

1 **Application guide for the CSM Assessment Body referred to in Regulation (EU) N°402/2013**
2 **and in OTIF UTP GEN-G of 1.1.2014 on the Common Safety Method (CSM) for risk assessment**

Author : Dragan JOVICIC

European Railway Agency - 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
Gryphenhübelweg, 30
CH-3006 Bern - Switzerland

Web page : www.otif.org

E-mail : bas.leermakers@otif.org

3 **Abstract :** in order to gain trust in risk assessments and to allow mutual recognition of the results of the application of
4 Regulation (EU) No 402/2013, or of the equivalent OTIF Uniform Technical Prescriptions - UTP GEN-G of 1.1.2014, on
5 the CSM for risk assessment, it is necessary to give confidence that the system under assessment can deliver the
6 required level of safety. For this purpose, whenever a significant change is made to the railway system the CSM
7 requires to appoint a CSM assessment body. This body is a competent external or internal individual, organisation or
8 entity, separate and independent from the "design, risk assessment, risk management, manufacture, supply,
9 installation, operation/use, servicing and maintenance" of the system under assessment. Its role is to check the
10 application of the CSM risk management process by the proposer and the risk assessment results in order to form a
11 judgement on whether the change management process and the safety requirements resulting from this process are
12 appropriate and adequate for the planned significant change so that the system can satisfy those safety requirements.
13 The objective of this paper is to summarise and highlight the main requirements to be fulfilled by this body, its role and
14 its responsibilities as defined in "Regulation (EU) No 402/2013⁽¹⁾ on the common safety method for risk evaluation and
15 assessment" or in the equivalent OTIF UTP GEN-G of 1.1.2014.

16 **Used terminology:** considering the equivalence of the requirements contained in Regulation (EU) No 402/2013 and in
17 the OTIF UTP GEN-G of 1.1.2014, the following generic terminology is used in the present document to simplify its
18 reading and understanding. "**CSM for risk assessment**" refers both to Regulation (EU) No 402/2013 and the
19 equivalent OTIF UTP GEN-G of 1.1.2014. "**State**" refers both to an EU Member State and an OTIF Contracting State.

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

22 **Foreword**

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

30 The construction of an interoperable, safe and integrated European railway network, without national frontiers, is
31 now made possible by the compliance with the harmonised European legislation for railway safety management⁽²⁾
32 and for railway interoperability⁽³⁾. The demonstration of compliance with the harmonised European railway legi-
33 slation makes compulsory, under given conditions, the mutual recognition of authorisations and risk assessments
34 within the territory of the European Union. Authorisations and risk assessments shall be accepted, under well
35 given conditions (among which the need for the CSM assessment bodies to be accredited or recognised), by
36 national safety authorities and any other relevant conformity assessment body. Additional authorisations, checks
37 or risk assessments must not be requested unless the existence of a substantial safety risk can be demonstrated.

38 The Contracting States of OTIF have adopted risk assessment requirements [OTIF UTP GEN-G of 1.1.2014]
39 equivalent to Regulation (EU) No 402/2013. However a part of the scope of application of this OTIF UTP GEN-G
40 differs in COTIF compared to the EU railway regulations. Those differences do however not influence the activities
41 and competences of the CSM assessment bodies. Therefore this application guide is also of use to the non-EU
42 Contracting States of OTIF.

43

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

(2) Safety Directive 2004/49/EC.

(3) Interoperability Directive 2008/57/EC.

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

45 Mutual recognition⁽⁴⁾ imposes the acceptance in another State or by another stakeholder of the results of a risk
46 assessment already performed by a proposer, assessed by an independent CSM assessment body and accepted in
47 compliance with the CSM for risk assessment without the need to repeat a full risk assessment. The work done
48 for the first acceptance is to be recognised as valid for any other acceptance provided that *"the system is used
49 under the same functional, operational and environmental conditions"* as the already accepted one, and that
50 *"equivalent risk acceptance criteria are applied"*. For a new application of an already accepted system, further
51 risk assessments and checks are to concentrate only on the deviations from the conditions in which the system
52 was originally accepted.

53
54 **2. What is the concept of independent CSM assessment body?**

55 Regulation (EC) N°352/2009 and its equivalent OTIF UTP GEN-G of 1.5.2012 are first to introduce the concept of
56 independent CSM assessment body. They require the CSM assessment body to carry out an independent safety
57 assessment of the risk assessment process and safety demonstration of the system under assessment in order to
58 provide additional assurance that the necessary level of safety can be achieved (see also section § 0 below).
59 Regulation (EC) N°352/2009 and its equivalent OTIF UTP GEN-G of 1.5.2012 define also:

- 60 (a) What general criteria according to Regulation (EC) N°352/2009 and its equivalent OTIF UTP GEN-G of
61 1.5.2012 must the CSM assessment body fulfil?
62 (b) What is the role of the CSM assessment body?
63 (c) Who can be the CSM assessment body?
64 (d) What is the relationship between the CSM assessment body and the CENELEC independent safety assessor?
65 (e) When is a CSM assessment body required?
66 (f) Who shall appoint the CSM assessment body?

67 Regulation (EU) N°402/2013⁽⁵⁾ and its equivalent OTIF UTP-GEN-G of 1.1.2014 revise and repeal Regulation (EC)
68 N°352/2009 and its equivalent OTIF UTP GEN-G of 1.5.2012 with effect from 21 May 2015. They bring an answer
69 to the following questions that remained open in Regulation (EC) N°352/2009 and its equivalent OTIF UTP GEN-G
70 of 1.5.2012:

- 71 (g) What specific criteria and requirements does the CSM assessment body have to fulfil?
72 (h) What are the areas of competence of the CSM assessment body?
73 (i) Is the CSM assessment body obliged to have internally all the necessary competence?
74 (j) Why is the ISO/IEC 17020:2012 standard appropriate for the CSM assessment body?
75 (k) How to check the competence of the CSM assessment body and establish sufficient trust of its work among
76 all the countries where the CSM for risk assessment is to be applied?
77 (l) What are the benefits of allowing the recognition of CSM assessment bodies?
78 (m) Can all CSM assessment bodies work EU wide and/or in all OTIF Contracting States?
79 (n) Can the criteria and requirements for the CSM assessment body be relaxed?
80 (o) Is it obligatory to have at least one CSM assessment body in the country?
81 (p) Where can a proposer find the list of all accredited and recognised CSM assessment bodies?
82 (q) When does the CSM assessment body start the independent safety assessment?
83 (r) When does the CSM assessment body finish the independent safety assessment?
84 (s) How is the independent safety assessment to be done by the CSM assessment body?
85 (t) What is the content of the independent safety assessment report of the CSM assessment body?
86 (u) Are the judgments and conclusions of the CSM assessment body binding for the proposer?
87 (v) What are the interactions between the CSM assessment body and the other conformity assessment bodies?

