

## Report on the *return of Experience (REX) with the use of the CSM for risk assessment (Regulations 402/2013 and 2015/1136)*

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### EXECUTIVE SUMMARY

*The European Union Agency for Railways would like to thank all national safety authorities (NSAs), ECM Certification Bodies (ECM CBs) and assessment bodies (ASBOs) which actively took part to the elaboration of this report and permitted to build a picture of the experience of the EU railway sector with the CSM for risk assessment.*

The (EU) Regulation 402/2013 on the CSM for risk assessment (amended by Regulation 2015/1136) must be applied when making any change to the railway system in a Member State. That Regulation requires: 1°) the European Union Agency for Railways (here after the Agency) to produce a report analysing the effectiveness of that CSM and the experience of railway stakeholders with its use and, where necessary, to make recommendations to the Commission for revising the CSM; 2°) the NSAs and ECM Certification Bodies to support the Agency in collecting the necessary information from the stakeholders for that work.

The present report contains the Agency analysis of the NSA, ECM Certification Body and ASBO inputs and the recommendations for improving the understanding and helping with the implementation of the CSM.

Basically, at this moment it is not possible to provide an accurate picture for every country and every category of stakeholders. The levels of understanding, application and implementation of that CSM differ a lot across the EU:

- Only a small minority of companies (*especially those more mature with the risk management concepts*), including IMs, RUs, ECMs and big manufacturers well understands and correctly apply the method;
- A large majority of companies across the EU (*usually more familiar with the application of rules rather than with risk management*), RUs, ECMs and a few IMs, still face difficulties in understanding and correctly applying the method. Their experience is still negative or insufficient to show a reliable picture;
- A number of countries or companies have neither understood nor applied the method yet.

Less than 5% of changes are considered significant and actually lead to the application of the CSM. As the railway legislation requires the use of a risk based approach at different levels of the railway sector, the demand for professionals in risk assessment and risk management, with railway knowledge and expertise, is quite high. However, the real market offer of such expertise remains insufficient. This difficulty to find qualified and competent experts for taking over internally the full responsibility of the correct implementation of the CSM can only encourage companies to keep classifying safety related changes as non-significant.

The positive experience of the first category of stakeholders proves that the CSM for risk assessment is effective for achieving the objectives set out in its Article 1 and Article 15(5). Thereby, the Agency has not identified any objective justification which would require the urgent revision of the CSM.

Many stakeholders have not yet really applied the method over a period sufficiently long to “learn by doing” and improve the understanding and the level of compliance with the CSM. To avoid unjustified amendments of the CSM, it is necessary to gather objective stakeholders’ observations on real weaknesses and problems with the method.

[→ See Agency recommendations on next page ←]

**The Agency recommends thus to :**

- put in place an agreed dissemination or training programme to increase the sector awareness with the risk management and risk monitoring concepts and help them achieving full compliance with the CSM;
- take strategic decisions and initiatives with the Member States in terms of education and training solutions in order to, on one side compensate the current lack of expertise on the market in the railway risk assessment field, and on the other side to anticipate the growing loss of railway expertise with a continually increasing number of employees reaching the age of retirement;
- combine the measurement of the return of experience of both the “CSM for risk assessment” (Reg. 402/2013 and 2015/1136) and “CSM for monitoring” (Reg. 1078/2012) since the effectiveness with the implementation of each of these two CSMs depends on the correct implementation of the other CSM;
- collect again the return of experience of both CSMs after the dissemination using the same process;
- based on more reliable and representative information decide whether the amendment of one of these two CSMs is actually justified and the areas where improvements might be needed.

**Document history**

Version	Date	Description of modifications
0.1	31/10/2018	First draft version of the document presented at the Cooperation meeting between the CSM Assessment Bodies (ASBOs) on 8 <sup>th</sup> November 2018
0.2	12/11/2018	Second draft version of the document presented at the NSA network meeting of 20 <sup>th</sup> November 2018. Version sent also to ECM Certification Bodies and the NRB network.
1.0	18/12/2018	Final version – Reviewed within the Agency

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## List of abbreviations

Abbreviation	Meaning
ASBO	CSM Assessment Body
CoP	Code of Practice
CSM	Common Safety Method
EC	European Commission
ECM	Entity in Charge of Maintenance
ECM CB	ECM Certification Body
ERADIS	European Railway Agency Database of Interoperability and Safety
EU	European Union
IM	Infrastructure Manager
NRB	Network of Representative Bodies
NSA	National Safety Authority
REX	Return of EXperience
RU	Railway Undertaking
SMS	Safety Management System

## 1. Why is a Report on the “Return of Experience (REX)” necessary?

### 1.1. Legal obligations

1.1.1. In line with the overall necessity for monitoring the effectiveness of EU railway legislation, Article 18<sup>(1)</sup> of the (EU) Regulation No 402/2013 on the CSM for risk assessment requires :

- (a) the Agency to “collect all information on the experience of the application ...” of the Regulation “... and, when necessary, ...” to “... make recommendations to the Commission with a view to improving ...” the Regulation;
- (b) the national safety authorities and ECM Certification Bodies to support the Agency in collecting the information required for achieving that work.
- (c) the Agency to “submit to the Commission a report analysing the effectiveness of the method and the experience of railway stakeholders” with its use;

1.1.2. Indeed, the analysis of the return of experience with EU railway legislation is of prime importance to decide whether the amendment or revision of the legislation is justified and needed :

- (a) Article 6(4) of Safety Directive 2004/49 requires that “the CSMs shall be revised at regular intervals, ..., **taking into account the experience gained from their application**”;
- (b) Article 6(2) of the recast of Safety Directive 2016/798 of the 4<sup>th</sup> Railway Package reinforces further the obligation for the Agency to amend or revise existing CSMs and to make the relevant recommendations to the Commission “on the basis of a **clear justification of the need for... an amended CSM ...**”.

### 1.2. Technical arguments - Continual improvement

1.2.1. Independently of the legal obligations, it must be kept in mind that the CSM for risk assessment is a harmonised method to be used for an effective and safe management of changes during the operation and maintenance of the railway system. It is to be used for the systematic identification of all reasonable risks that can arise from the change and for the definition of appropriate

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<sup>(1)</sup> According to Article 18 of Regulation 402/2013 :

- (1) Article 18(5) : “the Agency shall collect all information on the experience of the application of this Regulation and shall, when necessary, make recommendations to the Commission with a view to improving this Regulation”;
- (2) Article 18(6) : “The national safety authorities shall support the Agency in collecting such information”;
- (3) Article 18(3) : “The annual maintenance report of entities in charge of maintenance of freight wagons... shall include information about the experience of entities in charge of maintenance in applying this Regulation. The Agency shall gather this information in coordination with the respective certification bodies”;
- (4) Article 18(6), “the Agency shall submit to the Commission a report containing ...” :
  - (a) an analysis of the experience with the application of this Regulation, ...;
  - (b) an analysis of the experience of proposers concerning decisions on the level of significance of changes;
  - (c) an analysis of the cases where codes of practice have been used as set out in point 2.3.8 of Annex I;
  - (d) an analysis of the experience with the accreditation and recognition of assessment bodies;
  - (e) an analysis of the overall effectiveness of this Regulation”

measures that control those risks to an acceptable level. The measurement of the effectiveness of the CSM in fulfilling those objectives is fundamental to be able to decide on the appropriateness of revising the CSM in case of detection of serious deficiencies within the method.

