Explanatory note on the CSM Assessment Body referred to in Regulation (EU) N°402/2013[1] and in OTIF UTP GEN-G of 1.1.2016[2] on the Common Safety Method (CSM) for risk assessment

Author : *Dragan JOVICIC*
European Union Agency for Railways - Safety Unit
120, rue Marc LEFRANCQ
BP 20392 - FR 59307 Valenciennes Cedex – France
Web page : www.era.europa.eu
E-mail : Dragan.JOVICIC@era.europa.eu

Contact person for OTIF : *Bas LEERMAKERS*
OTIF Technical section
Gryphenhübeliweg, 30
CH-3006 Bern - Switzerland
Web page : www.otif.org
E-mail : bas.leermakers@otif.org

Abstract : *in order to gain trust in risk assessments and to allow mutual recognition of the results of the application of Regulation (EU) No 402/2013, or of the equivalent OTIF Uniform Technical Prescriptions - UTP GEN-G of 1.1.2016, on the CSM for risk assessment, it is necessary to give confidence that the system under assessment can deliver the required level of safety. For this purpose, whenever a significant change is made to the railway system the CSM requires to appoint a CSM assessment body (referenced also as AsBo in this paper). This body (or AsBo) has to be a competent external or internal individual, organisation or entity, separate and independent[3] from the "design, risk assessment, risk management, manufacture, supply, installation, operation/use, servicing and maintenance" of the system under assessment. Its role is to check the application by the proposer of the risk management process and also the risk assessment results in order to form a judgement on whether the change management process and the safety requirements resulting from this process are appropriate and adequate for the planned significant change so that the system can satisfy those safety requirements and that the residual risk is reduced to an acceptable level. The objective of this paper is to summarise and highlight the requirements to be fulfilled by this body, its role, responsibilities and working method as defined in "Regulation (EU) No 402/2013[4] on the common safety method for risk evaluation and assessment" or in the equivalent OTIF UTP GEN-G of 1.1.2016.*

Used terminology: *considering the equivalence of the requirements contained in Regulation (EU) No 402/2013 and in the OTIF UTP GEN-G of 1.1.2016, the following generic terminology is used in the present document to simplify its reading and understanding. "**CSM for risk assessment**" refers both to Regulation (EU) No 402/2013 and the equivalent OTIF UTP GEN-G of 1.1.2016. "**State**" refers both to an EU Member State and an OTIF Contracting State. The acronym AsBo refers to the CSM assessment body referred to in Article 6 of the CSM for risk assessment.*

Keywords: *common safety method (CSM), risk assessment, CSM assessment body, AsBo, independent safety assessment, safety assessment report, accreditation, recognition, mutual recognition, cross-acceptance.*

Foreword

Until beginning of 2000, Member States of the European Union have developed their own railway safety rules and railway standards, often based on national technical and operational concepts. This has progressively led to differences in principles, approaches and safety cultures making it difficult to break through technical and safety barriers and to establish international rail transport operations. International railway transport depended mostly on voluntary bilateral agreements and it was conditioned to additional, and very often unnecessary, checks, safety demonstrations and authorisations.

The construction of an interoperable, safe and integrated European railway network, without national frontiers, is now made possible by the compliance with the harmonised European legislation for railway safety management[5] and for railway interoperability[6]. The demonstration of compliance with the harmonised European railway legislation makes compulsory, under given conditions, the mutual recognition of authorisations and risk assessments within the territory of the European Union. Authorisations and risk assessments shall be accepted, under well given conditions (among which the need for the CSM assessment bodies (AsBos) to be accredited or recognised),

---

(1) *Commission implementing Regulation (EU) 2015/1136 of 13 July 2015 amends the implementing Regulation (EU) No 402/2013 on the common safety method for risk evaluation and assessment*

(2) *UTP GEN-G of 1.12.2016 repeals UTP GEN-G of 1.1.2014. In addition to that, EU referencing to Article y of (EU) Regulation 402/2013 is to be understood as reference to section y in the UTP GEN-G context.*

(3) *The types of independence and the associated requirements are defined in Annex A.1 to A.3 of the ISO/IEC 17020:2012 standard.*

(4) *Regulation (EU) No 402/2013 repeals Regulation (EC) No 352/2009 with effect from 21 May 2015.*

(5) *Safety Directive 2016/798.*

(6) *Interoperability Directive 2016/797.*

by national safety authorities and any other relevant conformity assessment body. Additional authorisations, checks or risk assessments shall not be requested unless the existence of a substantial safety risk can be demonstrated.

The Contracting States of OTIF have adopted risk assessment requirements [OTIF UTP GEN-G of 1.1.2016] equivalent to Regulation (EU) No 402/2013. However a part of the scope of application of this OTIF UTP GEN-G differs in COTIF compared to the EU railway regulations. Those differences do however not influence the activities and competences of AsBos. So, this explanatory note is also of use to the non-EU Contracting States of OTIF.

1. What is the concept of mutual recognition in the scope of the CSM for risk assessment?

In relation to the CSM for risk assessment, mutual recognition[7] imposes the acceptance in another State or by another stakeholder, without the need to repeat a risk assessment, of the results of a risk assessment that are already performed by a proposer, assessed by an independent CSM assessment body (AsBo) and accepted in compliance with the CSM for risk assessment. The work done for the first acceptance is to be recognised as valid for any other acceptance provided that *"the system is used under the same functional, operational and environmental conditions"* as the already accepted one, and that *"equivalent risk acceptance criteria are applied"*. For a new application of an already accepted system, further risk assessments and checks are to concentrate only on the deviations from the conditions in which the system was originally accepted.

2. What is the concept of independent CSM assessment body?

Regulation (EC) N°352/2009 and its equivalent OTIF UTP GEN-G of 1.5.2012 are first to introduce the concept of independent CSM assessment body (AsBo). They require the AsBo to carry out an independent safety assessment of the correct application of the risk assessment process, of the results of that process and of the safety demonstration of the system under assessment in order to provide additional assurance that the necessary level of safety can be achieved (see also section § 4 below). Regulation (EC) N°352/2009 and its equivalent OTIF UTP GEN-G of 1.5.2012 define also:

(a) see section 3 : what general criteria according to Regulation (EC) N°352/2009 and its equivalent OTIF UTP GEN-G of 1.5.2012 must the CSM assessment body fulfil?
(b) see section 4 : what is the role of the CSM assessment body?
(c) see section 5 : who can be the CSM assessment body?
(d) see section 6 : can the CENELEC independent safety assessor (ISA) perform the work of the CSM assessment body?
(e) see section 7 : when is a CSM assessment body required? → for a significant change
(f) see section 8 : who shall appoint the CSM assessment body?

Regulation (EU) N°402/2013[8] and its equivalent OTIF UTP-GEN-G of 1.1.2016 revise and repeal Regulation (EC) N°352/2009 and its equivalent OTIF UTP GEN-G of 1.5.2012 with effect from 21 May 2015. They bring an answer to the following questions that remained open in Regulation (EC) N°352/2009 and its equivalent OTIF UTP GEN-G of 1.5.2012:

(g) see section 9 : what specific criteria and requirements does the CSM assessment body have to fulfil?
(h) see section 10 : what are the areas of competence of the CSM assessment body?
(i) see section 11 : is the CSM assessment body obliged to have internally all the necessary competence?
(j) see section 12 : why is the ISO/IEC 17020:2012 standard appropriate for the CSM assessment body?
(k) see section 13 : how to check the competence of the CSM assessment body and establish sufficient trust of its work among all the countries where the CSM for risk assessment is to be applied?
(l) see section 14 : what are the benefits of allowing the recognition of CSM assessment bodies instead of accreditation?

---

[7] *Mutual recognition is a broad concept, defined elsewhere, and is not specific to the CSM for risk assessment. It is also referred to in some legislation or literature as mutual acceptance or cross acceptance.*

[8] *Regulation (EU) No 402/2013 repeals Regulation (EC) No 352/2009 with effect from 21 May 2015.*

(m) see section 15 : can all CSM assessment bodies work EU wide and/or in all OTIF Contracting States?
(n) see section 16 : can the criteria and requirements for the CSM assessment body be relaxed?
(o) see section 17 : is it obligatory to have at least one CSM assessment body in the country?
(p) see section 18 : where can a proposer find the list of all accredited and recognised CSM assessment bodies?
(q) see section 19 : when does the CSM assessment body start the independent safety assessment?
(r) see section 20 : when does the CSM assessment body finish the independent safety assessment?
(s) see section 21 : how is the independent safety assessment to be done by the CSM assessment body?
(t) see section 22 : what is the content of the safety assessment report of the CSM assessment body?
(u) see section 23 : are the judgments and conclusions of the CSM assessment body binding for the proposer?
(v) see section 24 : what are the interactions between the CSM assessment body and the other conformity assessment bodies?