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

89

(4) *Mutual recognition is also referred to in some legislation or literature as mutual acceptance or cross acceptance.*

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

90 **3. What general criteria according to Regulation (EC) N°352/2009 and its equivalent OTIF UTP GEN-G of**
91 **1.5.2012 must the CSM assessment body fulfil?**

92 Annex II of Regulation (EC) N°352/2009 and of the equivalent OTIF UTP GEN-G of 1.5.2012 define general type
93 criteria. These criteria are mainly related to the independence, competence, integrity and impartiality of the CSM
94 assessment body. Regulation (EC) N°352/2009 and the equivalent OTIF UTP GEN-G of 1.5.2012 do neither
95 prescribe any detailed requirement nor the way to check the fulfilment of the relevant criteria and requirements
96 by the CSM assessment body. These general criteria remain applicable until 21 May 2015 which is the date of
97 application of Regulation (EU) N°402/2013 and of the equivalent UTP GEN-G of 1.1.2014. Thereafter, the full set
98 of requirements contained in Regulation (EU) N°402/2013 and in the equivalent UTP GEN-G of 1.1.2014, including
99 these general criteria and additional specific ones for the open issues, will apply: see section § 9 below.

100

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

102 The CSM assessment body does neither perform the risk assessment required in Annex I of the CSM for risk
103 assessment nor provides advices or solutions that could compromise its independence. The proposer is
104 responsible for carrying out all the risk assessment and risk management activities specified in the CSM for risk
105 assessment. However, in order to build trust between stakeholders and to facilitate mutual recognition of the
106 results of risk assessments it is necessary to get the assurance that the proposer conducts properly those risk
107 assessment and risk management activities. Therefore to avoid unnecessary additional risk assessments or
108 duplication of work by other conformity assessment bodies, similarly to the CENELEC 50128 and 50129 standards,
109 the CSM for risk assessment requires also an independent safety assessment to be done by an independent,
110 competent and impartial CSM assessment body.

111 The CSM for risk assessment requires the CSM assessment body to:

- 112 (a) check the correct application by the proposer of the risk management process set out in Annex I of the CSM
113 for risk assessment and represented in Figure 1 below;
114 (b) check the suitability of application of that process by the proposer and the appropriateness of the risk
115 assessment results to fulfil safely the intended objectives of the change.
116 The proposer's decision on the significance of the change must not be assessed;
117 (c) deliver to the proposer a safety assessment report that contains the results of the check of compliance with
118 the requirements of the CSM for risk assessment and its judgement and conclusions on the safety of the
119 change under assessment.

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

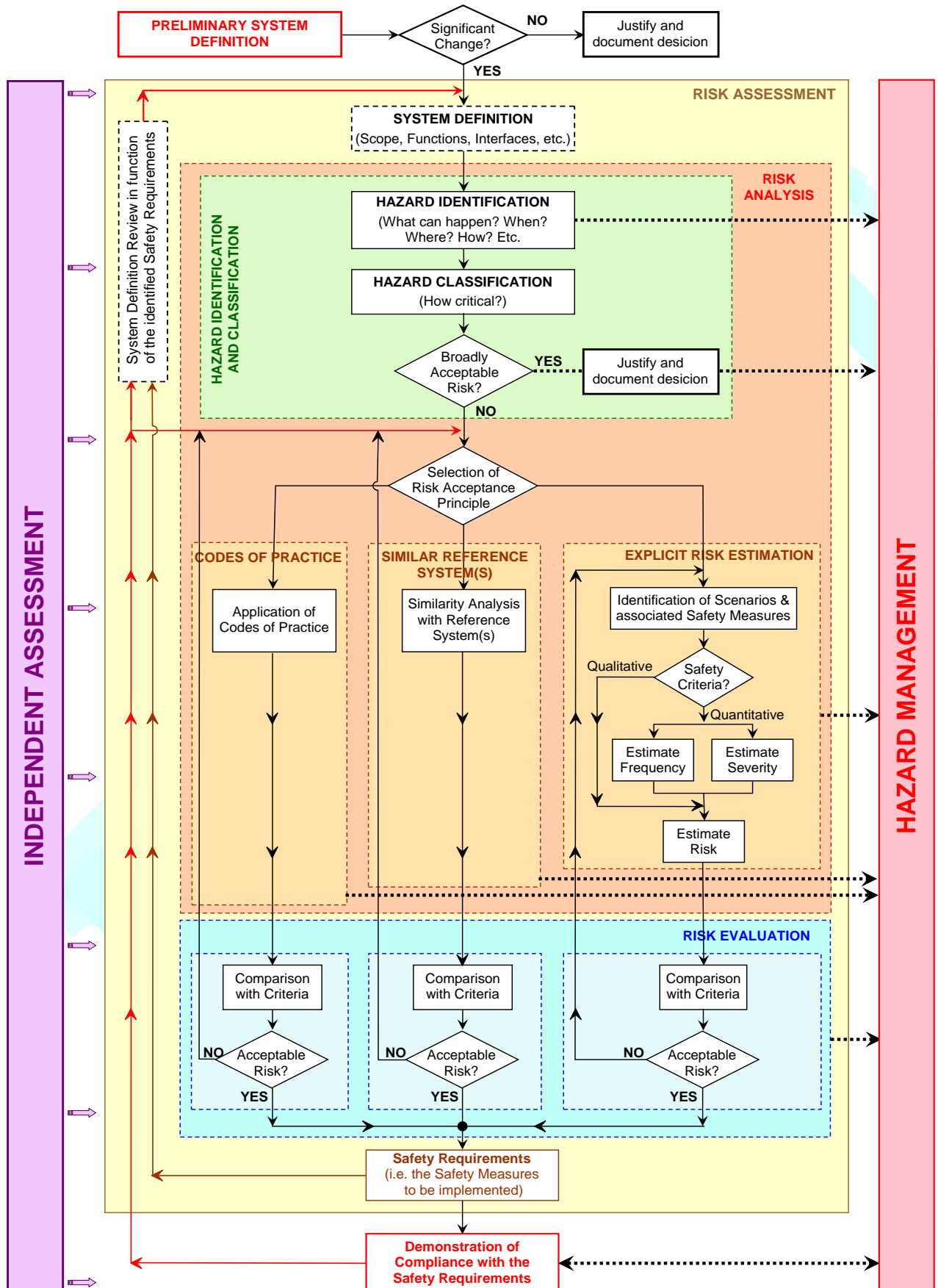
124 Based on the evidence collected through the activities in points (b) and (c) above, the CSM assessment body is
125 able to deliver to the proposer a safety assessment report. This report indicates whether the risk assessment and
126 risk management activities carried out by the proposer are compliance with the requirements of the CSM for risk
127 assessment and it contains the judgement and conclusions of the CSM assessment body on the suitability of the
128 significant change to fulfil its safety requirements.