- 1.2.2. To do this, it is thus essential to gather the actual railway stakeholders' feedback or experience [*i.e. to monitor the experience or "Retour d'EXpérience – REX in French"*] with the use of the CSM and the potential problems and weaknesses of the method the sector may encounter.
- 1.2.3. The driving motivations for revising the CSM for risk assessment should thus only be correction of problems and weaknesses within the CSM or the overall improvement and simplification of the EU railway legislation. The non-observation of those principles would create additional administrative burden, complexity and misunderstanding of the successive amendments of the legislation whereas the railway sector is trying to implement correctly the existing pieces of legislation, to learn and improve by doing and to set up a proper "risk based" safety culture in a very complex environment.

## 2. Collection of the return of experience [REX] with the CSM

### 2.1. Method for collecting the return of experience [REX] and cross-check of the content

- 2.1.1. In order to build a representative overview of the sector experience with the use of the CSM, it is not necessary to consult every individual RU, IM, ECM or manufacturer in the EU. Thereby, in compliance with Article 18(6) and Article 18(3) of the CSM for risk assessment, the Agency requested support from the NSAs and ECM Certification Bodies. They have the necessary information through the certification and supervision/surveillance activities of the RU/IM/ECM management system. The Agency consulted also all accredited/recognised CSM Assessment Bodies (ASBOs) registered in the ERADIS database. The ASBOs are in charge of the independent assessment of the correct application by the proposer of the risk assessment process of the CSM and of the suitability of the results from that process. To do this :
  - (a) the Agency produced a supporting questionnaire on the CSM for risk assessment;
  - (b) the questionnaire was sent for action to all NSAs on 30/11/2017 and, on 04/12/2017, to all ECM Certification Bodies and ASBOs registered in the ERADIS database. The questionnaire is contained in ANNEX B below.
- 2.1.2. The final report was planned to be sent to the European Commission before summer 2018. So, the consulted entities were given four months for providing the inputs. The initial planning was :
  - (a) deadline for returning the inputs 31 March 2018;
  - (b) Agency analysis of the inputs and writing the draft report by end of April 2018;
  - (c) check of the draft report by the NSAs, ECM Certification Bodies and ASBOs and sharing of views with them at the meetings with :
    - (1) NSA Network on 29 May 2018;
    - (2) Cooperation of CSM Assessment Bodies on 6 June 2018;
    - (3) Cooperation of ECM Certification Bodies on 27 June 2018;
  - (d) Agency updates the draft report based on those comments on the draft report;
  - (e) Agency sends the final report to the European Commission at latest on 15 July 2018.
- 2.1.3. Given the low reply rate by end of March 2018, the Agency extended several times that deadline for returning comments. The latest deadline was end of September 2018. This milestone

extension permitted to increase a little bit the reply rate but could not reach 100 % of replies. Although the NSAs and ECM Certification Bodies are legally obliged to support the Agency in this survey (see to section § 1.1.1. above), about 50 % of NSAs and 75 % of ECM Certifications Bodies did not return any input (see section § 2.2. below); they did neither ask for extra time for giving a consolidated picture of their experience with the method. Although the ASBOs were not legally obliged to take part to the survey, 30 % of consulted ASBOs took actively part to building this report.

- 2.1.4. As the Agency does not have enforcement power to oblige NSAs and ECM Certification Bodies to comply with their legal obligations in Article 18 of Regulation 402/2013, the Agency decided :
- (a) not to postpone further the delivery of the present report;
  - (b) draft the report and a picture of the sector experience based on the received inputs;
  - (c) send the draft report to those who were asked to provide inputs and cross check with them the reliability of the gathered inputs and sector experience. The report was shared with :
    - (1) the Cooperation of CSM Assessment Bodies on the meeting of 8 November 2018;
    - (2) the NSA Network meeting on 20 November 2018;
    - (3) the ECM Certification Bodies, using a written consultation;
  - (d) update the final report based on the received comments;
  - (e) send the final report to the European Commission by end of 2018.

## 2.2. Participation rate of NSAs, ECM Certification Bodies and ASBOs to the collection of the return of experience [REX]

- 2.2.1. Number of consulted NSAs, ECM Certification Bodies and CSM Assessment Bodies (ASBOs) :
- (a) The Agency consulted all EU NSAs, as well as the Swiss and Norwegian NSAs. Taking into account that 2 EU countries (Cyprus and Malta) do not operate railways, 28 NSAs were thus involved in the study;
  - (b) From the 41 ECM Certification Bodies registered in the ERADIS database under the ECM Regulation 445/2011, there are :
    - (1) 19 NSAs acting as ECM Certification Bodies;
    - (2) 22 ECM Certification Bodies (15 accredited and 7 recognised ones);
  - (c) The Agency consulted all ASBOs (65 companies) registered in ERADIS at the end of 2017.
- 2.2.2. So, taking into account that 19 NSAs act also as ECM Certification Bodies, the Agency consulted in total 115 different entities [28 NSAs, 22 ECM CBs (which are not NSAs) and 65 ASBOs].
- 2.2.3. Among those 115 consulted entities, the 38 entities below took part to the scrutiny and provided inputs to the Agency. The participation rate is therefore of about 33 % of the consulted entities :
- (a) 8 NSAs **acting also as ECM CBs** :
    - (1) Danish NSA;
    - (2) Dutch NSA;
    - (3) German NSA;
    - (4) Hungarian NSA;
    - (5) Polish NSA;
    - (6) Romanian NSA;

- (7) Swedish NSA;
  - (8) Swiss NSA;
  - (b) 4 NSAs **not acting as ECM CBs** :
    - (1) Norwegian NSA;
    - (2) Slovak NSA;
    - (3) Slovenian NSA;
    - (4) Spanish NSA;
  - (c) 5 ECM Certification Bodies (which are not NSAs, but 3 of them are also ASBOs) :
    - (1) Bureau Veritas Italia S.p.A;
    - (2) Sconrail AG;
    - (3) Swiss Association for Quality and Management Systems (SQS);
    - (4) TÜV Rheinland Rail Certification B.V. & TÜV Rheinland UK Ltd (Germany & UK);
    - (5) University of Zilina;
  - (d) 21 CSM Assessment Bodies (ASBO) :
    - (1) AIRTREN (Spain);
    - (2) Albold Consulting GmbH (German);
    - (3) AuxiTec (Spain);
    - (4) Belgorail CERTIFER (Belgium and France);
    - (5) Bureau Veritas (Spain);
    - (6) DB Systemtechnik GmbH (Germany);
    - (7) DEKRA Rail bv (The Netherlands);
    - (8) Exceltic (Spain);
    - (9) Faculty of Transport Warsaw University of Technology (Poland);
    - (10) IK Instytut Kolejnictwa (Poland);
    - (11) Ineco (Spain);
    - (12) Safety Advisor Oy (Finland);
    - (13) Schieneninfrastruktur-Dienstleistungsgesellschaft mbH (Austrian);
    - (14) Siemens Mobility GmbH SAC Braunschweig (Germany);
    - (15) Siemens Mobility GmbH SAC Erlangen (Germany);
    - (16) TINSA Ltd. (Bulgaria);
    - (17) Tor Audytor (Poland);
    - (18) Transportowy Dozór Techniczny (Poland);
    - (19) TÜV NORD Systems GmbH & Co. KG (Germany);
    - (20) VR Track Oy (Finland);
    - (21) VÚKV a.s. (Czech Republik);
- 2.2.4. The NSAs of the countries not included in the list above, the ECM Certification Bodies which are not NSAs and the ASBOs not mentioned in the list above did not provide any information.