The answers to all the questions in points (a) to (v) above are summarised in the sections below.

3. What general criteria according to Regulation (EC) N°352/2009 and its equivalent OTIF UTP GEN-G of 1.5.2012 must the CSM assessment body fulfil?

Annex II of Regulation (EC) N°352/2009 and of the equivalent OTIF UTP GEN-G of 1.5.2012 define general type criteria. These criteria are mainly related to the independence, competence, integrity and impartiality of the AsBo. Regulation (EC) N°352/2009, and the equivalent OTIF UTP GEN-G of 1.5.2012, does neither prescribe any detailed requirement nor the way to check the fulfilment of the relevant criteria and requirements by the AsBo. Regulation (EU) N°402/2013, and the equivalent UTP GEN-G of 1.1.2016, does not revoke those general criteria. It introduces additional general criteria and specific requirements, not yet defined in Regulation (EC) N°352/2009, and in the equivalent OTIF UTP GEN-G of 1.5.2012: see section § 9 below.

4. What is the role of the CSM assessment body?

Similarly to the assessment of the correct application of the CENELEC 50657, 50128 and 50129 standards, the CSM for risk assessment requires that an independent, competent and impartial CSM assessment body performs an independent safety assessment of its correct application (see next paragraph). The role of the AsBo is to build trust between stakeholders and to facilitate the mutual recognition of the results from risk assessments carried out in compliance with the process in Annex I of the CSM for risk assessment. The AsBo provides other conformity assessment bodies with the assurance that the proposer conducts properly the risk assessment and risk management activities, avoiding thereby unnecessary additional requests for risk assessments or duplication of independent assessment work by those other conformity assessment bodies.

Article 6(2) of the CSM for risk assessment requires the CSM assessment body to:

(a) check the correct application by the proposer of the risk management process set out in Annex I of the CSM for risk assessment (reminded in Figure 1 below) for the design and implementation of a significant change;
(b) check the suitability of the results from the risk assessment for the change under assessment.
The assessment of the proposer decision on the significance of the change is not in the AsBo scope of work;
(c) deliver to the proposer a safety assessment report that contains the results of the checks of compliance with all the requirements of the CSM for risk assessment, and its judgement and conclusions on the suitability of the change under assessment to fulfil its safety requirements.

To gain confidence that the safety requirements identified through the risk assessment are appropriate for the considered change and that the system under assessment complies with those safety requirements, it is necessary that the AsBo also analyses and evaluates the suitability, the quality and the consistency of the outputs of every step of the CSM risk management process represented in Figure 1 below.

Based on the evidence (i.e. documentary proofs) collected through the activities in points (a) and (b) above, the AsBo is able to deliver to the proposer a safety assessment report. This report indicates whether the risk assessment and risk management activities, the proposer carried out, are compliant with the requirements of the CSM for risk assessment. The report contains also the judgement and conclusions of the AsBo on the suitability of the significant change to fulfil successfully its safety requirements (see section § 22 below).

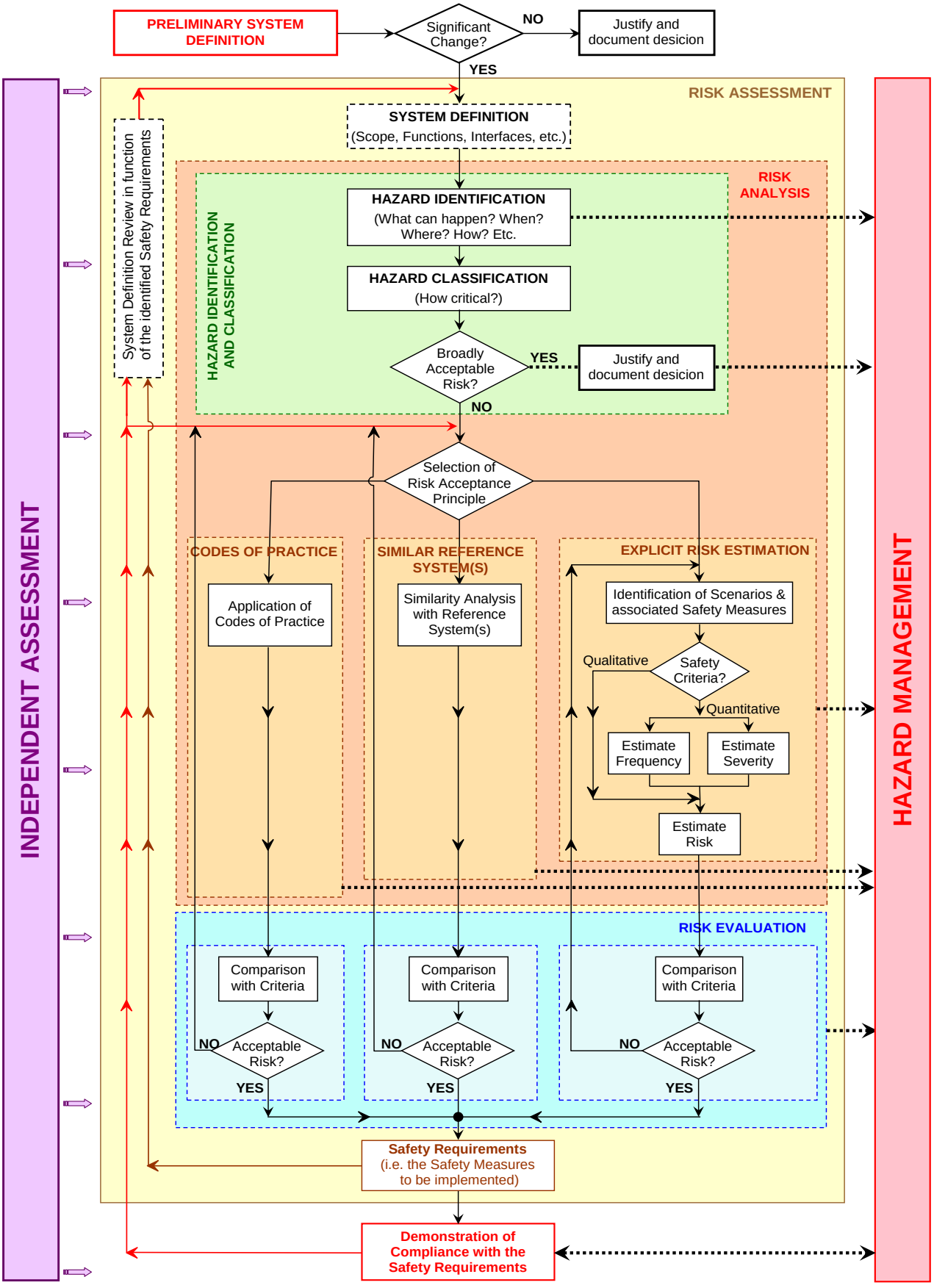

Figure 1 : Risk management process and independent safety assessment in the CSM for risk assessment.

It is important to emphasize that the AsBo is not in charge of carrying out the risk assessment and risk management activities required in Annex I of the CSM for risk assessment. The AsBo does neither provide advices nor solutions for controlling the risks associated with the identified non-compliances; that would compromise its independence (see section 22 for more details). The proposer is the solely responsible for carrying out all necessary risk assessment and risk management activities, including the demonstration that all risk(s) arising from the change is/are controlled to an acceptable level by appropriate risk control measures.

5. Who can be the CSM assessment body?

If they fulfil the requirements described in sections § 9 and § 13 below, the following organisations or entities can act as AsBo:

(a) a competent external or internal (i.e. in-house) individual, organisation or entity which is at least independent from the "*design, risk assessment, risk management, manufacture, supply, installation, operation/use, servicing and maintenance*" of the change under assessment.
(b) a national safety authority (NSA), an OTIF national authority competent for technical admission, an EU notified body (NoBo), an EU designated body (DeBo), an OTIF assessing entity.

Irrespectively which of those organisations or entities acts as AsBo, without prejudice to Article 12 of the CSM for risk assessment, it must meet the requirements and criteria listed in Annex II of the CSM for risk assessment (see section § 9 below), including independence, and it must be accredited or recognised with respect to those requirements and criteria (see section § 13 below).

The CSM for risk assessment allows thus the use of all three types (A, B and C) of the AsBo defined in section § 4.1.6 and Annex A of the ISO/IEC 17020:2012 standard, referenced within Annex II of the CSM for risk assessment. All three types of AsBo must demonstrate their independence at least from the "*design, risk assessment, risk management, manufacture, supply, installation, operation/use, servicing and maintenance*" of the system under assessment. According to section § 4 of the ISO/IEC 17020:2012 standard, the assessment body must also be free of any pressure and incentive, in particular of a financial type, which could affect their judgement or the results of their assessments, in particular from persons or groups of persons affected by the independent assessments.