129

130 **5. Who can be the CSM assessment body?**

131 The following organisations or entities can act as CSM assessment body: a national safety authority (NSA), an OTIF
132 national authority competent for technical admission, an EU notified body (NoBo), an EU designated body (DeBo),
133 an OTIF assessing entity, a competent external or internal (i.e. in-house) individual, organisation or entity which is
134 at least independent from the "*design, risk assessment, risk management, manufacture, supply,*
135 *installation, operation/use, servicing and maintenance*" of the change under assessment.

136 Irrespectively which of those organisations or entities acts as CSM assessment body, it must meet the criteria
137 listed in Annex II of the CSM for risk assessment (see section § 9 below) and it must be accredited or recognised
138 (see section § 13 below).



139

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

141 The CSM for risk assessment allows the use of all three types (A, B and C) of the CSM assessment body which are
142 referred to in section §4.1.6 and Annex A of the ISO/IEC 17020:2012 standard which is referred to in Annex II of
143 the CSM for risk assessment. All three types of CSM assessment body must demonstrate their independence at
144 least from the "design, risk assessment, risk management, manufacture, supply, installation, operation/use,
145 servicing and maintenance" of the system under assessment.

146 Permitting also the use of the type C of independence is crucial for the sector provided the CSM assessment body
147 is able to demonstrate its independence from the system under assessment, its integrity and its impartiality.
148 Indeed, knowing that the number of technical experts is limited in some fields of the railway system, it is not
149 always possible to find the appropriate technical expertise externally. For such specific cases, with lack of fully
150 independent technical expertise, technical competence may be preferred to full independence in order to
151 guarantee the quality of the independent technical safety assessment.
152

153 **6. What is the relationship between the CSM assessment body and the CENELEC independent safety assessor?**

154 Although the role of the CSM assessment body is similar to the one of the independent safety assessor (ISA)
155 referred to in the CENELEC 50128 and 50129 standards, there is a fundamental difference between the two
156 bodies:

- 157 (a) the CSM assessment body is obliged to be accredited or recognised (see section § 13 below) and to
158 demonstrate the compliance with all the requirements, including competence in well-defined areas, as set
159 up in Annex II, Articles 8 and 9 of the CSM for risk assessment, whereas;
- 160 (b) the current version of CENELEC standards does not impose similar requirements to independent safety
161 assessors which are neither required to demonstrate competence nor obliged to be accredited or recognised

162 Consequently, when the EU legislation, or the equivalent OTIF rules, requires the appointment of a CSM
163 assessment body to a project, and when either contractually or through a notified national rule the use of
164 CENELEC 50126, 50128 and 50129 standards is obligatory, the independent safety assessment carried out by the
165 CSM assessment body will at least include all the activities of a CENELEC independent safety assessor. Thereby,
166 for a significant change in order to avoid unnecessary duplication of independent safety assessments by different
167 conformity assessment bodies and unnecessary duplication of inherent costs, it is not necessary to appoint also
168 an independent safety assessor (ISA) for exactly the same scope of work: refer also to section § 24 below.

169 For the reasons in points (a) and (b), a CSM assessment body cannot be obliged to mutually recognise, without
170 being allowed to request additional checks, if deemed necessary, the independent safety assessment report of a
171 CENELEC independent safety assessor.
172

173 **7. When is a CSM assessment body required?**

174 A CSM assessment body is required to perform the checks referred to in section § 4 above when by application of
175 the CSM for risk assessment the proposer considers that the change under assessment is significant. The CSM
176 assessment body must not assess the proposer's decision⁽⁶⁾ on the significance of the change.

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

- 179 (a) understand the significant change, the proposer's organisation and the safety and quality processes put in
180 place by the proposer for managing the development and the risk assessment and risk management of the
181 significant change;
- 182 (b) plan the independent safety assessment activities.

183 In practice the work of the CSM assessment body preferably starts before the first results from the risk
184 assessment are available (see section § 19 below).
185

⁽⁶⁾ *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.*

186 **8. Who shall appoint the CSM assessment body?**

187 If the organisation or entity that is to act as CSM assessment body is not specified in existing European Union or
188 national legislation, the proposer is free to appoint its own CSM assessment body. He can choose among the
189 types of bodies listed in section § 5 above, including a CSM assessment body accredited and recognised in a third
190 country or in an OTIF Contracting State under equivalent criteria. Refer also to section § 15 below.
191

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

193 Regulation (EC) N°352/2009 and the equivalent OTIF UTP GEN-G of 1.5.2012 set up in Annex II the general criteria
194 of "*independence, competence, integrity and impartiality*" to be fulfilled by the CSM assessment body. As
195 Regulation (EC) N°352/2009 and the equivalent OTIF UTP GEN-G of 1.5.2012 did not specify who shall check the
196 compliance with these general criteria, it was difficult to get sufficient confidence in the CSM assessment body
197 work and thus to mutually recognise its independent safety assessment. This is made possible by Regulation (EU)
198 N°402/2013 and the equivalent OTIF UTP GEN-G of 1.1.2014 which revised Annex II and completed those general
199 criteria with additional requirements, including the formal acknowledgement of the CSM assessment body
200 competence: see section § 13 below. In addition to a full compliance with the ISO/IEC 17020:2012 standard,
201 Annex II of the latest CSM for risk assessment requires the CSM assessment body also to demonstrate the
202 following specific competence:

- 203 (a) competence in risk management, including the knowledge and experience of the standard safety analysis
204 techniques and of the relevant risk assessment and risk management standards;
205 (b) all relevant technical competence for assessing the change under assessment and its safe integration into the
206 railway system;
207 (c) competence in checking the correct application of safety and quality management systems or in auditing
208 management systems. This requirement is crucial given that the CSM assessment body is not required to
209 check all the activities and details of the risk assessment and risk management done by the proposer: see
210 section § 21 below.
211

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

213 By analogy to Article 28 of interoperability Directive 2008/57/EC concerning the notification of notified bodies,
214 the CSM assessment body shall be accredited or recognised for the different areas of competence within the
215 railway system, or parts of it for which an essential safety requirement exists. That includes the area of
216 competence in the operation and maintenance of the railway system. For example, possible classifications of
217 competence of a CSM assessment body can be:

- 218 (a) infrastructure;
219 (b) energy;
220 (c) control command and signalling;
221 (d) rolling stock;
222 (e) braking components;
223 (f) operation, maintenance and traffic management;
224 (g) overall consistency and system approach (system level);
225 (h) specific engineering disciplines such as embedded real-time systems, telecommunications, hardware,
226 software, human factor, ...
227 (i) etc.

228 In particular, the CSM assessment body can be accredited or recognised for the competence needed to assess the
229 overall consistency of the risk management and the safe integration of the system under assessment into the
230 railway system as a whole. This specific competence includes the ability of the CSM assessment body to check the
231 following:

- 232 (j) the organisation or arrangements put in place by the proposer to ensure a coordinated approach to
233 achieving system safety through a uniform understanding and application of risk control measures for its
234 composing sub systems;
235 (k) the methodology for the evaluation of the methods and resources deployed by various stakeholders to
236 support safety at both the sub-system and system levels; and

237 (l) the technical aspects necessary for assessing the relevance and completeness of risk assessments and the
238 level of safety for the system as a whole.

239 The CSM for risk assessment allows a CSM assessment body to be accredited or recognised for one, several or all
240 of these areas of competence. However, to fulfil the requirements of the CSM and to reduce the number of such
241 bodies required to assess the significant change, every CSM assessment body should be accredited or recognised
242 for at least one technical area of competence and the competence for assessing the overall consistency of the risk
243 management and the safe integration of the system under assessment into the railway system as a whole.
244

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

246 The CSM assessment body is not obliged to have internally (i.e. within its organisation or entity) all the technical
247 competences necessary for carrying out the independent safety assessment work. The ISO/IEC 17020:2012
248 standard referred to in the CSM for risk assessment allows the use of subcontractors: see section §6.3 of that
249 standard. The practical arrangements and the capability of achieving the consistent fulfilment of the
250 requirements contained in that International Standard, where relevant with the use of subcontractors, need to be
251 documented in the management system of the CSM assessment body.

252 Where the CSM assessment body subcontracts any part of the independent safety assessment, it has to ensure
253 and be able to demonstrate that the subcontractor is competent to perform the activities in question and, where
254 applicable, complies with the relevant requirements stipulated in the ISO/IEC 17020:2012 standard or in other
255 relevant conformity assessment standards. The CSM assessment body needs thus to be organised and managed
256 so as to enable it to maintain the capability to perform independent safety assessment in the area of its
257 accreditation or recognition. The CSM assessment body remains also responsible for the whole independent
258 safety assessment work, including thus for the part of independent safety assessment that is subcontracted.
259

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

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

272 Considering the specific work of the CSM assessment body (see section § 4), the CSM assessment body can be
273 considered as an inspection body. The objective of the independent safety assessment carried out by the CSM
274 assessment body is therefore to provide information about the conformity of the ["*inspected item*", i.e. of "the
275 risk assessment and risk management activities carried out by the proposer for a significant change"] with the
276 ["*requirements of the process*" defined in the CSM for risk assessment]. The tasks of the CSM assessment body
277 include:

- 278 (a) the assessment of quality, safety and fitness for purpose of the risk assessment and risk management
279 activities performed by the proposer for a significant change;
280 (b) the examination of those activities and the determination of their conformity with the requirements of the
281 risk assessment and risk management process in Annex I of the CSM for risk assessment and Figure 1.

282 To determine whether the proposer's activities are compliant with the requirements of the CSM for risk
283 assessment, the independent safety assessment requires professional judgement in the field of risk assessment
284 and risk management. As this specific competence is not contained in the general requirements of the ISO/IEC
285 17020:2012 standard, the necessary additional requirements were explicitly added in points § 1 and § 3 of Annex
286 II of the CSM for risk assessment. These are described in sections § 9 and § 0 above.
287