### 2.3. Summary of all received answers to the survey questionnaire

- 2.3.1. For readability purposes of this report, the details of the NSA, ECM Certification Body and ASBO answers to the survey questionnaire (available in ANNEX B) are contained in ANNEX A below.

### 3. Analysis of the collected results

#### 3.1. Analysis of the sector experience with the application of the CSM

##### 3.1.1. Introduction

- 3.1.1.1. 33 % of contacted participants took actively part to the collection of the “Return of Experience” on the use of the CSM : 12 NSAs, 5 ECM Certification Bodies (which are not NSAs) and 21 ASBOs.
- 3.1.1.2. For significant changes, including those managed by manufacturers, the CSM requires an ASBO to independently assess the correct application of the risk assessment process and the suitability of the results from this process. As the ASBOs are also involved in the collection of the present return of experience, the collected results are representative of the experience of RUs, IMs, ECMs and manufacturers with the use, application and implementation of the CSM for risk assessment.

##### 3.1.1.3. Considering the conditions of this survey (see sections § 2.1. and § 2.2. above) :

- (a) the detailed analysis of the results contained in ANNEX A below does not lead to a common experience of all stakeholders across the EU;
- (b) the level of understanding and difficulties faced with the application of the CSM for risk assessment vary a lot from country to country, from company to company in a country and even from project team to project team in a company;
- (c) anyway, the objective of the work is not to get the return of experience of every individual country or of every individual company. The survey and average experience reflected in this report cannot be considered as a general picture for every RU, IM, ECM or manufacturer;
- (d) the survey aims at looking for an overall picture of the situation and of the experience with the understanding and application of the method. It is thus possible that an NSA, an ECM Certification Body or an ASBO does not fully recognise the inputs it provided to the Agency;
- (e) considering a participation rate of 33 % (see section § 2.2. above), the picture shown in this report is based on the inputs collected from the consulted entities and reflects at least the overall picture in the respective countries. However, the Agency has not found or received any evidence that would allow thinking that the situation is much different in countries that did not take part to the present survey;
- (f) at the ASBO Cooperation meeting of 8 November 2018 and the NSA Network meeting of 20 November 2018, the ASBOs and NSAs acknowledged the overall sector experience reflected in the report. Some NSAs and ASBOs estimated even the picture and experience of big IM or RU companies (including incumbent ones) being represented nicer than what they actually observe. The NSAs of countries having not provided inputs did not disapprove the content of the report. On the contrary some of them expressed that, although they did not give feedback, the sector experience in their country is not different from the reported one.

##### 3.1.2. Overall trends

- 3.1.2.1. The following three main trends emerge in the replies contained in ANNEX A. They are consistent throughout the different questions. They are representative of the experience of RUs, IMs, and ECMs (although these later ones are not systematically differentiated in the replies, unless the experience was actually different) and manufacturers :



- (a) Stakeholders having well understood and correctly implemented the CSM;
- (b) Stakeholders for whom the understanding, the application and implementation of the CSM were challenging but they are “learning by doing” and “continually improving” its use;
- (c) Stakeholders having not (yet) well understood or not understood at all the CSM and thus having not correctly implemented, or not implemented at all, the CSM.

3.1.2.2. Some reasons for those differences among the stakeholders can be found in :

- (a) a different historical and safety culture background of the country (e.g. countries more familiar with the application of rules rather than with risk management or vice versa);
- (b) a difference in the type and extent of the company operations [type of service<sup>(2)</sup> and volume of goods/passengers transported];
- (c) a difference in the size of the company and in particular in the number of employees;
- (d) a different complexity of the organisational structure of every company;
- (e) although RUs, IMs and ECMs have a certified management system, there can still be a lack of a structured and clear description of the allocation of roles and responsibilities throughout the structural organisation of the companies concerning the risk assessment and risk management activities;
- (f) a lack of sharing of information and experience between the different teams in the company.

3.1.2.3. Although those differences might justify partially the gradation of difficulties the stakeholders are facing, the main reason for those differences of understanding and difficulties in correctly applying the CSM for risk assessment is a lack of time to actually “learn by doing”. The first Regulation 352/2009 on the CSM for risk assessment was applicable to technical changes from July 2010 and to all types of changes from July 2012. Regulation 402/2013 is applicable since May 2015.

3.1.2.4. For many stakeholders, and in particular for those not yet fully familiar with the risk management, (safety) management system and continuous improvement concepts, this is not long enough to be able to understand well the CSM requirements, to implement them, to “learn by doing” and to improve the deficiencies discovered by themselves or through the independent safety assessment activities by ASBOs. These are reasons for differences in the experience and the stakeholders’ maturity with the use of the CSM.

### 3.1.3. Main differences in the experience vs. the category of stakeholders

3.1.3.1. Although an accurate classification of all stakeholders across the EU is not possible, the differences below are observed.

- (a) **Stakeholders which have not (yet) well understood, or have not understood at all the CSM,**  
This category of stakeholder has not correctly implemented, or not implemented at all, the CSM. It faces the greatest difficulties with the understanding and the (correct) application of the method.
- (b) **Usually (big) IMs, big RUs** (in general in the countries where the railway sector is more mature with the risk management concepts) **and usually big manufacturers :**

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<sup>(2)</sup> The main “types of service” are “passenger transport”, including/excluding high-speed services, “freight transport”, including/excluding dangerous goods services, and “shunting only”.

- (1) in general, they demonstrate a better understanding and more correct implementation of the requirements in the CSM for risk assessment. Big manufacturers gained experience on risk assessment and risk management through the application of the CENELEC 50126 standard in the past;
  - (2) usually the CSM for risk assessment is an integrated part of their quality and safety management processes for the safe management of changes. So, the method is used proactively from the beginning of projects in order to identify the possible risks that can arise from changes and to define appropriate measures for controlling those risks to an acceptable level;
  - (3) risk assessment and risk management activities are better documented with respect to the requirement of the CSM;
  - (4) enough resources are allocated to risk assessment and risk management activities. They are usually under the responsibility of a Safety Department in the company;
  - (5) the understanding of the CSM is continually improving based on the results and experience gained through the previous projects where the method was used.
- (c) **ECMs** : given that this category of stakeholders was not particularly differentiated in a most of the received replies, it is difficult to give a reliable feedback for them. Although some ECMs seem to understand and apply correctly the CSM, the other ECMs face difficulties with the “risk based thinking” and the understanding of the CSM. Those ECMs struggle with the understanding and correct application of the CSM.
- (d) **Small RUs** and RUs in the countries more familiar with the application of rules rather than with risk management :
- (1) they have more difficulties to understand the CSM and to apply it correctly;
  - (2) resources for risk assessment and risk management activities are tight. As those companies perform a limited number of changes, they cannot afford having a permanent safety staff only in charge of the risk assessment and risk management activities. Usually this is under the single responsibility of a person in charge also of many other operational tasks in the company. So, they often use sub-contracting;
  - (3) a few year period is too short to measure a visible improvement of maturity with the CSM for risk assessment.