Permitting also the use of the type C of independence is crucial for the sector provided the AsBo is able to demonstrate its independence from the system under assessment, its integrity and its impartiality. Indeed, knowing that the number of technical experts is limited in some fields of the railway system, it is not always possible to find the appropriate technical expertise externally. For such specific cases, with lack of fully independent technical expertise, technical competence may be preferred to full independence (i.e. to a type A body) in order to guarantee the quality of the independent technical safety assessment.

6. Can the CENELEC independent safety assessor (ISA) perform the work of the CSM assessment body (AsBo)?

The CSM assessment body (AsBo) and the CENELEC independent safety assessor (ISA) are not equivalent conformity assessment bodies. The CENELEC ISA does not exist in EU railway legislation (e.g. CSM for risk assessment, TSIs or equivalent OTIF Uniform Technical Prescriptions). Thereby the CENELEC ISA can neither replace the AsBo, nor perform on its behalf, the independent safety assessment under the AsBo responsibility (refer to sections § 4 above and § 21 below). In particular, care should be taken not to misinterpret the requirements in section § 3.2.1 of the CCS TSI[9]. That TSI explicitly makes compulsory the independent safety assessment by an AsBo instead of

---

[9] *Section § 3.2.1 of the CCS TSI [i.e. Regulation (EU) 2016/919 amended consecutively by Regulations (EU) 2019/776, 2020/378 and 2020/420) explicitly requires the following "for the ETCS Class A system" :*

(a) "the changes made by railway undertakings and infrastructure managers shall be managed in compliance with the processes and procedures of their safety management system", where the process in Annex I of the CSM for risk assessment is to be applied for significant changes;

(b) "the changes made by other actors (e.g. manufacturers or other suppliers) shall be managed according to the risk management process set out in Annex I …" of the CSM for risk assessment;

an ISA. That obligation remains unchanged regardless of whether the proposer manages the changes of CCS sub-systems according to the CSM for risk assessment, or to the CENELEC 50126, 50128 and 50159 standards.

In addition to that, although the roles and working methods of the AsBo are similar to the ones of the independent safety assessor (ISA) referred to in the CENELEC 50128, 50657:2017 and 50129 standards, there is a fundamental difference between the two bodies:

(a) without prejudice to Article 12 of the CSM for risk assessment, the AsBo is obliged to be accredited or recognised (see section § 13 below), and to demonstrate formally the compliance with all the requirements to an acknowledged authority, including competence in well-defined areas, as set up in Annex II, Articles 8 and 9 of the CSM for risk assessment, whereas;

(b) although the CENELEC 50129, 50128 and 50657 standards setup requirements for the competence (see Table B.8 of CENELEC 50128:2011 and 50657:2017) and independence of the ISA (see e.g. Figure 2 and section § 5.1.2 of CENELEC 50128:2011 and 50657:2017), those standards do neither require the ISA to demonstrate its independence and competence, nor oblige the ISA to be accredited or recognised by an acknowledged authority vs. the ISO/IEC 17020 standard requirements;

(c) the scope of work of the AsBo is broader than the CENELEC ISA. The CENELEC 50128 and 50129 standards request an ISA only for signalling[10] systems/applications. The CSM for risk assessment makes compulsory the appointment of the AsBo for the independent safety assessment of all significant changes, regardless of whether they relate to signalling systems, rolling stock or any technical, operational or organisational ones.

Consequently, when the EU legislation, or the equivalent OTIF rules, requires the appointment of an AsBo to a project, and when contractually, or through a notified national rule, the use of CENELEC 50126, 50128 and 50129 standards (with an independent safety assessor) is obligatory, the proposer is free to appoint a single AsBo : 1°) which is accredited or recognised according to the criteria and requirements of Annex II of the CSM for risk assessment, and 2°) which fulfils also the competence requirements of a CENELEC ISA (see point (b) above). In that case, the independent safety assessment carried out by such an AsBo can include also all necessary independent safety assessment activities that should be fulfilled by the CENELEC ISA. Thereby, for a significant change in order to avoid unnecessary duplication of independent (safety) assessments by different conformity assessment bodies and unnecessary duplication of inherent costs, it is not necessary to appoint also an ISA for exactly the same scope of work: refer also to section § 24 below.

When an accredited or recognised AsBo is responsible for the overall independent safety assessment activities, for the reasons explained in points (a) and (b) above, an accredited or recognised AsBo cannot be obliged to mutually recognise the work and the report of a CENELEC ISA, without either:

(d) being able to verify itself that the ISA has the right level of competence and independence, and that the ISA uses working methods similar to the ones described in section § 21 below, or;

(e) being allowed to request additional checks, if deemed necessary.

If the CENELEC ISA is also accredited vs. the ISO/IEC 17020 standard, the mutual recognition might be achieved by checking that the ISA fulfils also all the other requirements contained in Annex II of the CSM for risk assessment.

"… The correct application of the risk management process … set out in Annex I of …" the CSM for risk assessment "… , as well as the appropriateness of the results from this application, shall be independently assessed by a CSM assessment body according to Article 6 of …" the CSM for risk assessment. "The CSM Assessment Body shall be accredited or recognised according to the requirements in Annex II of …" the CSM for risk assessment "… in the fields of 'Control-command and signalling' and 'System safe integration'…".

"The application of the specifications … referred to in Annex A, Table A 3 …" (i.e. application of CENELEC 50126, 50128 and 50129 standards) "… is an appropriate means to fully comply to the risk management process … set out in Annex I of …" of the CSM for risk assessment.

Whenever those specifications/standards "… are used … to … comply to the risk management process…, the independent safety assessment activities that are required by …" the CENELEC standards "… shall be carried out by an Assessment Body … instead of a CENELEC independent safety assessor".

[10] *CENELEC 50657 standard requires an ISA for Rolling Stock sub-system.*

7. When is a CSM assessment body required?

An AsBo is required to perform the checks referred to in section § 4 above when by application of the CSM for risk assessment the proposer considers that the change under assessment is significant. The assessment of the proposer's decision[(11)] on the significance of the change is not in the scope of work of the AsBo.

It is very important that the independent safety assessment starts at the earliest appropriate stage of the project (see section § 19 below) in order to:

(a) understand thoroughly the significant change, the proposer's organisation and the safety and quality processes put in place by the proposer for managing the development, and the risk assessment and risk management of the significant change;
(b) plan the independent safety assessment activities that it intends to undertake for the significant change.

In practice the work of the AsBo preferably starts before the first results from the risk assessment are available (see section § 19 below).

8. Who shall appoint the CSM assessment body?

If the organisation or entity that is to act as AsBo is not already designated in existing European Union or national legislation, the proposer is free to appoint any AsBo competent in the technical field of the significant change and compliant with the criteria and requirements of Annex II of the CSM for risk assessment. The proposer can choose among the types of bodies listed in section § 5 above, including an AsBo accredited or recognised in a third country or in an OTIF Contracting State under equivalent criteria and rules. Refer also to sections § 13 and § 15 below.

9. What specific criteria and requirements does the CSM assessment body have to fulfil?

Annex II of the CSM for risk assessment requires the AsBo to fulfil the following requirements :

(a) all requirements of the ISO/IEC 17020:2012 standard, and of its subsequent amendments. Those are general criteria and requirements concerning the AsBo "*independence, competence, integrity and impartiality*";

(b) specific criteria and requirements needed for carrying out the independent safety assessments requested in Article 6 of the CSM for risk assessment. Those criteria and requirements related to :

  (1) competence in risk management, including the knowledge and experience of the standard safety analysis methods and techniques, as well as knowledge of the relevant risk assessment and risk management standards;

  (2) all relevant technical competence from paragraphs 2 and 3 in Annex II of the CSM for risk assessment for assessing the correct application of the CSM for risk assessment to the change under assessment, the suitability of the results and the safe integration of the change into the railway system (see also section § 10 below);

  (3) competence in checking the correct application of safety and quality management systems or in auditing management systems. This requirement is crucial given that the **AsBo is not required to check all the activities and details of the risk assessment and risk management done by the proposer**: see section § 21 below.

Section § 13 below describes the way, the process and the actor(s) in charge of verifying that the AsBo fulfils all the requirements defined in Annex II of the CSM for risk assessment.

---

(11) The proposer is requested to justify and document its decisions on "non-significant changes" to enable the national safety authority (respectively the ECM certification body) to verify during the supervision (respectively during surveillance) activities that the associated risks are also under control. This means that for safety-related non-significant changes, the justification needs also to be done through risk assessment.