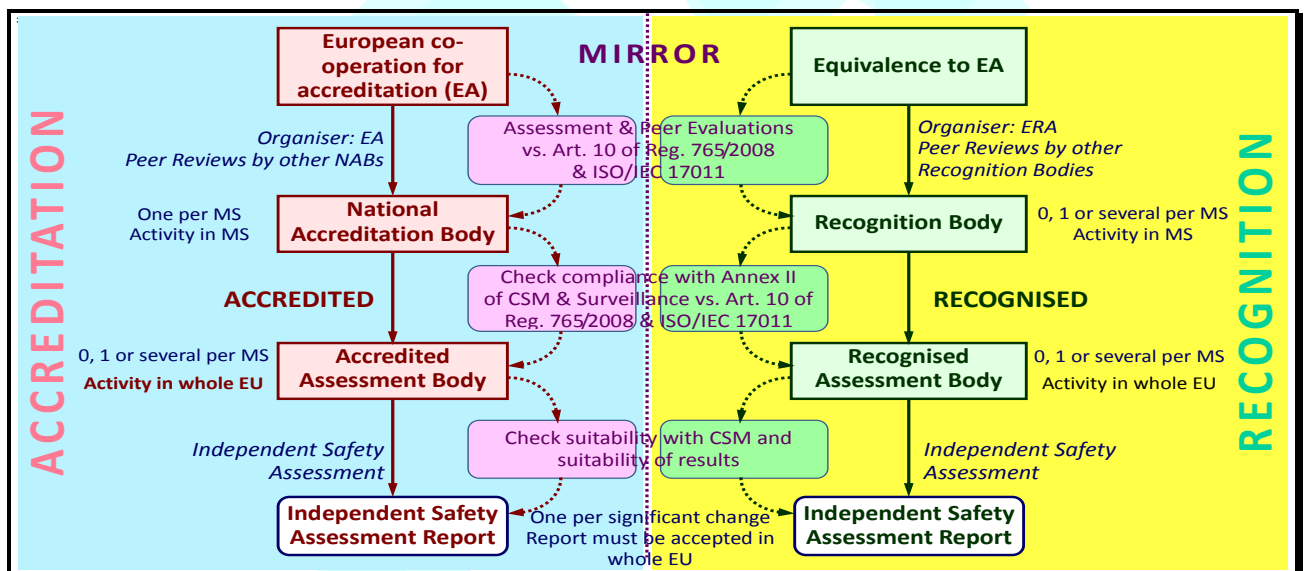
288 **13. How to check the competence of the CSM assessment body and establish sufficient trust of its work among**
 289 **all the countries where the CSM for risk assessment is to be applied?**

290 In order to ensure they are acknowledged in the same way in whole EU, as well as in all OTIF Contracting States,
 291 and that they deliver a similar quality of independent safety assessment, the CSM assessment bodies shall fulfil
 292 the requirements in Annex II of the CSM for risk assessment and be either:

- 293 (a) **accredited** by the national accreditation body (NAB) of the State where it is established; or
- 294 (b) **recognised** by a recognition body of the State where it is established; or
- 295 (c) for the EU, the national safety authority, or for the OTIF Contracting States the OTIF national authority
 296 competent for technical admission, recognised by the State⁽⁷⁾.

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

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



313
 314 **Figure 2 : Accreditation and recognition of CSM assessment bodies.**
 315

316 Whereas accreditation is the preferred means for the EU of demonstrating technical competence of conformity
 317 assessment bodies, Article 5(2) of Regulation 765/2008 allows a State not to use the accreditation provided it
 318 makes available to the European Commission and the other States all the documentary evidence necessary for

(7) When the Member State recognises its national safety authority (NSA) as CSM assessment body, the Member State is responsible for ensuring that the NSA fulfils the requirements set out in Annex II. In addition to that, the assessment body functions of the NSA shall be demonstrably independent of the other functions of the NSA. OTIF UTP GEN-G of 1.1.2014 sets a similar requirement for OTIF Contracting States when they recognise a national authority competent for technical admission as CSM assessment body.

319 the verification of the competence of the conformity assessment bodies. Therefore, in order to ensure the same
320 confidence in both the recognition and accreditation of CSM assessment bodies, the CSM for risk assessment sets
321 out for the recognition the same requirements as Regulation 765/2008 does for the accreditation. Similarly to the
322 European Co-operation for Accreditation (EA), the role of the European Railway Agency is to coordinate the peer
323 evaluations between the recognition bodies necessary to ensure that all recognition bodies work in a similar way
324 across EU. Similarly, the role of the OTIF Committee of Technical Experts (through the OTIF Secretary General) is
325 to coordinate the peer evaluations between the recognition bodies necessary to ensure that all recognition
326 bodies work in a similar way in all OTIF Contracting States. Use of the ISO/IEC 17011 standard is also
327 recommended to support the recognition bodies. The functioning of the recognition of the CSM assessment
328 bodies is represented on the right side of Figure 2.
329

330 **14. What are the benefits of allowing the recognition of CSM assessment bodies?**

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

- 334 (a) for the EU the safety management system⁽⁸⁾ of railway undertakings and infrastructure managers is certified
335 by the national safety authority;
336 (b) for the EU and OTIF Contracting States the system of maintenance of entities in charge of maintenance of
337 freight wagons is certified by ECM certification bodies.

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

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

345 Those recognition bodies can evaluate, for the EU, during the assessment of the safety management system
346 (point (a) above) or, for the EU and OTIF, during the assessment of the system of maintenance (point (b) above)
347 the ability of the railway undertaking, infrastructure manager or entity in charge of maintenance to manage safely
348 its business, as well as to act as an in-house CSM assessment body
349

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

351 The independent safety assessment report of any CSM assessment body referred to in section § 5 above,
352 accredited or recognised in an EU Member State or an OTIF Contracting State in accordance with the
353 requirements of the CSM for risk assessment, must be mutually recognised in whole EU and in all OTIF
354 Contracting States.

355 A CSM assessment body accredited in an EU Member State in accordance with the requirements of Regulation
356 (EU) N°402/2013 can carry out independent safety assessment in whole EU and in all OTIF Contracting States. By
357 analogy a CSM assessment body accredited in accordance with the requirements of the equivalent UTP GEN-G of
358 1.1.2014 can carry out independent safety assessment in all OTIF Contracting States, including those which are
359 also Member States of the EU.

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

365 Although the CSM for risk assessment does not exclude it explicitly, recognised CSM assessment bodies are not
366 expected to carry out independent safety assessment outside their own companies/organisations and therefore

(8) COTIF does not prescribe the use of safety management systems (SMS).

367 to provide consulting services. The benefits of permitting the recognition of CSM assessment bodies is described
368 in section § 14 above. However, it is worth to mention that:

- 369 (a) as the COTIF does not prescribe the use of safety management systems (SMS), the recognition of in-house
370 CSM assessment bodies through the certification of the safety management system of railway undertakings
371 and infrastructure managers by the national safety authority is not possible in OTIF Contracting State;
372 (b) the ECM certification body can be entitled by its EU state or its OTIF Contracting State⁽⁹⁾ to recognise an in-
373 house CSM assessment body through the certification of the system of maintenance of an entity in charge of
374 maintenance of freight wagons.
375

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

377 Accreditation or recognition of CSM assessment bodies is required to enable mutual recognition of their inde-
378 pendent safety assessment reports and therefore of the results of risk assessments performed in compliance with the
379 CSM for risk assessment. Article 12 of that CSM is an exception to those rules and principles. It is intended to be
380 used for national purposes only when the significant change is not subject to mutual recognition and where the
381 appointment of an accredited or recognised CSM assessment body would not be acceptable from the economical
382 point of view. Article 12 could be used for example for changes that affect only the domestic market, i.e. parts of
383 the railway system where international trains would never operate. It should therefore be used with precautions
384 and in duly justified cases.