### 3.1.3.2. Overall differences between big and small companies with the understanding and application of the CSM :

Although big companies can afford allocating more resources to risk assessment and risk management activities than the small companies, the size of the company is not always the (only) determining parameter;

#### (a) Big companies :

- (1) usually big companies have complex organisational structures with many internal interfaces. As they perform more changes, the needs for risk assessment and risk management are higher and require the proper involvement and the sharing of safety related information throughout the organisational structure of the company;
- (2) they can afford allocating sufficient resources to risk assessment and risk management activities. Usually a dedicated Safety Department is responsible for its management and correct implementation throughout the company organisational structure (e.g. central company with regional units);

- (3) they have a higher knowledge of the risk concepts, in particular big manufacturers. They are more familiar with the “process thinking” and the concept of systematic and top-down approach to risk management. So, they understand better the CSM for risk assessment and apply it proactively, from the very beginning of the change management. However, being dispersed (e.g. a central company with regional units), they are facing different challenges due to the complexity of their organisations and internal interfaces and therefore have more complex management systems. So, they are still “learning by doing” and continually improving the application of the CSM;
- (4) as they implement a higher number of significant changes, they have a higher opportunity to “learn by doing”.

**(b) Small companies :**

- (1) they take longer to react to changes of legislation and need more time to adapt;
- (2) usually they have smaller needs for changes. Consequently, as the method is applied less often, they have less opportunities to “learn by doing” and gain sufficient experience to improve the weaknesses they encounter;
- (3) frequently, small companies face more problems regarding the resources they are capable to allocate to the risk assessment and risk management activities. As they cannot afford having permanent staff responsible only for those activities, usually when done internally, risk assessment and risk management is carried out directly by the operational staff responsible also for other activities within the company;
- (4) they sub-contract more often the application of the CSM for risk assessment to external companies. Consequently, this reduces even further the opportunities to “learn by doing” and to gain sufficient experience to become able to carry out alone risk assessments for future changes;
- (5) however, some small companies are flexible and able to implement sometimes smarter solutions. They tend to better capture the essence of the CSM for risk assessment. They can also carry out the risk assessment in a very comprehensive manner with very good results, focussing on the necessary demonstrations, but without being overwhelmed by unnecessary paperwork;
- (6) in case of deficiencies, they tend to solve the problems instead of debating on them.

**3.1.3.3. Differences between former incumbent and newcomer railway companies :**

The comparison between these two categories of railway companies is difficult. Many replies report the lack of experience or availability of information :

**(a) Former incumbent railway companies :**

- (1) they are more resistant to change and to the application of new, in particular if they feel the method requires more resource. They prefer to continue thinking in former processes and solutions;
- (2) they have more rigid ways of thinking, managing, solving issues, etc. usually based on the CENELEC 5012x guidelines. So they consider the CSM as unnecessary duplication of CENELEC (which is well understood);
- (3) they have more resources and railway experience for being able to apply the CSM for risk assessment, even if they do not completely understand the necessity of doing it;

**(b) Newcomer railway companies :**

- (1) as they have often a very flat organisation, they have less resources and rarely staff competent in risk assessment and risk management;

- (2) when necessary, often they hire externally supporting staff or sub-contract completely the application of the CSM for risk assessment;
  - (3) they are capable adapting faster to the terminology used in the CSM;
  - (4) they are flexible and can change easier their way of thinking in a more constructive way. They tend to be proactive and implement the CSM for staying on the market;
- (c) In countries more familiar with the application of rules rather than with risk management :
- (1) newcomer RUs seem to have even more difficulties than the former incumbent railways in understanding and implementing, according to their saying, “abstract and theoretical requirements of the CSM” into a practical and safe management of changes;
  - (2) although the newcomer RUs are trying to learn from the experience gained by the state railways, they face difficulties in actually understanding the requirements in the CSM. Some of them even miss the underlying purpose of the CSM;
- (d) In some countries more mature with risk management, big differences in knowledge, understanding and application of the CSM have not been observed.

3.1.3.4. More details about the differences of the railway stakeholders’ experience with the CSM can be found in ANNEX A below.

## **3.2. Analysis of the experience of proposers with the decisions on the significance of changes**

3.2.1. As reported in the sections above, the CSM for risk assessment is largely perceived as an unnecessary, heavy and costly legal obligation that does not add value. Thereby, the concept of “significant” and “non-significant” change is being completely misused. Instead of checking whether the independent pair of eyes of an ASBO provides assurance that risks arising from a safety related change are well identified and correctly controlled, Article 4 of the CSM is actually being used to justify the non-significance of changes. Almost all changes are classified as non-significant just to avoid applying the formal risk assessment process of the CSM and appointing an independent ASBO.

3.2.2. Anyhow the need to appoint an ASBO for assessing independently a significant change is considered as an obligation rather than an external advisory support. Thereby the role and cost of having an ASBO discourage a lot of companies from deciding that a change is significant. Although the ASBO is bound by confidentiality obligations and must not disclose any information, many companies fear also to make their “internal” problems visible outside.

3.2.3. However, as the “non-significance” of safety related changes cannot easily be demonstrated without proper risk assessment (including the identification and correct control of all associated risks), a large majority of proposers states that the assessment of the significance of changes is complex and poses difficulties to arrive at the right decision. Of course, such a statement is motivated by the reasons explained above where the objective is usually to demonstrate the non-significance of the change.

3.2.4. Only 2 to 5% of all changes are considered significant, independently on whether the countries are “rule based” or familiar with the “risk based thinking”. Most of those 2 to 5% of changes are of “technical nature”. So, the experience with the risk assessment of significant technical changes is much better than for operational and organisational changes.

- 3.2.5. The CSM is less understood and less applied to “operational and organisational” changes. The companies do not know how to use the 6 criteria of Article 4(2) of the CSM for deciding on the significance of those changes. So, the decisions on their significance are even more difficult than for the technical changes.
- “Operational and organisational” changes are rather subject to the use of standards and codes of practice, especially for justifying the non-significance of a safety related change, without necessarily having formal and documented evidence of it. Therefore the Agency wonders if this kind of changes should be better managed within the framework of the certification and supervision by the NSA of the RUs/IMs SMS : refer to sections § 3.4.2.10. below.
- 3.2.6. The justifications of “non-significance of changes” are usually very poor or non-existent. The meaning of “*keep adequate documentation to justify the decisions*” is misunderstood and is rather considered by many as a “permission to do nothing”.
- When a justification exists, it is a rough preliminary hazard analysis or a kind of form/table where the 6 criteria of Article 4(2) of the CSM are covered with a few explanations. But the assessment of the significance does not seem to formally identify, assess and accept the risks of non-significant safety related changes. There is thus no assurance that appropriate risk control measures are systematically identified and actually put in place for controlling the risks arising from non-significant safety-related changes. Even the risks controlled to an acceptable level by provisions of the RU/IM SMS are poorly documented, and sometimes they are even not linked to the relevant SMS processes/procedures.
- 3.2.7. The decision on the significance of changes is also strongly dependent on previous experience of people/teams in charge of the assessment. Consequently, for the same change in the same company or in the same country, different people can arrive at different decisions with proper or poor justifications of a correct control of risks associated to the non-significant change.
- 3.2.8. Although the processes for Change Management Control and Risk Management are part of the RU/IM/ECM management system, some NSAs and ECM Certification Bodies report that they do not know how the proposers assess and control the risks associated to safety related non-significant changes. As NSAs and ECM Certification Bodies are certifying, supervising and surveying the RU/IM/ECM management system, they should have an insight on how it is done in practice.
- 3.2.9. Some NSAs explicitly report not to include in their supervision activities of the RU/IM SMS the check of the application of the CSM for risk assessment.