10. What are the areas of competence of the CSM assessment body?

The AsBo shall be accredited or recognised for different areas of competence within the railway system, or parts of it, for which an essential safety requirement exists. That includes the area of competence in operation and maintenance of the railway system. In practice, this led to the following high level areas of competence for the different structural and functional sub-systems of the EU railway system :

(a) infrastructure;
(b) energy;
(c) control command and signalling;
(d) rolling stock;
(e) traffic operation and management;
(f) maintenance;
(g) system safe integration, related to the assessment of the overall consistency and system approach (system level – see next paragraph);
(h) a spare area in the ERADIS database on the website of the European Union Agency for Railways, where the AsBos are registered. The accreditation or recognition body can use it for any other area not covered by the previous ones.

In particular, point 3 in Annex II of the CSM for risk assessment requires that the AsBo shall be accredited or recognised for the competence needed to assess the overall consistency of the risk management and the safe integration of the system under assessment into the railway system as a whole. This specific competence includes the ability of the AsBo to check the following :

(i) the organisation or arrangements put in place by the proposer to ensure a coordinated approach to achieving system safety through a uniform understanding and application of risk control measures for its composing sub systems;
(j) the methodology for the evaluation of the methods and resources deployed by various stakeholders to support safety at both the sub-system and system levels; and
(k) the technical aspects necessary for assessing the relevance and completeness of risk assessments and the level of safety for the system as a whole.

Point 4 in Annex II of the CSM for risk assessment allows an AsBo to be accredited or recognised for one, several or all of these areas of competence. However, to fulfil the requirements of the CSM and to reduce the number of such bodies required to assess the significant change, every AsBo could be accredited or recognised for "at least one technical area of competence in point 2 in Annex II and the competence in point 3 in Annex II for assessing the overall consistency of the risk management and the safe integration of the system under assessment into the railway system as a whole". For those reasons, it is important that the accreditation or recognition indicates clearly and unambiguously all the areas of competence of the AsBo.

It is important to know that the CSM for risk assessment does not give details for the competence requirements defined in its Annex II. For example, it does not specify the specific engineering disciplines, such as embedded real-time systems, telecommunications, hardware, software, human factor, etc. necessary for every structural sub-system. The European Union Agency for Railways created a Cooperation Group with all accredited and recognised AsBos to develop recommendations for use (RFUs) on various subjects. One RFU will cover the detailed competence requirements necessary for every area listed in section § 10, as well for every specific competence listed in section § 9(b) above. All recommendations for use developed in the AsBo Cooperation Group will be made available on the webpage of the European Union Agency for Railways, under the following link https://www.era.europa.eu/common_safety_methods_for_risk_evaluation_and_assessment, in the area dedicated to the CSM for risk assessment.

11. Is the CSM assessment body obliged to have internally all the necessary competence?

The AsBo is not obliged to have internally (i.e. within its organisation or entity) all the technical competences necessary for carrying out the independent safety assessment work. The ISO/IEC 17020:2012 standard referred to in the CSM for risk assessment allows the use of either subcontractors, or individuals or employees of other organisations, to provide additional resources or expertise: see section §6.3 of that standard. The practical arrangements and the capability of achieving the consistent fulfilment of the requirements contained in that

International Standard, where relevant with the use of subcontractors, or individuals or employees of other organisations[12], need to be documented in the management system of the AsBo.

Where the AsBo subcontracts any part of the independent safety assessment, according to the accreditation rules (and similarly applicable to recognition), the AsBo must have the accreditation (respectively recognition) also for the competence which is subcontracted. Indeed, the AsBo has to ensure and be able to demonstrate that the subcontractor is competent to perform the activities in question and, where applicable, complies with the relevant requirements stipulated in the ISO/IEC 17020:2012 standard, or in other relevant conformity assessment standards. The AsBo needs thus to be organised and managed so as to enable it to maintain the capability to perform independent safety assessment in the area of its accreditation or recognition. The AsBo remains also responsible for the whole independent safety assessment work, including thus for the part of independent safety assessment that is subcontracts.

12. Why is the ISO/IEC 17020:2012 standard appropriate for the CSM assessment body?

The ISO/IEC 17020:2012 is a standard that defines general criteria and requirements concerning the competence, impartiality, independence, administration capabilities, organisation, resources, processes and management system for the operation of various types of bodies **performing inspection**. The standard harmonises those general requirements, the inspection bodies are required to comply with, in order to ensure that their services are accepted by clients and by supervisory authorities. The standard is usable for checks of conformity of an "*inspected item*" with the "*requirements of a process*" or with "*general requirements of a regulation*". The standard can be used by an accreditation or a recognition body for the assessment of conformity of inspection bodies. The ISO/IEC 17020:2012 standard is thus directly applicable for the accreditation or recognition of the CSM assessment bodies. The AsBo is required to check the **conformity of the risk assessment done by the proposer** [i.e. the "*inspected item*"] **with the requirements of the CSM for risk assessment** [i.e. with the "*requirements of a process*" and the "*requirements of a regulation*"].

Considering the specific work of the AsBo (see section § 4), which does not deal with product certification[13], the AsBo can be considered as an inspection body. The objective of the independent safety assessment carried out by the AsBo is to provide information about the conformity of the ["*inspected item*", i.e. of "the risk assessment and risk management activities carried out by the proposer for a significant change"] with the ["*requirements of the process*" defined in the CSM for risk assessment]. The tasks of the AsBo include:

(a) inspection activities consisting in the assessment of:

  (1) the suitability of the quality, safety and fitness for purpose of the risk assessment and risk management activities performed by the proposer for a significant change;
  (2) the appropriateness of the results from the risk assessment for the change to fulfil safely the intended objectives;

(b) statement of the conformity of those activities with the requirements of the risk assessment and risk management process set out in Annex I of the CSM for risk assessment and Figure 1. This includes the judgement and conclusions of the AsBo on the suitability of the significant change to fulfil its safety requirements.

To determine whether the proposer's activities are compliant with the requirements of the CSM for risk assessment, the independent safety assessment requires both technical competence and professional judgement[14] not only in the technical field of the system being assessed but in particular in the fields of risk assessment and

---

[12] *According to note 3 in section § 6.3.1 of the ISO/IEC 17020:2012 standard, "where the inspection body engages individuals or employees of other organisations to provide additional resources or expertise, these individuals are not considered to be subcontractors provided they are formally contracted to operate under the inspection body's management system" (see also point § 6.1.2 of that standard).*

[13] *The use of the ISO/IEC 17065 standard related to the certification of products, processes and services is not appropriate for the AsBo accreditation/recognition, which is expected to perform inspection activities.*

[14] *"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.*

risk management. As this specific competence is not contained in the general requirements of the ISO/IEC 17020:2012 standard, the necessary additional requirements for the railways were explicitly added in points § 1, § 2 and § 3 of Annex II of the CSM for risk assessment. They are described in sections § 9 and § 10 above.

13. How to check the competence of the CSM assessment body and establish sufficient trust of its work among all the countries where the CSM for risk assessment is to be applied?

In order to ensure that the AsBos are acknowledged in the same way in whole EU, as well as in all OTIF Contracting States, and that they deliver an equivalent or similar quality of independent safety assessment, the AsBos shall fulfil the requirements in Annex II of the CSM for risk assessment. They shall be either:

(a) **accredited** by the national accreditation body (NAB) of the State where it is established; or
(b) **recognised** by a recognition body of the State where it is established; or
(c) for the EU, the national safety authority, or for the OTIF non-EU Contracting States the OTIF national authority competent for technical admission, recognised by the State[15].

The purpose of the accreditation is to provide an authoritative statement of the competence of a body to perform conformity assessment activities. Its functioning is represented on the left side of Figure 2. As shown, it is governed in the EU by Regulation (EC) N° 765/2008. The ISO/IEC 17011 standard specifies the general requirements for accreditation bodies assessing and accrediting conformity assessment bodies. These two documents lay down:

(d) the general rules on the organisation and operation of the accreditation by the national accreditation body of different conformity assessment bodies as defined for the EU in Article 2 of Regulation (EC) No 765/2008. These are also applicable to the AsBo;
(e) the monitoring or surveillance by the national accreditation body of conformity assessment bodies to which they have issued an accreditation. This is also applicable to the AsBo;
(f) the peer evaluations by other national accreditation bodies for the assessment of a national accreditation body. These peer evaluations are managed by the European co-operation for Accreditation (EA). They are carried out in the EU in accordance with the requirements of Regulation (EC) No 765/2008 and, where applicable, additional sectorial technical specifications (e.g. Annex II of the CSM for risk assessment concerning the specific railway needs on risk assessment and risk management).