385 Article 12 allows bypassing the accreditation or recognition of a CSM assessment body provided the following key
386 requirements are met: independence, integrity, impartiality and competence in the railway area related to the
387 change under assessment, as well as in the fields described in points (a), (b) and (c) in section § 9 above. The
388 other requirements of paragraph 1 in Annex II of the CSM for risk assessment [mainly some of the
389 "administrative" requirements of the ISO/IEC 17020:2012 standard] may be relaxed in a non-discriminatory way
390 in agreement with the national safety authority, or with the OTIF national authority competent for technical
391 admission. Article 12 does not list the criteria and requirements that could actually be relaxed, or the types A, B or
392 C of independence of the ISO/IEC 17020:2012 standard that are permitted. "Non-discriminatory" means that any
393 assessment body fulfilling the same relaxed criteria and requirements should be allowed to be appointed on the
394 considered significant change.

395 Contrary to accreditation or recognition, Article 12 does neither prescribe the process to be used nor the actor
396 who should be responsible for checking that the relaxed criteria and requirements are actually fulfilled by such
397 types of assessment bodies albeit the agreement of the national safety authority, or with the OTIF national
398 authority competent for technical admission, is required. It also does neither specify requirements for the
399 surveillance of such bodies nor peer evaluations between the actors who would check the compliance with those
400 relaxed criteria and requirements.

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

407 Article 12 is not intended to be used as the normal and standard way of acknowledging the independence,
408 integrity, impartiality and competence of CSM assessment bodies. As it does not enable mutual recognition of
409 results of risk assessments and of the associated independent safety assessment reports, Article 12 does not support
410 the opening of the European railway market. Article 12 should be used exceptionally and in duly justified cases.

411 Assuming the text in Article 12 "*in agreement with the national safety authority*" or "*with the OTIF national*
412 *authority competent for technical admission*" means that the check of fulfilment of the relaxed criteria and
413 requirements is actually done by the national safety authority, or by the OTIF national authority competent for
414 technical admission, then recognition of in-house CSM assessment bodies according to Article 9 of the CSM for

⁽⁹⁾ The Annex A of the OTIF ATMF is equivalent to Regulation (EU) No 445/2011 on a system of certification of entities in charge of maintenance of freight wagons.

415 risk assessment should be preferred to the use of Article 12 : refer to section § 14 above. That recognition would
416 be done through the certification and supervision or surveillance of the management system of the company. On
417 the contrary, other types of stakeholders than railway undertakings, infrastructure managers and entities in
418 charge of maintenance of freight wagons (e.g. railway consulting companies) are not required to have a certified
419 management system in place, they should not be recognised by the national safety authority, or by the OTIF
420 national authority competent for technical admission. Those other types of stakeholders should be rather
421 submitted to accreditation.

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

425

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

427 Considering the explanations in section § 15 above, States are not obliged to have in place a CSM assessment
428 body. Bodies from other States can be used. In practice there may be several CSM assessment bodies, variously
429 accredited or recognised, or no bodies at all within a State. A State is also able to use either the accreditation or
430 the recognition of those bodies or both of these two options. However a CSM assessment body which is already
431 accredited does not need also to be recognised and vice versa. It would be an unnecessary and not cost effective
432 "double acknowledgement of its competence".

433

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

435 The European Railway Agency is responsible for registering in the ERADIS data base the following information for
436 the EU:

- 437 (a) the Member State choice concerning the use of accreditation and/or recognition, or not any of these two
438 options (see section § 17);
- 439 (b) where applicable, the CSM assessment bodies directly recognised by the Member state;
- 440 (c) where applicable, the national accreditation body and/or recognition bod(y/ies) in the Member State;
- 441 (d) the accredited and recognised CSM assessment bodies with their area(s) of competence and the Member
442 State where they are accredited/recognised;
- 443 (e) the changes⁽¹⁰⁾ to the situation of a CSM assessment body following a notification from the national
444 accreditation body or recognition body.

445 The Secretary General of OTIF should make publicly available this information for OTIF non-EU Contracting States.
446

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

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

451 Considering the role of the CSM assessment body (see section § 21 below), it is important, especially for complex
452 projects or changes to detect the following as early as possible: any non-compliance with the company
453 organisation, safety and quality processes, with the risk management process set out in Annex I of the CSM for
454 risk assessment or inappropriate risk control measures. This is crucial to enable the proposer to take corrective
455 actions before the acceptance of the significant change under assessment. Thereby, the CSM assessment body
456 should start its independent safety assessment work "at the earliest appropriate stage of the risk assessment
457 process". It should follow the project till the completion of the process. In practice this requires sufficient project
458 documentation (e.g. project organisation, project plans, definition of the change, risk assessment plans, etc.) to
459 be available to enable the CSM assessment body to plan and target the key areas for further safety assessment.

(10) *If it appears during the periodical surveillance by the national accreditation body (by the recognition body) that the CSM assessment body no longer satisfies the criteria set out in Annex II of Regulation 402/2013, 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.*

460 To understand the significant change under assessment and the way its management is planned, the CSM
461 assessment body usually needs the system definition, a description of the project, the description of the safety
462 and quality processes, the organisation and information about the experts appointed to carry out the risk
463 assessment process. Based on these inputs, the CSM assessment body is able to produce an "independent safety
464 assessment plan" to cover the assessment of every step of the CSM risk management process represented in
465 Figure 1. The aim of this plan is to highlight the key milestones of the independent safety assessments necessary
466 to ensure the completion of the project on time. To enable the proposer taking timely remedial actions, it is
467 important for every step of the risk management process in Figure 1 that the CSM assessment body regularly
468 reports any identified cases of non-compliance with the company organisation, safety or quality processes, with
469 the provisions of the CSM for risk assessment or the detected inadequacies of results from the risk assessment
470 that compromise the system under assessment from fulfilling safely the intended objectives of the change.