#### **Agency recommendation :**

In the Safety Directive 2004/49, the risk based approach and risk assessment are cornerstones of the certification and supervision by the NSA of the RU/IM safety management system. In the scope of the 4<sup>th</sup> Railway Package activities, among others the European Union Agency for railways will monitor the NSA supervision activities. This NSA monitoring needs thus to take particular care of how the NSAs supervise the RU/IM Change Management Control process (in principle using the CSM for risk assessment - Regulation 402/2013 - and CSM for monitoring - Regulation 1078/2012)

### **3.3. Analysis of the experience when Codes of Practice (CoPs) are used**

- 3.3.1. The majority of stakeholders estimates that explicit risk estimation requires the highest knowledge and experience in risk assessment and risk management, more efforts and leads to higher costs. So, the sector uses rarely explicit risk estimation. It remains nevertheless the preferred

principle, with the support of the CENELEC 50126 standard, for the CCS sub-system or for the assessment of innovative technical solutions.

- 3.3.2. Although the sector preferably uses Codes of Practice and, at some extent Reference Systems, the actual experience with their use is very poor and unsatisfactory with respect to the requirements in the CSM. As far as possible, CoPs are also used to justify the non-significance of changes. As those two risk acceptance principles are considered easier to use, the proposers often forget linking them in the hazard record to the hazards they are controlling.
- 3.3.3. In order to limit the risk assessment efforts, whenever a well-known standard or a railway CoP exists, it is used without further consideration. The side effect of that can be the implementation of quite constraining operational risk control measures instead of integrating preventive risk control measures through technical improvements of the design. In addition to that, the verification of the achievement of the conditions in point § 2.3.2. in Annex I of the CSM, in particular of the relevance of the CoP for the identified hazards, is often forgotten.
- Likewise, when comparison is made to similar reference systems, the verification of the achievement of the condition in point § 2.4.2.(a) in Annex I of the CSM (i.e. the reference system “... *has already been proven in-use to have an acceptable safety level and would therefore still qualify for approval in the Member State where the change is to be introduced*”) is often forgotten.
- 3.3.4. As the overall concept of the CSM is misunderstood, the proposer also carries out an unnecessarily detailed hazard identification even if a low level of detail is largely sufficient to match with the use of CoPs and Reference Systems. This leads to unnecessary additional work and unnecessary additional costs for the risk assessment and risk management of all identified hazards in the hazard record.
- 3.3.5. As the sector is not yet familiar with the risk based approach, when CoPs are used for controlling the identified hazards, detailed hazard checklists are sometimes misused for cross-checking the completeness of the hazard identification. This is particularly the case when the levels of detail of the hazards identified by the application of the CSM and the supporting hazard checklists<sup>(3)</sup> are incompatible. There is then no assurance that the hazards specific to the change are actually identified and properly managed, especially if the level of detail of the hazard identification is influenced by the quality of the supporting hazard checklists or reference tables.
- 3.3.6. Deviations of the system under assessment with respect to Codes of Practice are usually assessed using explicit risk estimation. Deviations with respect to the similar reference system are usually assessed using Codes of Practice or explicit risk estimations.

3.3.7. **Remark on the use of explicit risk estimation :**

Explicit risk estimation can be done either qualitatively or quantitatively. Only two replies mention a ratio of 90% qualitative vs 10% quantitative risk assessments. Although the other replies do not quote any figure, qualitative risk acceptance, based on expert judgement, seems to be the most often used way within explicit risk estimation.

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<sup>(3)</sup> *Sometimes the hazards are highly aggregated in the checklists and do not contain detailed sub-hazards. Sometimes the hazards are identified in the checklists only at the operational and maintenance levels whereas it is a technical change assessed at the design/construction stage.*

### 3.4. Analysis of the experience with the accreditation and recognition of assessment bodies

#### 3.4.1. Legal requirements

3.4.1.1. Short reminder : the CSM for risk assessment requires that :

- (a) for a significant change the correct application of the risk assessment process and the suitability of the resulting outcomes are independently assessed by an ASBO;
- (b) the ASBO meets the criteria and requirements in Annex II of the CSM and the ASBO is either accredited or recognised according to Articles 7 and 9 of the CSM.

3.4.1.2. According to recital (15) of the CSM and recital (12) of Regulation 765/2008 on the functioning of the accreditation, “... *transparent accreditation, as provided for in Regulation (EC) No 765/2008, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of those bodies*”.

3.4.1.3. Nevertheless, Article 7 of the CSM gives the Member States the free choice between the three options below; the ASBO shall be either :

- (a) *accredited by the national accreditation body ...; or;*
- (b) *recognised by the recognition body referred to in Article 13(1) of the CSM, or;*
- (c) *the national safety authority.*

3.4.1.4. In order to ensure equivalence between accreditation and recognition, Article 14(2) of the CSM requires that “*the Agency shall organise peer evaluations between the recognition bodies based on the same principles as set out in Article 10 of Regulation (EC) No 765/2008*”.

#### 3.4.2. State with the use of accreditation and recognition

3.4.2.1. The Table 1 below shows the full picture across the EU, Switzerland and Norway on the use of accreditation and recognition of ASBOs :

**Table 1: Use of accreditation and recognition**

N°	Use only accreditation	Use both accreditation and recognition	Use only recognition	Not yet decided
1.	Austria	Croatia <b>(recognition by the Ministry)</b>	Bulgaria (by the NSA)	Estonia
2.	Belgium	Czech Republic (recognition by the NSA)	Germany (by the NSA)	Hungary
3.	Denmark	Norway <b>(recognition by the NSA)</b>	Ireland (by the NSA)	
4.	Finland		Italy (by the NSA)	
5.	France		Latvia (by the NSA)	
6.	Greece		Romania <b>(by the Ministry)</b>	
7.	Lithuania		Slovenia <b>(by the Ministry)</b>	
8.	Luxembourg			
9.	Poland			
10.	Portugal			
11.	Slovak Republic	<b>Countries that stopped using recognition and use only accreditation</b>		
12.	Spain	Belgium <b>(recognition by the NSA)</b>	Luxembourg <b>(recognition by NSA)</b>	
13.	Sweden	Spain <b>(recognition by the NSA)</b>	The Netherlands <sup>(*)</sup> <b>(recognition by NSA)</b>	
14.	Switzerland			
15.	The Netherlands <sup>(*)</sup>			
16.	United Kingdom			

- 3.4.2.2. (\*) **Note :** The Netherlands announced the abandon of the use of recognition by the NSA and the use of accreditation instead of it. However, the decision is not yet official. It will be official in the scope of transposition of the 4th Railway Package by The Netherlands.
- 3.4.2.3. All accredited or recognised ASBOs are registered in the ERADIS database, accessible on the Agency web page under the following link [ERADIS - European Railway Agency Database of Interoperability and Safety - Assessment Bodies](#)
- 3.4.2.4. On 1 December 2018, 86 ASBOs (51 accredited and 35 recognised) were registered in ERADIS.
- 3.4.2.5. When appointing an ASBO to a significant change, because of language barriers (i.e. language of documents and correspondence with the proposer) preference is given to domestic ASBOs, when they exist. The countries which do neither use accreditation nor recognition (Estonia and Hungary) and the countries not having ASBOs in a technical area, appoint ASBOs from abroad.
- 3.4.2.6. On one hand, some accredited ASBOs consider to be subject to an accreditation and regular surveillance process more rigorous than the recognised ASBOs. On the other hand, some NSAs acting as recognition body consider that the accreditation is not as good as the ASBO recognition. And finally, some NSAs estimate that the quality of the ASBO independent assessments is insufficient no matter whether the ASBOs are accredited or recognised.