Whereas accreditation is the preferred means for the EU of demonstrating technical competence of conformity assessment bodies (refer to recital (12) of Regulation (EC) No 765/2008), Article 5(2) of that Regulation allows a State not to use the accreditation provided it makes available to the European Commission and the other States all the documentary evidence necessary for the verification of the competence of the conformity assessment bodies. For the purposes of the CSM for risk assessment, the alternative way for acknowledging the technical competence of the AsBo is called “recognition”.

In order to ensure the same confidence in both the use of recognition and accreditation for AsBos, the CSM for risk assessment sets out for the recognition the same requirements as Regulation (EC) No 765/2008 does for the accreditation. Similarly to the European co-operation for Accreditation (EA), the role of the European Union Agency for Railways is to coordinate the peer evaluations between the recognition bodies of the EU necessary to ensure that all recognition bodies work in a similar way across EU. Similarly, the role of the OTIF Committee of Technical Experts (through the OTIF Secretary General) is to coordinate the peer evaluations between the recognition bodies of OTIF non-EU Contracting States necessary to ensure that all recognition bodies work in a similar way in all OTIF Contracting States. Use of the ISO/IEC 17011 standard is also recommended to support the recognition bodies. The functioning of the recognition of AsBos is represented on the right side of Figure 2.

(15) *When the Member State recognises its national safety authority (NSA) as AsBo, the Member State is responsible for ensuring that the NSA fulfils the requirements set out in Annex II. In addition to that, the AsBo functions of the NSA shall be demonstrably independent of the other functions of the NSA. OTIF UTP GEN-G of 1.1.2016 sets a similar requirement for OTIF non-EU Contracting States when they recognise a national authority competent for technical admission as AsBo.*

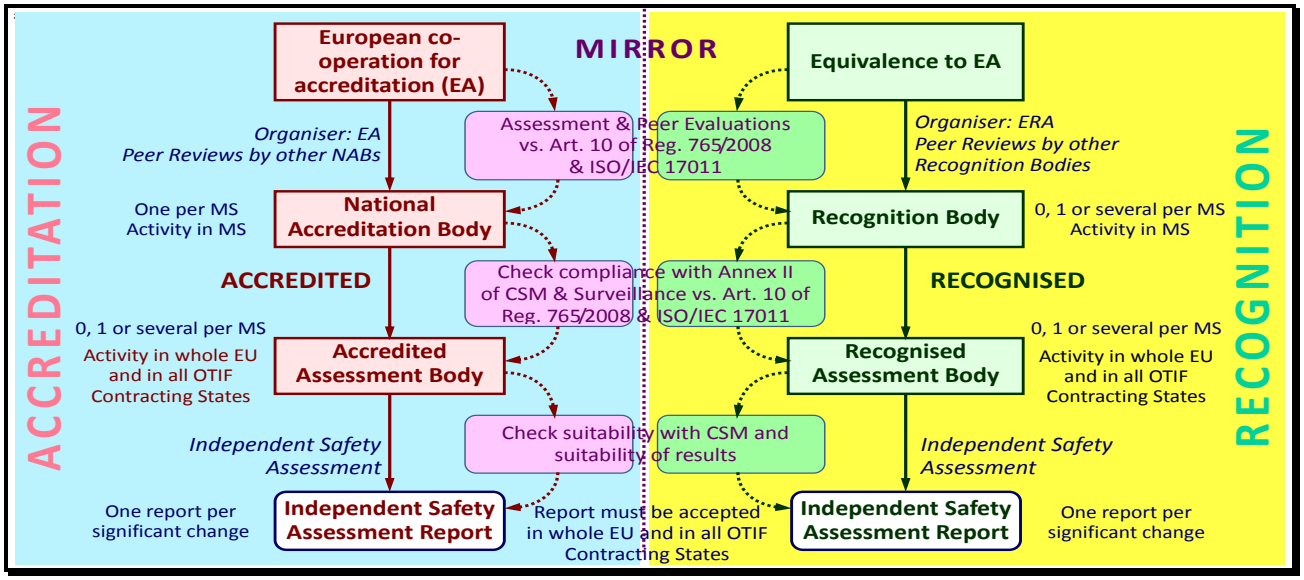

Figure 2 : Accreditation and recognition of CSM assessment bodies.

14. What are the benefits of allowing the recognition of CSM assessment bodies instead of accreditation?

To avoid unnecessary duplication of conformity assessments, and the duplication of inherent costs, it is important to allow the use of recognition in the CSM for risk assessment, in particular for some in-house AsBos, instead of accreditation. Indeed, compliance with existing legislation already requires that:

(a) for the EU the safety management system[16] of railway undertakings and infrastructure managers is certified by the national safety authority;
(b) for the EU and OTIF non-EU Contracting States the system of maintenance of entities in charge of maintenance of freight wagons is certified by ECM certification bodies.

To support the railway sector, Article 9 of the CSM for risk assessment leaves thus flexibility:

(c) to the EU Member States to entitle their national safety authorities and ECM certification bodies to act as recognition bodies of AsBos internal to railway undertakings, infrastructure managers or entities in charge of maintenance of freight wagons;
(d) to the OTIF non-EU Contracting States to entitle their national authority competent for technical admission and their ECM certification bodies to act as recognition bodies of AsBos internal to entities in charge of maintenance of freight wagons.

Those recognition bodies can evaluate, for the EU, during the assessment of the safety management system (point (a) above) or, for the EU and OTIF non-EU Contracting States, during the assessment of the system of maintenance (point (b) above) the ability of the railway undertaking, infrastructure manager or entity in charge of maintenance to manage safely its business, as well as to act as an in-house AsBo.

The CSM for risk assessment allows the recognition of both external and in-house AsBos for stakeholders other than railway undertakings, infrastructure managers and entities in charge of maintenance of freight wagons. However, as only these later ones are legally required to have in place a certified management system, recognition was initially foreseen to enable the recognition of their in-house AsBos (by the competent conformity assessment body) in the scope of the certification of their management system. For the other stakeholders (e.g. manufacturers or railway consulting companies - refer to recital (12) of Regulation 765/2008) there are no particular reasons for using the recognition instead of the accreditation. In the EU Member States, the use of recognition for the other stakeholders would divert the attention of national safety authorities from their key roles in granting the safety certificate/authorisation, the authorisation for placing into service structural sub-systems and vehicles, and in particular, from supervising the safety performance of railway undertakings and infrastructure managers.

[16] *COTIF does not prescribe the use of safety management systems (SMS).*

15. Can all CSM assessment bodies work EU wide and/or in all OTIF Contracting States?

The safety assessment report of any AsBo referred to in section § 5 above, accredited or recognised in an EU Member State, or in an OTIF non-EU Contracting State, in accordance with the requirements in Annex II of the CSM for risk assessment, must be mutually recognised in whole EU and in all OTIF Contracting States.

An AsBo accredited or recognised in an EU Member State in accordance with the requirements of Regulation (EU) N°402/2013 can carry out independent safety assessment in whole EU and in all OTIF Contracting States. By analogy an AsBo accredited or recognised in accordance with the requirements of the equivalent UTP GEN-G of 1.1.2016 can carry out independent safety assessment in all OTIF Contracting States, including those which are also Member States of the EU.

A national safety authority, or an OTIF national authority competent for technical admission, recognised by its State as AsBo in accordance with the requirements of the CSM for risk assessment cannot provide independent safety assessment in other States, unless bilateral agreements are concluded between these two States. Furthermore, Article 6(4) of the CSM for risk assessment limits the cases where the national safety authority can act as AsBo.

The CSM for risk assessment does not forbid in-house accredited or recognised AsBos (except type B bodies – see point A.2 in the ISO/IEC 17020:2012 standard) to carry out independent safety assessment outside their own companies/organisations. The main reasons for permitting in-house AsBos (in particular type C bodies – see section § 5 above) are not motivated by the opportunity to provide consulting services. The benefits of permitting the recognition of AsBos are described in section § 14 above. However, it is worth to mention that:

(a) as the COTIF does not prescribe the use of safety management systems (SMS), the recognition of in-house AsBos through the certification of the safety management system of railway undertakings and infrastructure managers by the national safety authority is not possible in OTIF Contracting State;
(b) the ECM certification body can be entitled by its EU state, or by its OTIF non-EU Contracting State[17], to recognise an in-house AsBo through the certification of the system of maintenance of an entity in charge of maintenance of freight wagons.

16. Can the criteria and requirements for the CSM assessment body be relaxed?

Accreditation and recognition of AsBos are put in place to get the assurance these bodies are equally competent to deliver the tasks described in section § 4 above. The use of an accredited or recognised AsBo enables to achieve the mutual recognition of the results of risk assessments performed in compliance with the CSM for risk assessment (see also section § 1 above). Article 12 of that CSM is an exception to those rules and principles. It is intended to be used for national purposes only when the significant change is not subject to mutual recognition, and where the appointment of an accredited or recognised AsBo might result in higher costs for the significant change. Article 12 could be used for example for changes that affect only the domestic market, i.e. parts of the railway system where international trains would never operate. It should therefore be used with precautions and in duly justified cases with clearly stated limitations in the safety assessment report of the assessment body.

