Ax III, "Introduction" & § 7.1.2 in ISO/IEC 17020:2012, § 1.1.5, § 1.1.6, § 1.2.1, § 1.2.3, § 1.2.4 & § 1.2.7 in Ax I

(5) *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).*

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

(7) *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.*

(f) To make possible the mutual recognition of the AsBo independent safety assessment report, according to Annex III of Regulation 402/2013, the final report shall include a summary of the independent safety assessment plan built in section § 4 above, a description of what was actually assessed and the reference of the complete independent safety assessment plan[8].	(b) in Ax III
5. **Independent safety assessment, evidence gathering and follow up of the proposer's action plan(s)**	
Reminder	
For the independent safety assessment by an AsBo, as understood by Article 6(2) of Regulation 402/2013, Annex II of that Regulation requires the AsBo to have technical competence, experience and professional judgement[9] in all the following fields without exceptions :	Ax II
(1) the technical field(s) of the system being assessed;	§ 2, § 4 in Ax II
(2) the fields of risk assessment and risk management;	§ 1(a)&(b), § 3 in Ax II
(3) the fields of correct application of safety and quality management systems or in auditing such management systems.	§ 1(c) in Ax II
This requirement is crucial given that, by virtue of the ISO/IEC 17020:2012 standard, the AsBo is an inspection body which has to provide a professional judgement about the conformity of the proposer's risk assessment and risk management with the process regulated in Regulation 402/2013.	Art. 3(14), (b) in Ax III, "Introduction" & § 7.1.2 in ISO/IEC 17020:2012
So, compared to the "conformity assessments with TSIs"[10], or with the equivalent OTIF Uniform Technical Prescriptions, by notified bodies, the "independent safety assessment by an AsBo"[11] is a distinct activity, with a different purpose, a different scope and requires therefore different competence and different working methods. Thereby the modules setting out a particular methodology for the conformity assessment with a TSI (or with the equivalent OTIF Uniform Technical Prescriptions), by notified bodies, are not applicable to the work of the AsBo.	Art. 6(2), § 7.1.2 in ISO/IEC 17020:2012
Once the AsBo has understood the significant change, and the proposer's organisation for the change management and for the risk management, the AsBo must implement the independent safety assessment strategy set out in its plan. This means that the AsBo has to :	Art. 6(2)(a), § 1.1.6, § 5.2(a) in Ax I

[8] *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 section § 4.2 of the ISO/IEC 17020:2012 standard).*

[9] *"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.*

[10] *The conformity assessments by notified bodies aim at checking that all the requirements of the considered TSIs (or the equivalent OTIF Uniform Technical Prescriptions) are met. These are "standard based checks".*

[11] *The independent safety assessment by an AsBo is "more about making a professional judgement on the suitability of the system under assessment to fulfil its safety requirements", focussing the thorough assessments on the areas of highest or most critical risks.*

(a) *"independently assess what is written in the proposer's plans" :*	Art. 6(2)(b)&(c)
(1) if they are not already certified by a relevant conformity assessment body, the AsBo will conduct an assessment of the proposer's organisation, safety and quality processes in place (i.e. the inputs provided to the AsBo in section § 3 above) the proposer intends to use for managing the design and the implementation of the significant change. *In practice the AsBo will carry out those assessments during the setting out of the independent safety assessment plan and strategy in sections § 3 and § 4 above*.	Art. 6(2)(b), § 1.1.6 in Ax I
(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 the national safety authority), the AsBo shall not reassess them but anyway must understand thoroughly the organisation and those processes in order to carry out the assessments in bullet point § 5(b)(1) below.	§ 1.1.4, § 5.2(a) in Ax I
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;	Art. 5(2), § 3.1, § 3.2 & § 3.3 in Ax I
(b) *"independently assess what is actually done by the proposer"*	Art. 6(2)(c), § 5.2(a) in Ax I
This consists in conducting an assessment[(12)] of the actual organisation and actual management of the significant change, with the supporting 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 :	Art. 6(2)(c), § 1.1.6, § 5.2(a) in Ax I
(1) conduct a **thorough vertical slice assessment**[(13)] at least on the areas the AsBo considers to be of highest or most critical risks[(14)], independently on the proposer's risk classification, as well as on the areas of medium and low risks the AsBo considers necessary in its assessment strategy in section § 4(d) above, in order to :	Art. 3(14), (b) in Ax III, "Introduction" & § 7.1.2 in ISO/IEC 17020:2012
(i) check whether the proposer applies correctly the requirements for every step of the risk management process in Annex I of Regulation 402/2013.	Art. 6(1), § 2.1.2, § 2.1.3, § 2.1.4, § 2.1.5, § 2.1.6, § 2.1.7 in Ax I