The Agency takes note of those observations but underlines the lack of sufficiently reliable information which would permit to actually state on the effectiveness of the use of accreditation and recognition of ASBOs.

The Agency recommends however to coordinate with the European Cooperation for accreditation, the national accreditation and recognition bodies in order to harmonise further the acknowledgement of the ASBO competence across the whole EU. That coordination has to be synchronised with the ASBO Cooperation Group where representatives of accreditation and recognition bodies are regularly invited (refer to section § 3.4.2.9. below).

- 3.4.2.7. Unnecessary use of too constraining requirements for the recognition of ASBOs :

A given number of ASBOs report being discriminated by their recognition body compared to other recognised or accredited ASBOs. Their recognition body imposes additional and stronger requirements for recognition than those contained in Annex II of the CSM. Those ASBOs are obliged to demonstrate the knowledge of specific national rules before being recognised and allowed to work in the country whereas the knowledge of such rules was explicitly excluded from the requirements in Annex II during the drafting of Regulation 402/2013. Obviously, this is breaching the principles of functioning of the accreditation as ruled by Regulation 765/2008. According to Regulation 765/2008, an accredited ASBO shall be allowed to provide its services across the entire EU without additional demonstrations.

The Agency takes note of this information. But it considers that the roles and responsibilities are not clearly separated between the DEBO (i.e. the body designated according to Article 17 of Directive 2008/57/EC) and the ASBO. The DEBO should know ALL national rules, not just the technical ones. To avoid any duplication of independent assessments between those two bodies, the DEBOs verification of conformity should not be limited to Notified National Technical Rules (NNTRs) but should also include the Notified National Safety Rules (NNSRs). In this way, the ASBO would not need to assess again the part of checks that was already carried out by the DEBO.

The Agency recommends to have a discussion with the European Commission on that subject and to clearly separate the roles and responsibilities of DEBOs and ASBOs.



3.4.2.8. In addition to the issues above, many stakeholders (NSAs, accreditation bodies, RUs, IMs, manufacturers but also ASBOs) report that the current granularity of the requirements and criteria in the CSM and the ISO/IEC 17020:2012 standard referenced therein are of a rather general level. As different interpretation may be given across the EU :

- (a) there is no assurance that all accreditation and recognition bodies are checking the compliance with the same detailed requirements for the different ASBO technical areas as meant in point § 2 in Annex II of the CSM;
- (b) there is no assurance that all ASBOs understand in the same way the requirements in Article 6 and in particular in Article 6(2) concerning their working method;
- (c) there is no assurance that all needed technical areas are exhaustively and explicitly included in point § 2 in Annex II of the CSM;
- (d) etc.

3.4.2.9. In order to discuss and clarify all such issues, in 2017 the Agency created a Cooperation Group between all ASBOs. That cooperation includes all ASBOs registered in ERADIS but also representatives from the railway sector (RUs, IMs and manufacturers), NSAs, accreditation and recognition bodies. Four meetings have taken place so far (until the end of 2018). The agreements reached in the ASBO Cooperation Group will be formalised under Recommendations For Use [RFUs]; the same process is applied as the one used by NB Rail (the NOBO association). The agreed clarifications or RFUs will also be made available to National Accreditation and Recognition Bodies to help them better understanding the needs of Regulation 402/2013 and the ISO/IEC 17020:2012 standard for the railway sector. Later on, when it will be decided to revise Regulation 402/2013, those RFUs will certainly be taken as inputs for including any necessary requirement in the revised text.

3.4.2.10. In relation to sections § 3.2.4. and § 3.2.5. above, considering that :

- (a) the proposers classify almost all operational and organisational changes as “non-significant”;
- (b) the railway sector and ASBOs have less experience with the risk assessment and independent safety assessment of operational and organisational changes. The majority of significant changes are related to technical systems;
- (c) the operational and organisational changes are usually impacting the management system of RUs/IMs/ECMs which is by default under the coverage of the certification and supervision/surveillance by the NSA/ECM Certification Body;

**Note :** the safety related application conditions/constraints (SRACs) identified by the risk assessment of a technical system and exported to other actors for the safe management and control of risks shared with those actors across the interfaces are fully managed by the risk assessment of the technical system. The completeness and appropriateness of those exported constraints are independently assessed by the ASBO of the technical system.

NSAs and the Agency consider that by default the independent assessment of the correct application of the risk assessment process and suitability of results of “operational and organisational changes” has to be carried out by the NSA/ECM Certification Body **in the scope of the certification and supervision/surveillance of the RU/IM/ECM management system, no matter whether the change is significant or non-significant.**

Indeed, for points (c), (d), (e) and (f) in Article 6(4)<sup>(4)</sup> of the CSM it is superfluous to leave the free choice to the proposer to appoint another ASBO and then to oblige the NSA/ECM Certification Body to mutually recognise the safety assessment report of that ASBO for such types of changes. Manufacturers which do not deal with such types of changes are not affected by that recommendation.

This separation of independent assessment between the NSAs [for operational and organisational changes] and ASBOs [for technical changes] could permit to simplify the use of the CSM for risk assessment, to avoid a misclassification of safety related operational and organisational changes into non-significant ones and to comply more easily with Article 6(3)(a) of the CSM, i.e. to avoid duplication of independent assessment between an ASBO and an NSA/ECM Certification Body.

### 3.4.3. Peer Evaluations between the Recognition Bodies

3.4.3.1. Between 2017 and 2018, the Agency established a project with recognition bodies. The objective was to set up a scheme for the Peer Evaluations (called also Peer Reviews in some literature) between the recognition bodies. The basic documents (i.e. Policy, Procedure, Requirements for Peer Evaluators) were developed and discussed with the relevant national recognition bodies. Mid 2018, the Agency organised also a first training course for the Peer Evaluators. A pilot Peer Evaluation was also planned with a volunteer recognition body to test those basic documents.

3.4.3.2. At the beginning of the project (April 2017), 14 Member States were using the recognition. Meanwhile (see Table 1 above), four of countries have revised their original decision and decided to abandon the recognition and apply only the accreditation (process in The Netherlands<sup>(5)</sup> is still on-going). The recognition bodies have recognised the following numbers of assessment bodies :

**Table 2: Number of recognised ASBOs.**

Member State	Number of recognised assessment bodies	Remarks
Bulgaria	1	
Croatia	1	NSA recognised by the Ministry
Czech Republic	5	
Germany	14	
Ireland	0	No entry in ERADIS
Italy	6	
Latvia	1	Assessment body part of the main RU
Norway	0	No entry in ERADIS
Romania	1	NSA recognised by the Ministry
Slovenia	1	NSA recognised by the Ministry
The Netherlands <sup>(5)</sup>	5	Recognition is being abandoned for accreditation
<b>Total number</b>	35	

(4) Although points (c), (d), (e) and (f) in Article 6(4) of the CSM relate specifically to an NSA, by analogy the same principle applies to ECM Certification Bodies with regard to operational and organisational changes to the system of maintenance of entities in charge of maintenance of freight wagons.

(5) The Netherlands announced the abandon of the use of recognition by the NSA and the use of accreditation instead of it. However, the decision is not yet official. It will be official in the scope of transposition of the 4<sup>th</sup> Railway Package by The Netherlands.