Article 12 allows that the AsBo is neither accredited nor recognised provided the following key requirements are still met : independence, impartiality and competence in the railway area related to the change under assessment, as well as in the fields described in point (b) in section § 9 above. The other requirements of paragraph 1 in Annex II of the CSM for risk assessment [mainly some of the "administrative" requirements of the ISO/IEC 17020:2012 standard] may be relaxed in a non-discriminatory way in agreement with the national safety authority, or with the OTIF national authority competent for technical admission. Article 12 does not list the criteria and requirements that could actually be relaxed, or the types A, B or C of independence of the ISO/IEC 17020:2012 standard that are permitted. "Non-discriminatory" means that any assessment body fulfilling the same relaxed criteria and requirements should be allowed to be appointed on the considered significant change.

[17] *The Annex A of the OTIF ATMF is equivalent to Regulation (EU) No 2019/779 on a system of certification of entities in charge of maintenance of freight wagons.*

Contrary to accreditation or recognition, Article 12 does neither prescribe the process to be used nor the actor who should be responsible for checking that the relaxed criteria and requirements are actually fulfilled by such types of assessment bodies. However, the national safety authority, or the OTIF national authority competent for technical admission, is required to agree on the criteria and requirements of paragraph 1 in Annex II of the CSM for risk assessment that may be relaxed. Article 12 also does neither specify requirements for the surveillance of such bodies nor peer evaluations between the actors who would check the compliance with those relaxed criteria and requirements. Considering that the agreement of the national safety authority, or of the OTIF national authority competent for technical admission, is needed for relaxing the other criteria and requirements, it would be logical that this authority is also in charge of supervising the correct application of its agreement.

Considering these uncertainties and differences of criteria and requirements for the assessment body, compared to accreditation or recognition, Article 12 does not contribute to establish mutual trust between railway stakeholders. It does not provide the same assurance for the different parts of the railway system concerning the independent safety assessment of the correct application of the CSM for risk assessment and of the suitability of the associated risk assessment results. The safety assessment report of an assessment body accepted under Article 12 cannot thus benefit from mutual recognition granted to accredited or recognised AsBos.

Article 12 is not intended to be used as the normal and standard way of acknowledging the independence, impartiality and competence of AsBos. As it does not enable mutual recognition of the results of risk assessments and of the associated safety assessment reports, Article 12 does not support the opening of the European railway market. Article 12 should be used exceptionally, and in duly justified cases, with clearly stated limitations in the safety assessment report of the assessment body.

Assuming the text in Article 12 "*in agreement with the national safety authority*" or "*with the OTIF national authority competent for technical admission*" means that the check of fulfilment of the relaxed criteria and requirements is actually done by the national safety authority, or by the OTIF national authority competent for technical admission, then recognition of in-house AsBos according to Article 9 of the CSM for risk assessment should be preferred to the use of Article 12 : refer to section § 14 above. That recognition would be done through the certification and supervision or surveillance of the management system of the company. On the contrary, other types of stakeholders than railway undertakings, infrastructure managers and entities in charge of maintenance of freight wagons (e.g. railway consulting companies) are not required to have a certified management system in place. For the reasons described in section § 14 above, they should not be recognised by the national safety authority, or by the OTIF national authority competent for technical admission. Those other types of stakeholders should be rather submitted to accreditation, although the use of recognition is also legally permitted.

Whenever Article 12 is used, for transparency reasons, the safety assessment report of the assessment body should clearly list the criteria and requirements of Annex II of the CSM for risk assessment that are relaxed.

17. Is it obligatory to have at least one CSM assessment body in the country?

Considering the explanations in section § 15 above, States are not obliged to have in place an AsBo. Bodies from other States can be used if they are accredited or recognised for the areas of competence relevant for the change under assessment. In practice there may be several AsBos, variously accredited or recognised, or no bodies at all within a State. A State is also able to use either the accreditation, or the recognition of those bodies, or both of these two options, to verify that the AsBos comply with the requirements set out in Annex II of the CSM for risk assessment. However **an AsBo which is already accredited does not need also to be recognised and vice versa**. It would be an unnecessary and not cost effective "double acknowledgement of its competence".

18. Where can a proposer find the list of all accredited and recognised CSM assessment bodies?

The European Union Agency for Railways is responsible for registering in the ERADIS data base the following information for the EU and the OTIF non-EU contracting states :

(a) the Member State choice concerning the use of accreditation and/or recognition, or not any of these two options (see section § 17);
(b) where applicable, the AsBos directly recognised by the Member state;
(c) where applicable, the national accreditation body and/or recognition bod(y/ies) in the Member State;
(d) the accredited AsBos with their area(s) of competence and the Member State where they are accredited;

(e) the recognised AsBos with their area(s) of competence and the recognition body that recognised them;
(f) the changes[18] to the situation of an AsBo, including the extension or the reduction of the areas of competence, following a notification from the national accreditation body or recognition body.

Although the Secretary General of OTIF should make publicly available this information for OTIF non-EU Contracting States, in practice by virtue of the agreements between the European Commission, the European Union Agency for Railways and OTIF, this is managed through the ERADIS data base of the Agency.

19. When does the CSM assessment body start the independent safety assessment?

As described in the previous sections of this paper, an AsBo is required by the CSM for risk assessment when a proposer makes a significant change to the railway system, or when required by other EU legislation such as a TSI or equivalent OTIF Uniform Technical Prescriptions.

Considering the proactive role of the AsBo (see section § 21 below), it is important, especially for complex projects or changes to detect the following as early as possible: any non-compliance with the company organisation[19], safety and quality processes, with the risk management process set out in Annex I of the CSM for risk assessment or inappropriate risk control measures. This is crucial to enable the proposer to take timely any necessary remedial actions and to accept the significant change under assessment. Thereby, the AsBo should start its independent safety assessment work *"at the earliest appropriate stage of the risk assessment process"*. It should follow the project till the completion of the process. In practice this requires sufficient project documentation (e.g. project organisation, project plans, definition of the change, risk assessment plans, etc.) to be available to enable the AsBo to plan and target the key areas for further or more detailed independent safety assessment.

To enable the proposer taking timely remedial actions, it is important for every step of the risk management process in Figure 1 that the AsBo regularly reports any identified cases of non-compliance with the company organisation, safety or quality processes, with the provisions of the CSM for risk assessment or the detected inadequacies of results from the risk assessment that compromise the system under assessment from fulfilling safely the intended objectives of the change.

If not involved from the very beginning of the project, it is important that the AsBo finds out the outstanding issues and communicates these to the proposer as a priority for their resolution.

20. When does the CSM assessment body finish the independent safety assessment?

The work of the AsBo finishes when it delivers its safety assessment report to the proposer: refer also to sections § 22 and § 23 below.

21. How is the independent safety assessment to be done by the CSM assessment body?

According to the definition of the assessment body in Article 3(14) of the CSM for risk assessment, 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.

---

[18] *If it appears during the periodical surveillance by the national accreditation body (by the recognition body) that the AsBo no longer satisfies the criteria set out in Annex II of the CSM for risk assessment, the accreditation body (the recognition body) shall limit the scope of application of the accreditation (recognition), suspend or withdraw it, depending on the degree of non-compliance.*

[19] *The term organisation refers here to the proposer's (project) organisation, including the safety and quality processes and assigned resources and responsibilities, 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.*

Having regard to the requirements contained in Article 6(2)[20] of the CSM for risk assessment and in section § 7.1[21] 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 :

(a) **1st step :** the understanding of the change and of the proposer's organisation for the change management and for the risk management;

(b) **2nd step :** the planning and prioritisation of the AsBo independent safety assessment activities;

(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 documented evidence of the identified non-compliances and the follow up of their management by the proposer;

(d) **4th step :** the delivery of the independent safety assessment conclusions and report.

AsBo WORKING METHOD :

(a) **1st step : understand the change and the proposer's organisation for the change management and for the risk management :**

(1) based on documentation provided by the proposer, the AsBo must get a clear and thorough understanding of the following :

(i) 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;

(ii) the proposer's plans and organisation for the management of the change;

(2) to do that, the AsBo usually needs the following information :

(i) the complete system definition of the change as required in paragraph § 2.1.2 in Annex I of the CSM for risk assessment, including the interfaces with other sub-systems and other actors impacted by the change through those interfaces;

(ii) 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;

(iii) the description of the organisation[22], 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 bullet point § (a)(2)(i) above]) and of the competencies of the experts appointed for carrying out the risk management process for the change.