471 If not involved from the very beginning of the project, it is important that the CSM assessment body finds out the
472 outstanding issues and communicates these to the proposer as a priority for their resolution.
473

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

475 The work of the CSM assessment body finishes when it delivers its independent safety assessment report to the
476 proposer: refer also to sections § 22 and § 23 below.
477

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

479 The independent safety assessment⁽¹¹⁾ does neither require the CSM assessment body to perform a complete and
480 thorough review of all outputs of the risk management activities nor to check all details and all the results from
481 the risk assessment performed by the proposer. This would neither be cost effective nor necessary.

482 Compared to the conformity assessments with TSIs, or with the equivalent OTIF Uniform Technical Prescriptions,
483 by notified bodies, which aim at checking that all the requirements of the considered TSIs (or the equivalent OTIF
484 Uniform Technical Prescriptions) are met (these are "standard based checks"), the independent safety assessment
485 by a CSM assessment body is "more about making a judgement on safety", focussing the assessment on areas of
486 highest risks. This is a distinct activity, with a different purpose and also with different competences. Thereby the
487 modules that set out a particular methodology for the conformity assessment with a TSI (or with the equivalent
488 OTIF Uniform Technical Prescriptions) are not entirely applicable to the work of the CSM assessment body.
489 Instead, for the specific needs of the independent safety assessment, according to Article 6(2) of the CSM for risk
490 assessment, the CSM assessment body needs to check the correct application of a "full quality management
491 system"⁽¹²⁾ and a "full safety management system" for managing the significant change under assessment.

492 To provide a judgement, based on evidence, of the suitability of the system under assessment to fulfil its safety
493 requirements⁽¹³⁾, the CSM assessment body needs to:

- 494 (a) have a thorough understanding of the significant change based on the documentation provided by the
495 proposer;
- 496 (b) conduct an assessment of the organisation and processes used by the proposer for managing the safety and
497 quality during the design and implementation of the significant change, if those organisation and processes
498 are not already certified by a relevant conformity assessment body. If they are certified, the CSM
499 assessment body must not reassess them but do the point (c) below;
- 500 (c) conduct an assessment of this organisation put in place for managing the change and an assessment of the
501 application of those safety and quality processes for designing and implementing the significant change;

(11) The CSM for risk assessment specifies the assessments to be done by the CSM assessment body (refer to section § 4 above) but it does not impose any specific working method. Section § 7.1 of the ISO/IEC 17020:2012 standard referred to in Annex II of that Regulation specifies some general requirements on the inspection methods and procedures.

(12) This is the principle of modules CH1 and SH1 from Commission Decision 2010/713 to be used in the EU for the assessment of conformity and suitability for use of the interoperability constituents and for the EC verification of subsystems.

(13) Refer to definition of "assessment body" in Article 3(14) of the CSM for risk assessment.

- 502 (d) conduct a **vertical slice assessment**⁽¹⁴⁾ on key risks to check whether the safety and quality processes are
503 correctly applied by the proposer and whether appropriate risk control measures are produced by the risk
504 assessment;
- 505 (e) have for that adequate assessment methods and sampling techniques, as well as sufficient knowledge of
506 statistical techniques to ensure on one side that the sampling method is statistically correct and on the other
507 side that the assessment and interpretation of the risk assessment results is correct.
- 508 (f) when it uses methods or procedures which are non-standard, document them appropriately and fully, for
509 transparency reasons and to enable the mutual recognition of its independent safety assessment report.

510 The CSM assessment body needs to be convinced that the application of the risk assessment process by the
511 proposer captures (i.e. identifies), understands, analyses and mitigates all reasonably foreseeable hazards
512 associated with the significant change under assessment. The key tasks of the independent safety assessment by
513 the CSM assessment body are therefore:

- 514 (g) getting an appreciation of the scope and context of the significant change and consequently of the necessary
515 intensity of independent safety assessment or size of the vertical slice to be assessed;
- 516 (h) selecting and planning a cost-effective assessment strategy based on risk, risk prioritisation and professional
517 judgement;
- 518 (i) gathering relevant evidence by applying the selected assessment strategy;
- 519 (j) based on this evidence, forming a judgement on the compliance of the risk assessment and risk management
520 with the requirements of the CSM for risk assessment and on the suitability of the significant change to fulfil
521 its safety requirements;
- 522 (k) managing any outcomes, including the following:
- 523 (1) a proactive and early identification of (potential) issues;
- 524 (2) a regular reporting of the identified issues to the proposer to enable the later taking timely remedial
525 actions;
- 526 (3) tracking the issues raised to a satisfactory resolution.

527 The use of a risk-based strategy for setting up the priorities for its assessment activities enables the CSM
528 assessment body not only to focus the assessment efforts on the areas with the highest risks but ensures also that
529 the level of the independent safety assessment activity is proportionate to the level of the risk.

530 The gathering of evidence from independent safety assessment is likely to be a combination of audits and
531 inspections including document reviews⁽¹⁵⁾, observations, interviews, organisational and personnel competency
532 checks, safety culture and organisation assessment, sampling and vertical slice analyses, use of checklists, etc.
533 The precise scope and level of detail or size of the selected samples or of the vertical slices for the independent
534 safety assessment depend on the complexity of the risk assessment activities, complexity or novelty of the
535 technology, safety criticality and level of risk introduced by the change.

536 It is important that the CSM assessment body promptly reports (e.g. verbally, via telephone, using e-mails, etc.)
537 the identified issues and non-compliances, especially on major concerns, to enable the proposer to take timely
538 any necessary remedial actions. To foster the mutual recognition, it is also important that those issues and non-
539 compliances are systematically and formally recorded in the independent safety assessment report of the CSM as-
540 sessment body, assigned a priority and tracked down till their resolution by the proposer. This provides a trace-
541 able evidence of a proactive involvement of the CSM assessment body in the identification and resolution of
542 problems based on the level of risk associated with the change or on the priority associated with the raised
543 finding.