3.4.3.3. In practice, only the Recognition Bodies of the Czech Republic, Germany, Italy and The Netherlands have recognised more than one ASBO. For the other countries having recognised just one ASBO, the effectiveness of conducting a peer evaluation of the “recognition body capability and procedures for recognition” is quite doubtful from the methodology point of view. This particularly applies to countries where the Ministry has recognised the NSA capability to act as ASBO. In those countries, it is very likely that the respective Ministry carries out the recognition body task just once over a five year period, excluding the surveillance activities (if any).

In addition to those problems, the countries where the Ministry acts as recognition body, the implementation of peer evaluations raises issues of non-correspondence of functional positions between the evaluator and the evaluated entity. The “NSA of a Member State” will be in the situation to cross-check the correct recognition by the “Ministry of another Member State”.

3.4.3.4. Among the four recognition bodies, which have recognised more than one assessment body :

- (a) The Netherlands<sup>(5)</sup> are in the process of revising their decision to go for the accreditation;
- (b) the Czech Republic so far has not really co-operated in the project.

3.4.3.5. There are thus only two Recognition Bodies, which regularly recognise assessment bodies/renew the recognition and co-operated fully in the project development : the German and Italian NSAs.

3.4.3.6. Finally, although the peer evaluation project agreed to carry out a pilot test of application of the “Peer Evaluation Scheme”, in practice the initial volunteer withdrew its candidacy. Several Member States expressed their wish to avoid visits to Member States for on-site peer evaluations as far as possible. They suggested to use preferably an off-line written peer evaluation process.

3.4.3.7. Considering all those circumstances and discrepancies with respect to the peer evaluations run among the national accreditation bodies, the Agency has serious doubts whether “off line peer evaluations” with the Recognition Bodies of only three countries can actually lead to a reasonable level of control of the effectiveness of functioning of the recognition of ASBOs. The Agency recommends then to put the project in the standby mode and to have a discussion with the European Commission in order to decide on the next steps forward.

#### **3.4.4. Peer Evaluations between National Accreditation Bodies**

3.4.4.1. The peer evaluations between National Accreditation Bodies are formally organised, with on-site and witnessing visits, and managed by the European Co-operation for Accreditation (EA). National Accreditation Bodies which do not take appropriate action plans to address non-conformities identified by the peer evaluations are withdrawn from the Multi-Lateral Agreement (MLA) of EA.

3.4.4.2. In the scope of the ASBO Cooperation Group mentioned in the sections above, the Agency foresees to coordinate with EA for improving the common understanding of the requirements to be fulfilled by the ASBOs.

### 3.5. Analysis of the overall effectiveness of the CSM

- 3.5.1. The EU railway legislation<sup>(6)</sup> has introduced a totally new concept for many European railway stakeholders : the use of a risk based approach for the safe management of railway activities. In the past, in order to operate, it was sufficient for the railway companies to comply with well-established national rules and (national) standards. The EU railway legislation requires now the railway companies to use harmonised methods and to think proactively in terms of risks in order to identify all risks arising from the operation and maintenance of railways and to implement preventive measures that control those risks to an acceptable level.
- 3.5.2. The analysis of the sector “Return of Experience” with the CSM for risk assessment shows that the “concept of risk” and “thinking in terms of risk rather than in terms of rules” are not yet well understood, and therefore not well applied, by a large majority of stakeholders.
- 3.5.3. Only a small minority of companies, in general those more mature with risk management (refer to section § 3.1. above), understand well the CSM and apply the method correctly. Their return of experience on the overall effectiveness of the CSM is positive. Usually big manufacturers, who in the past followed the risk assessment process of the CENELEC 50126 standard, do not face special difficulties with the understanding and application of the CSM. Usually they also document better the evidence from the correct application of the CSM.

Based on the level of detail of collected replies, the Agency cannot give with sufficient confidence an accurate estimation of the ratio of stakeholders who have a positive experience with the CSM and actually understand and implement correctly the method. **However not more than “10 % to 15%” of RUs, IMs and ECMs fall in that category.**  
For manufacturers, more familiar with the CENELEC 50126 standard and risk management concepts, this ratio is probably much higher.

In those companies with positive experience :

- (a) The CSM for risk assessment is an integrated part of their quality and safety management processes for the safe management of changes;
- (b) The method is used proactively from the beginning of the project in order to identify the possible risks that can arise from changes they intend to undertake, to define and implement in the design appropriate measures for controlling those risks to an acceptable level;
- (c) Enough resources (usually specialised safety people) are allocated to the management and application of the CSM. The roles and responsibilities are better understood;
- (d) The other actors involved across the interfaces are better involved in the risk identification, risk assessment and risk management of the risks that are shared between several actors across those interfaces;
- (e) Although achieved in different ways and continually improving (e.g. paper documents, electronic files or dedicated databases depending on the size, organisational complexity of the company and the type and extent of operation), the risk assessment and risk management are better documented;

<sup>(6)</sup> *Safety Directive 2004/49, the CSM for conformity assessment [Regulations 1158/2010 (RUs) and 1169/2010 (IMs)], the ECM Regulation 445/2011, Regulation 402/2013 on the CSM for risk assessment and Regulation 1078/2012 on the CSM for monitoring.*

**Based on the experience of this category of stakeholders, there is no sufficient and objective evidence which would show that the CSM for risk assessment is not effective for achieving the objectives that are set out in Article 1<sup>(7)</sup> and Article 15(5)<sup>(8)</sup> of the (EU) Regulation 402/2013 on the CSM for risk assessment.**

3.5.4. Concerning the other categories of stakeholders in section § 3.1.2.1., in general less advanced with risk management concepts, it results that :

- (a) for a large majority of stakeholders, the period of application of the CSM is not long enough to be able to understand well the CSM requirements, to apply them correctly, to “learn by doing” and to improve the deficiencies they discover or those reported by the ASBO during the independent safety assessment activities of the correct application of the CSM;
- (b) the main problem is the lack of understanding of the risk based concepts which hinders the correct application of the CSM. They fail to make a link between the requirements of the CSM and the risks that arise from the changes they intend to undertake. Very often, they do not notice that some risks are already controlled to an acceptable level by the internal operational processes, procedures and risk control measures they have in place in their management system;
- (c) the lack of sufficient application of the CSM cannot be interpreted as ineffectiveness of the method but insufficient experience with the method of the concerned categories of stakeholders;
- (d) therefore, there is no yet any objective evidence showing that the CSM for risk assessment is not effective.

3.5.5. Based on the analysis in section § 3.1. above of the railway sector experience with the use of the CSM and of its overall effectiveness, it can be concluded that the method is effective for achieving the objectives that are set out in its Article 1<sup>(7)</sup> And Article 15(5)<sup>(8)</sup> of the CSM.