---

[20] *Article 6(2) of the CSM for risk assessment specifies the main steps of the independent safety assessment activities, without imposing any specific working method.*

[21] *Section § 7.1 of the ISO/IEC 17020:2012 standard referred to in Annex II of the CSM for risk assessment 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.*

[22] *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 the CSM for risk assessment, the AsBo is required to independently assess whether the project organisation matches with the applicable Safety Integrity Levels.

(b) **2nd step : plan and prioritise the AsBo independent safety assessment activities :**

(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.

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.

(2) Considering that independent safety assessment is an inspection activity within the framework of Article 6(2) of the CSM for risk assessment 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 the first paragraph of this section (§ 21), the AsBo independent safety assessment strategy must :

(i) 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;
(ii) 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;

(3) In practice, the planning of the AsBo independent safety assessment activities is done as an integrated part of the assessments done in bullet point § (c) below. Before starting the independent safety assessment, the AsBo has to review beforehand and to understand thoroughly all the inputs listed in bullet point § (a) above. Based on that documentary review, the AsBo has to produce the "independent safety assessment plan"[(23)] 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 the CSM for risk assessment and of its flowchart, it shall not be limited to that. In practice, as explained in bullet point § (a) above, the setting up of the plan for the independent safety assessment will permit the AsBo to achieve all the following :

(i) a thorough understanding of the significant change.

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;

(ii) the understanding of the proposer's organisation for the management of the change and of the risk management;
(iii) description of the methodology for assessing the correct application and correct management of the risk management in accordance with both the requirements of the CSM for risk assessment and the proposer's supporting safety and quality processes. This includes the description of :

- the assessment of the correct application of the proposer's risk management process and of the suitability of the results from that process;
- the gathering and reporting of documented evidence of the identified non-compliances with respect to the CSM for risk assessment and the proposer's safety and quality processes, and then;

(23) *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 (b)(4) and* (b)(5) *here after in section § 21.*

- 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;

(iv) have a clear view on the set of activities to be completed for the delivery of the independent safety assessment conclusions and report.

(4) 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 the CSM for risk assessment 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 :

(i) risks related to the organisation, application and effectiveness of the safety and quality processes for managing the change;
(ii) risks in the correct application of the risk management process of the CSM;
(iii) independently of the proposer's risk classification, all risks arising from the change which could potentially result in collisions[24], derailments[25] or other types[26] 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.

Remark: the risks in bullet points (i) and (ii) can also result in the accidents listed in point (3). It is thus important they are also independently assessed.

(5) The use of a risk-based strategy and professional judgement for setting up the priorities for the independent safety assessment activities enables the AsBo :

(i) to focus the thorough assessment efforts on the areas the AsBo considers to be the highest or most critical risks, and;
(ii) 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.

(6) To make possible the mutual recognition of the AsBo independent safety assessment report, according to Annex III of the CSM for risk assessment, the final report shall include a summary of the independent safety assessment plan built in bullet point § (b) above, a description of what was actually assessed and the reference of the complete independent safety assessment plan[27].

---

[24] *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).*

[25] *Types of derailments : plain track, curves, junctions.*

[26] *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.*

[27] *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).*

(c) 3rd step : independent safety assessment, evidence gathering and follow up of proposer's action plan(s)

Reminder

For the independent safety assessment by an AsBo, as understood by Article 6(2) of the CSM for risk assessment, Annex II of that Regulation requires the AsBo to have technical competence, experience and professional judgement[28] in all the following fields without exceptions :

- the technical field(s) of the system being assessed;
- the fields of risk assessment and risk management;
- the fields of correct application of safety and quality management systems or in auditing such management systems.

  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 the CSM for risk assessment.

So, compared to the "conformity assessments with TSIs"[29], or with the equivalent OTIF Uniform Technical Prescriptions, by notified bodies, the "independent safety assessment by an AsBo"[30] 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.

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 :

(1) *"independently assess what is written in the proposer's plans" :*

(i) 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 bullet point § (a) 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 bullet points § (a) above and § (b) above*.

(ii) 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 (c)(2) below.

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;

(2) "*independently assess what is actually done by the proposer*" :

---

[28] *"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.*

[29] *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".*

[30] *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.*

This consists in conducting an assessment[31] 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 the CSM for risk assessment for every step of the risk management process in Annex I of the Regulation. In order to do so, the AsBo shall :

(i) conduct a **thorough vertical slice assessment**[32] at least on the areas the AsBo considers to be of highest or most critical risks[33], 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 bullet point § (b)(4) above, in order to :

- check whether the proposer applies correctly the requirements for every step of the risk management process in Annex I of the CSM for risk assessment.

  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;
  - 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;

- check whether the proposer actually applies the safety and quality processes for the design and the implementation of the change;
- 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;
- check the absence of non-compliances, including for the sub-contractors, with :

  - the provisions of the risk management process in the CSM for risk assessment;
  - the company (and project) organisation as described in the documentation mentioned in bullet point § (a)(2)(iii) above;
  - the safety or quality processes;

- 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);
  - weaknesses in the processes and insufficient documentation of the activities actually done;
  - etc.

- be able to arrive at the professional judgement needed in bullet point § (d) below;

(ii) 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 :

- assigned to an actor who is in charge of controlling the identified hazard;
- if the hazard falls under the domain of control of the proposer, it is controlled to an acceptable level by the proposer, or;

---

[31] *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.*

[32] *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 the CSM for risk assessment.*

[33] *See also the strategy in bullet point § (b) concerning the assessment of medium and low risks.*

- 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;

Note : by virtue of point § 1.1.5 in Annex I of the CSM for risk assessment, 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.

(iii) as the AsBo usually uses sampling techniques[34] (see bullet point § (b) above), the AsBo has to ensure that the independent safety assessment and the interpretation of the results from the proposer's risk management process are correct and cover all steps of the risk management process.

(3) "*gather the evidence and follow up the proposer's action plan(s)*" : this includes the following :

(i) the gathering of any relevant evidence (i.e. documentary proofs) of the actual deployment of the strategy set out in the assessment plan in bullet point § (b) above;

(ii) the management of any outcomes from the independent safety assessment, including :

- a proactive and early identification of (potential) issues;
- a regular reporting of the identified issues to the proposer to enable the proposer to take timely remedial actions;
- 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;

(iii) 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[35], 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 technology, safety culture of the proposer, safety criticality and level of risk introduced by the change;

(iv) 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[36]. 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

---

[34] *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 (32)) 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.

[35] *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.*

[36] *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).*

assessment report of the AsBo has to clearly document all issues and non-compliances on which according to Article 15(1) of the CSM for risk assessment the proposer disagrees at the end of the independent safety assessment.

(d) 4th step : independent safety assessment conclusions and report

The independent safety assessment report has to comply with Annex III of the CSM for risk assessment. This point is addressed in section § 22 below.

22. What is the content of the safety assessment report of the CSM assessment body?

Based on the evidence (i.e. documentary proofs) from the independent safety assessment activities, the AsBo delivers to the proposer a safety assessment report with its judgement and conclusions on the suitability of the significant change to fulfil successfully its safety requirements. Annex III of the CSM for risk assessment requires that at least the following information is included in that report :

(a) the identification of the AsBo;
(b) the independent safety assessment plan referred to in bullet point § (b) above in section § 21. Usually, a summary[37], and a reference to the complete plan, are sufficient;
(c) the definition of the scope of the independent safety assessment as well as its limitations;
(d) the results of the independent safety assessment including in particular:
    (1) detailed information on the independent safety assessment activities for checking the compliance with the provisions of the CSM for risk assessment;
    (2) any identified cases of non-compliances with the provisions of the CSM for risk assessment and the assessment body's recommendations;
    (3) all issues and non-compliances on which according to Article 15(1) of the CSM for risk assessment the proposer disagrees at the end of the independent safety assessment, and;
    (4) the limitations of the independent safety assessment (this is linked to bullet point (c) above);
(e) the conclusions of the independent safety assessment concerning the compliance of the proposer's risk assessment and risk management with the requirements of the CSM for risk assessment. They shall include a clear statement and expert judgement on whether :
    (1) the proposer applied correctly the risk management process in Annex I of the CSM for risk assessment;
    (2) the results from the proposer's risk management are suitable for the change under assessment to fulfil its safety requirements;
    (3) any safety related application conditions (SRACs - with a reference to the conditions), or exported constraints, are necessary for the safe use of the change.

In case Article 12 is used, for transparency reasons, the safety assessment report of the assessment body should clearly list the criteria and requirements of Annex II of the CSM for risk assessment that are relaxed.