544

⁽¹⁴⁾ 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 for the key risks of the change under assessment. The purpose is to check a representative cross-sectional slice of the results from the risk assessment and to cover all the steps of the risk management process of Figure 1.

⁽¹⁵⁾ In particular, the review of documentation will include the analysis and evaluation of the quality and consistency of the outputs at each step of the risk management process of the CSM for risk assessment.

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

546 Based on the evidence from the independent safety assessment activities, the CSM assessment body delivers to
547 the proposer a safety assessment report with its judgement and conclusions on the suitability of the significant
548 change to fulfil its safety requirements. At least the following information needs to be included in that report:

- 549 (a) the identification of the CSM assessment body;
550 (b) the independent safety assessment plan;
551 (c) the definition of the scope of the independent safety assessment as well as its limitations;
552 (d) the results of the independent safety assessment including in particular:
- 553 (1) detailed information on the independent safety assessment activities for checking the compliance with
554 the provisions of the CSM for risk assessment;
555 (2) any identified cases of non-compliances with the provisions of that Regulation and the assessment
556 body's recommendations;
- 557 (e) the conclusions of the independent safety assessment on the compliance of the risk assessment and risk
558 management performed by the proposer with the requirements of the CSM for risk assessment and the
559 appropriateness of the associated results to fulfil safely the intended objectives of the change.

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

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

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

- 571 (f) Examples of advices which could be given include safety management process best practice, guidance on the
572 interpretation of standards and the consequences of specific technology choices.
573 (g) Examples of advice which could compromise the independence include which design, operational or
574 organisational option should be taken to control the identified risks, what technology to use and any specific
575 mitigation for hazards. Such advices cannot be given.
576

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

578 As explained in section § 4 above, the proposer is responsible for carrying out all the risk assessment and risk
579 management activities specified in the CSM for risk assessment. The independent safety assessment report of the
580 CSM assessment body is an important input for the proposer to be taken into account for the safety acceptance
581 of the change. Based on that report and on the results of application of the CSM for risk assessment by its safety
582 experts, the proposer can judge on whether all identified hazards and associated risks are controlled to an
583 acceptable level. Both of these inputs contribute in making the proposer confident that the system under
584 assessment can fulfil safely the intended objectives of the change. Article 16 of the CSM for risk assessment
585 explicitly requires the proposer to *"produce a written declaration that all identified hazards and associated
586 risks are controlled to an acceptable level"*.

587 Although this should not occur because of a proactive involvement of the CSM assessment body from the
588 beginning of the project (see section § 21 above), the proposer can disagree with some of the conclusions of the
589 CSM assessment body. For example, despite a different opinion of the CSM assessment body, the proposer may
590 decide that the implemented safety requirements will keep the risk to an acceptable level. He will monitor in
591 practice the effectiveness of those predictive risk control measures using the Regulation 1078/2012. In such
592 cases, the proposer is required to justify and document the part of the independent safety assessment report for
593 which he eventually disagrees with the conclusions of the CSM assessment body.
594

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

596 The overall purpose of appointing a competent and independent CSM assessment body, accredited or recognised,
597 is to set up the foundation for mutual recognition. Consequently, by virtue of Article 6(3) of the CSM for risk
598 assessment, duplication of unnecessary work between the different conformity assessment bodies⁽¹⁶⁾ is to be
599 avoided.

600 When authorising the placing in service of vehicles⁽¹⁷⁾ and other structural sub-systems, the national safety
601 authority, or the OTIF national authority competent for technical admission, must accept the proposer's
602 declaration referred to in section § 23; it is based on the independent safety report of the CSM assessment body.
603 For the EU Member States and without prejudice to Article 16 of Directive 2008/57/EC, the national safety
604 authority, or the OTIF national authority competent for technical admission, may not request additional checks or
605 risk analyses unless it is able to demonstrate the existence of a substantial safety risk.

606 As a technical specification for interoperability (TSI), or equivalent OTIF Uniform Technical Prescriptions, may
607 request risk assessments to be performed, legally the EU notified body, or the OTIF assessing entity, is responsible
608 for checking that the risk assessment is duly performed. If the EU notified body, or the OTIF assessing entity, does
609 not fulfil the criteria in Annex II of the CSM for risk assessment for performing itself the independent safety
610 assessment of the correct application of the CSM and of the appropriateness of the results, it can subcontract the
611 work to a CSM assessment body who meets those criteria. In this case, for the EU by virtue of Article 7(1) of
612 Commission Decision 2010/713, "where a notified body subcontracts specific tasks connected with
613 conformity assessment or EC verification ..., it shall take full responsibility for the tasks performed by
614 subcontractors". So:

- 615 (a) the EU notified body has the responsibility to check that the tasks of the CSM assessment body are duly
616 performed;
- 617 (b) the CSM assessment body who performs the independent safety assessment delivers its conclusions to the
618 EU notified body within an independent safety assessment report;
- 619 (c) the EU notified body includes the independent safety assessment report in the technical file that has to
620 accompany the EC declaration of verification.

621 The same principles apply to OTIF Contracting States by the application of the ATMF Articles 4, 5, 7 and 10. The
622 admission is the task of the OTIF national authority competent for technical admission, or where applicable of an
623 OTIF assessing entity, and it is based on the procedures and prescriptions in force through the ATMF. The OTIF
624 national authority competent for technical admission or the OTIF assessing entity will have therefore the final
625 responsibility for the results of the independent safety assessment carried out by the CSM assessment body in the
626 framework of vehicle admission.

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

⁽¹⁶⁾ For the EU, the other conformity assessment bodies are national safety authorities (NSAs, as defined in Article 3(g) of Directive 2004/49/EC), notified bodies (NoBos, as defined in Article 2(j) of Directive 2008/57/EC), designated bodies (DeBos, as defined in Article 17(3) of Directive 2008/57/EC), 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.

⁽¹⁷⁾ In OTIF the equivalent process is referred to as admission to international operation.

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

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

657

658 **25. More information**

659 *Regulation (EU) No 402/2013 on the common safety method for risk evaluation and assessment* can be found in all EU
660 languages on the EUR-Lex site under the following link:

661 <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1403261951556&uri=CELEX:32013R0402>

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

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

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