(12) *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.*

(13) *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.*

(14) *See also the strategy in section § 4 concerning the assessment of medium and low risks.*

The AsBo has to pay particular attention to :	
↳ the methods the proposer applies for the hazard identification phase and whether the used methods ensure that all reasonably foreseeable hazards are systematically identified for the whole system under assessment, its functions and its interfaces. Indeed, hazards can be controlled only if they are identified;	§ 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 § 2.4 when Ref. Syst. used § 2.5 when explicit estimation
↳ the correct implementation by the proposer of the safety requirements (risk control measures) defined by the risk management, including thus when codes of practice 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 estimation
(ii) 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
(iii) 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" & § 7.1.2 in ISO/IEC 17020:2012
(iv) check the absence of non-compliances, including for the sub-contractors, with :	Art. 5(2)
↳ the provisions of the risk management process in Regulation 402/2013;	Art. 5(2)
↳ the company (and project) organisation as described in the documentation mentioned in section § 3(b)(3) above;	Art. 6(2)(b), § 1.1.6, § 1.1.2 & § 5.2(a) in Ax I
↳ the safety or quality processes;	Art. 6(2)(c)
(v) detect any other potential problems such as :	
↳ 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
↳ weaknesses in the processes and insufficient documentation of the activities actually done;	Art. 6(1), § 5.1, § 5.2 in Ax I
↳ etc.	
(vi) be able to arrive at the professional judgement needed in section § 6 below;	Art. 6(1), Art. 3(14), (e) in Ax III, "Introduction" & § 7.1.2 in ISO/IEC 17020:2012
(2) 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
(i) 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
(ii) 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

	(iii) 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
(3)	as the AsBo usually uses sampling techniques[(15)] (see section § 4 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" & § 7.1.2 in ISO/IEC 17020:2012
(c)	"*gather the evidence and follow up the proposer's action plan(s)*" : this includes the following :	Art. 6(2), Art. 15(1), Ax III 3rd paragraph in "Introduction", §7.4 and Annex B of ISO/IEC 17020:2012
(1)	the gathering of any relevant evidence (i.e. documentary proofs) of the actual deployment of the strategy set out in the assessment plan in section § 4 above;	Art. 6(2), Art. 15(1), Ax III § 7.3, § 7.4 and Annex B of ISO/IEC 17020:2012
(2)	the management of any outcomes from the independent safety assessment, including :	
	(i) a proactive and early identification of (potential) issues;	Art. 6(1)
	(ii) 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
	(iii) 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 § 7.3, § 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[(16)], 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	Art. 3(14), (b) in Ax III, "Introduction" & § 7.1.2 in ISO/IEC 17020:2012

(15) *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.*

Sections § 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 (13)) 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.

(16) *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.*

	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 technology, safety culture of the proposer, safety criticality and level of risk introduced by the change;	
(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. However, in order to foster the mutual recognition, it is important that all issues and non-compliances are formally confirmed afterwards in a written form. The history of all identified issues and non-compliances needs also to be systematically and formally recorded in a history log[17]. 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. 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.	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", § 7.4 and Annex B of ISO/IEC 17020:2012
6.	**Independent safety assessment conclusions and report**	
(a)	the independent safety assessment report has to comply with Annex III of Regulation 402/2013. It will thus include :	Art. 6(2), Art. 15(1), § 5(3) in Ax I, Ax III
(1)	the definition of the scope;	(c) in Ax III
(2)	a summary of the independent safety assessment plan referred to in section § 4 above and a reference to the complete independent safety assessment plan[17];	(b) in Ax III
(3)	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, and;	(d) in Ax III
(4)	the limitations of the independent safety assessment;	(c) in Ax III
(b)	it must also give a clear statement and the expert judgement on :	§ 7.4.2(f) of ISO/IEC 17020:2012
(1)	the correct application or not of the risk management process in Annex I of Regulation 402/2013, and on;	Art. 6(1), § 7.4.2(f) of ISO/IEC 17020:2012
(2)	the suitability of the results from the risk management for the change under assessment to fulfil its safety requirements;	Art. 6(1), § 7.4.2(f) of ISO/IEC 17020:2012
(3)	a reference to any safety related application conditions, or exported constraints (if applicable), for the safe use of the change.	(c) in Ax III

[17] *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 section § 4.2 of the ISO/IEC 17020:2012 standard).*

4. DECISION

Cooperation decision:	Accepted
Plenary meeting nr:	9
Date of decision:	5 November 2020

5. ANNEX

Additional details on the solution: No further details needed	
Annex documents:	There are no annexed documents