The term "recommendations" in point (d)(2) above refers to the observations, and the general type of advice [if it is clear that such advice cannot compromise the independence of the AsBo (see below)], raised by the AsBo during the checks of compliance referred to in section § 4 above.

Given that the AsBo must be independent, it cannot deliver advices or solutions on how to address the detected non-compliances with the requirements of the CSM for risk assessment or any organisational concerns related to safety and quality assurance processes. The AsBo may only provide advice if it is clear that the advice cannot compromise the independence of the assessment body. This could be general type advice or guidance, not specific to the system under assessment and such as it could be given to any broadly similar project:

[37] *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).*

(f) Examples of advices which could be given include safety management process best practice, guidance on the interpretation of standards and the consequences of specific technology choices.

(g) Examples of advice which could compromise the independence include which design, operational or organisational option should be taken to control the identified risks, what technology to use and any specific mitigation for hazards. Such advices are not allowed.

23. Are the judgments and conclusions of the CSM assessment body binding for the proposer?

As explained in section § 4 above, the proposer is the sole responsible for carrying out correctly all the risk assessment and risk management activities specified in the CSM for risk assessment. Notwithstanding that, the safety assessment report of the AsBo is an important input for the proposer to be taken into account for the safety acceptance of the significant change. Based on the AsBo report and on the results of application of the CSM for risk assessment by its safety experts, the proposer can judge with increased assurance on whether all identified hazards and associated risks are controlled to an acceptable level. Both of these inputs contribute in making the proposer confident that the system under assessment can fulfil safely the intended objectives of the change. Article 16 of the CSM for risk assessment explicitly requires the proposer to *"produce a written declaration that all identified hazards and associated risks are controlled to an acceptable level"*.

Although this should not occur because of a proactive involvement of the AsBo from the beginning of the project (see section § 21 above), the proposer can disagree with some of the conclusions of the AsBo. For example, despite a diverging opinion of the AsBo, the proposer may decide that the implemented safety requirements will keep the risk to an acceptable level. The proposer will monitor in practice the effectiveness of those predictive risk control measures using the Regulation 1078/2012. In such cases, the proposer is required to justify and document the part of the safety assessment report for which it eventually disagrees with the conclusions of the AsBo.

24. What are the interactions between the CSM assessment body and the other conformity assessment bodies?

The overall purpose of appointing a competent and independent AsBo, accredited or recognised, is to set up the foundation for mutual recognition. Consequently, by virtue of Article 6(3) of the CSM for risk assessment, duplication of unnecessary work between the different conformity assessment bodies[(38)] is to be avoided.

When authorising vehicles[(39)] and/or other structural sub-systems, the national safety authority, or the OTIF national authority competent for technical admission, shall take into account the proposer's declaration which is referred to in section § 23 and which is based on the independent safety assessment report of the AsBo. For the EU Member States and without prejudice to Article 12 of Directive 2016/797, the national safety authority, or the OTIF national authority competent for technical admission, may not request additional checks or risk analyses unless it is able to demonstrate the existence of a substantial safety risk.

If a technical specification for interoperability (TSI), or equivalent OTIF Uniform Technical Prescriptions, may request risk assessments to be performed, legally the EU notified body, or the OTIF assessing entity, is responsible for checking that the risk assessment is duly performed. If the EU notified body, or the OTIF assessing entity, does not fulfil[(40)] the criteria in Annex II of the CSM for risk assessment for performing itself the independent safety

---

(38) *For the EU, the other conformity assessment bodies are national safety authorities (NSAs, as defined in Article 3(7) of Directive 2016/798), notified bodies (NoBos, as defined in Article 2(42) of Directive 2016/797), designated bodies (DeBos, as referred to in Article 15(8) of Directive 2016/797), independent safety assessors (ISAs, as defined in the CENELEC 50128 and 50129 standards), ISO 9001 conformity assessment body, etc. In OTIF Contracting States, the other conformity assessments bodies are understood to include the National Authority Competent for technical admission, the Assessing Entity and, depending on national provisions, also the independent safety assessors and other conformity assessment bodies.*

(39) *In OTIF the equivalent process is referred to as admission to international operation.*

(40) *In practice, in order to perform itself the independent assessment of both the correct application of the CSM for risk assessment and of the suitability of the results from the risk assessment, the EU notified body, or the OTIF assessing entity, has also to fulfil the requirements described in sections § 9 and § 13 of this explanatory note.*

assessment of the correct application of the CSM and of the appropriateness of the results, it can subcontract the work to an AsBo who meets those criteria. In this case, for the EU by virtue of Article 7(1) of Commission Decision 2010/713, "*where a notified body subcontracts specific tasks connected with conformity assessment or EC verification …, it shall take full responsibility for the tasks performed by subcontractors*". So, for the specific case described in this paragraph :

(a) the EU notified body has the responsibility to check that the tasks of the AsBo are duly performed, only if a technical specification for interoperability, or equivalent OTIF Uniform Technical Prescriptions, requires the application of the CSM for risk assessment;
(b) the AsBo who performs the independent safety assessment delivers its conclusions to the EU notified body within a safety assessment report;
(c) the EU notified body includes the safety assessment report in the technical file that has to accompany the EC declaration of verification.

The same principles apply to OTIF non-EU Contacting States by the application of the ATMF Articles 4, 5, 7 and 10. The admission is the task of the OTIF national authority competent for technical admission, or where applicable of an OTIF assessing entity, and it is based on the procedures and prescriptions in force through the ATMF. The OTIF national authority competent for technical admission, or the OTIF assessing entity, will have therefore the final responsibility for the results of the independent safety assessment carried out by the AsBo in the framework of vehicle admission.

In practice, as the applicant/proposer appoints both the EU notified body, or the OTIF assessing entity, and the CSM assessment body, the applicant/proposer is free to contract to the EU notified body, or to the OTIF assessing entity, the check of conformity with the technical specifications of the TSIs, or with the equivalent OTIF Uniform Technical Prescriptions, and to the AsBo the check of the correct application of the CSM for risk assessment. The applicant/proposer can then request contractually the EU notified body, or the OTIF assessing entity, and the AsBo to find an agreement for the independent safety assessment of the risk assessment activities carried out by the proposer. They have to agree on who will do what part of the independent assessment work and who will mutually recognise whose work. As described here above, if a TSI (or the equivalent OTIF Uniform Technical Prescriptions) requires the proposer to perform risk assessments, although the independent safety assessment work can be contracted to an AsBo, the EU notified body, or the OTIF assessing entity, keeps the responsibility also for all the independent safety assessment activities.

So, if a risk assessment is required by a technical specification for interoperability (TSI), or by an equivalent OTIF Uniform Technical Prescriptions, the EU notified body, or the OTIF assessing entity, in charge of delivering the conformity certificate must accept the proposer's declaration referred to in section § 23 (it is based on the independent safety assessment report of the AsBo), unless it justifies and documents its doubts concerning the assumptions made or the appropriateness of the results.

In the EU, Article 9(4) of Regulation (EC) N° 765/2008 requires the national accreditation bodies to "*have in place the necessary procedures to deal with complaints against the conformity assessment bodies they have accredited*". Similar requirements should also exist for the recognition of AsBos. Consequently, when a national safety authority, or an OTIF national authority competent for technical admission, or an EU notified body, or an OTIF assessing entity, discovers a problem with the independent safety assessment work of an AsBo, they can inform the national accreditation body which has accredited it, or the recognition body which has recognised it. The national accreditation body, or the recognition body, will then take the complaint into account for the monitoring or surveillance of the AsBo. For the EU, by virtue of Article 5(4) of Regulation (EC) N° 765/2008 for the accreditation, and by analogy for the recognition, where a national accreditation or recognition body ascertains that an AsBo which has received an accreditation/recognition certificate is no longer competent to carry out a specific conformity assessment activity, or has committed a serious breach of its obligations, that national accreditation body/recognition body shall take all appropriate measures within a reasonable timeframe to restrict, suspend or withdraw the accreditation certificate/the recognition.

25. More information

Regulation (EU) No 402/2013 on the common safety method for risk evaluation and assessment can be found in all EU languages on the EUR-Lex site under the following link:
http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1403261951556&uri=CELEX:32013R0402

Regulation (EC) No 765/2008 sets out the requirements for the accreditation. It can be found under the following link: http://eur-lex.europa.eu/legal-content/FR/ALL/?uri=OJ:L:2008:218:TOC

ISO/IEC 17011 standard specifies the general requirements for accreditation bodies assessing and accrediting conformity assessment bodies. Its use is also recommended to support the recognition bodies.

ISO 19011 standard, that despite being a guideline for auditing management systems, provides also the general guidance on the management of an "audit programme", on the "planning and conducting of an audit", as well as on the competence and evaluation of an auditor and an audit team.