### 3.6. Main concerns with respect to the correct application of the CSM

3.6.1. The analysis of inputs in section § 3.1. above shows that the level of understanding and difficulties faced with the application of the CSM for risk assessment cannot be generalised to all companies of the EU railway sector, especially considering that the NSAs did not all answer to the survey :

<sup>(7)</sup> Point 2 in Article 1 of Regulation 402/2013 states the following :

*“This Regulation shall facilitate the access to market ... through harmonisation of :*

- (a) the risk management processes used to assess the impact of changes on safety levels and compliance with safety requirements;*
- (b) the exchange of safety-relevant information between different actors within the rail sector in order to manage safety across the different interfaces which may exist within this sector;*
- (c) the evidence resulting from the application of a risk management process*

<sup>(8)</sup> Point 5 in Article 15 of Regulation 402/2013 states that *“When a system or part of a system has already been accepted following the risk management process specified in this Regulation, the resulting safety assessment report shall not be called into question by any other assessment body in charge of performing a new assessment for the same system. Mutual recognition shall be conditional upon demonstration that the system will be used under the same functional, operational and environmental conditions as the already accepted system, and that equivalent risk acceptance criteria have been applied”.*

see sections § 2.1., § 2.2. and § 3.1.1.3. above. There are of course companies which are more mature than others with the risk management concepts. As they understand well and apply correctly the CSM, they have a positive return of experience with the method. Presumably, those companies do not fit within the categorisations in the sections below. However, as a large majority of companies still faces serious difficulties in understanding and correctly applying the method, the Agency considers it important to highlight the main problems encountered by those companies with poor understanding and incorrect application of the CSM.

### 3.6.2. Lack of maturity with the benefits of a risk based approach :

- (a) In general, almost all stakeholders (RUs, IMs, ECMs and manufacturers) perceive the CSM for risk assessment only as a legal obligation. Although exceptions can be found, usually the stakeholder maturity with the risk management and management system concepts is not yet at a level where they would use the CSM for risk assessment as an active tool also for optimising the company costs and competitiveness. *This shows an immature and insufficient stakeholders' awareness of the importance of an effective and proactive risk management.*
- (b) A very large majority of stakeholders still perceives the obligation to apply the CSM as unnecessary bureaucratic burden with additional efforts, costs, delays, project risks and uncertainties which does not bring added value.
- (c) As reported in section § 3.2. above, the concept of “significant” and “non-significant” change is completely misused in order to avoid applying the formal risk assessment process of the CSM and appointing an independent ASBO. Therefore, almost all changes are classified as non-significant. Only 2 to 5% of all changes are considered significant, independently on whether the countries are “rule based” or familiar with the “risk based thinking”.

### 3.6.3. Weakest experience with risk assessments of “operational and organisational changes” :

- (a) The assessment of the significance of operational and organisational changes is considered much more difficult than for technical changes.
- (b) Most of the 2 to 5% of significant changes are of a “technical nature”. So, the experience with the risk assessment of significant technical changes is much better than for operational and organisational changes.
- (c) The application of the CSM is less understood and less applied for “operational and organisational” changes. These later ones are rather subject to the use of standards and codes of practice without necessarily having formal and documented evidence of it.
- (d) The operational and organisational changes are usually managed through the management system of the RU/IM/ECM. The way they are assessed and managed is thus accessible to the NSA/ECM Certification Body during the certification and supervision/surveillance of the RU/IM/ECM management system.
- (e) The roles and responsibilities in terms of independent safety assessment activities of operational and organisational changes are not clearly separated between the ASBO and the NSA/ECM Certification Body. There is thus unavoidably duplication of conformity assessment between the ASBO and the NSA/ECM Certification Body.

### 3.6.4. Description of the organisation and management of the risk assessment :

- (a) The management of the change, the appointment of the experts in charge of risk management activities and the allocation of roles and responsibilities to every involved actor are either not well described or totally missing.

- (b) For complex projects involving many actors and contractors, it is difficult for the ASBO to understand clearly the respective roles and responsibilities, their interactions and the overall coordination of the risk management activities.
- (c) When a description exists, usually it does not reflect the actual project organisation. Because the risk assessment is often performed at the end of the project, backdated “cosmetic documents” can be built just to fulfil the legal requirements.

3.6.5. **Poor quality of risk assessment documentation - Cosmetic paper work built at the end of the project just for demonstrating compliance with the legislation :**

- (a) The quality, structuring and completeness of the evidence from the risk assessment and risk management are generally low.
- (b) Although some lately improvement is noticeable, often formal risk assessment process is applied at the end of the project just for building the proper paper evidence and for demonstrating the right choices are done. The outcomes of the risk assessment are not largely used for influencing the design choices.
- (c) The outcomes from the risk management are still very general. The identified safety requirements are unclear and are not properly linked to the hazards/risks they are controlling. As they are not always registered in the Hazard Record, their correct management cannot be demonstrated transparently. Often, the outcomes sound more useless paper work, or a cosmetic presentation vs. the requirements of the CSM, rather than an attempt to identify and control the risks that can arise from the change.
- (d) the concept of “demonstration of compliance with the safety requirements” is not well understood, implemented and demonstrated. For some stakeholders, the risk assessment is simply cosmetic paper work built at the end of the project; it does not thus identify any safety requirement. Consequently, there is nothing to be implemented and to comply with.
- (e) The assumptions, constraints and assessments related to “interfaces” and “safety integration” are the least well-documented. For example, when a project is split among several actors, every actor could have its own risk assessment, ASBO report and exported constraints. But often the overall risk assessment on the boundaries and interfaces between the different sub-systems are either not well documented or totally missing.
- (f) It is thus premature to assume that the CSM is understood and that the (right) risks are properly identified and adequately managed. The sector does not use yet the “proactive risk-based approach” of the CSM to manage the safety. The “rule based approach” continues to play a very important role. If something is not addressed by a rule, the “reactive approach” (following an incident or an accident) is used to define appropriate measures and to complement the rules for preventing similar events to happen in future.

3.6.6. **No trust in the added value of an ASBO - Late appointment and involvement of the ASBO :**

- (a) The ASBO independent assessment of the correct application of the risk assessment process and of the suitability of the results is considered unnecessary bureaucratic validation that does not provide benefits.
- (b) The obligation to appoint an ASBO for the independent assessment of a significant change discourages a lot of companies from deciding that the change is actually significant. Although the ASBO is bound by confidentiality obligations and must not disclose any information, many companies fear to make their “internal” problems visible outside.

- (c) Although the independent safety assessment is expected to start as early as possible, i.e. during the planning phases of the change, in practice often the ASBO is appointed systematically very late at the end of the risk assessment process. The design choices are then already frozen, the design is done and validated. Very rarely it is acceptable from the project point of view to implement “last minute design modifications” for addressing non-compliances raised by the ASBO. In such cases the ASBOs do not really have the possibility to influence the proposer’s design choices; they can agree or disagree with the proposer’s justifications of the non-compliances.
- (d) In some countries not familiar with the “risk based thinking”, because of a late ASBO appointment, it is too late for implementing corrective measures in the design. So, it is often a natural practice to ignore the ASBOs conclusions without documenting at all the parts of the ASBO safety report subject to disagreement.
- (e) Some big companies tend to limit the scope of the ASBO independent safety assessment. But they do not want the ASBO to make clear the limitations and implications in the independent safety assessment report. They want to benefit of mutual recognition for a much broader scope than what the ASBO is actually allowed to assess through the scope of independent assessment contractually narrowed.

### 3.6.7. **Incomplete and poor system definition :**

- (a) Usually the system definition is incomplete and it is poorly described. Although the system boundaries and the interfaces are included, usually they are not completely and clearly defined. The environmental constraints and limitations or assumptions for the risk assessment are often missing;
- (b) The proposer/applicant can also decide to exclude whole parts of the system from the risk assessment and from the ASBO independent assessment, without showing proper risk analyses and justifications. In both cases (i.e. intentionally excluded parts or unwanted deficiencies in the system definition) and especially in case of gaps in the identification and description of interfaces and links with the other stakeholders and sub-systems, there are serious concerns with respect to :
  - (1) the completeness of the hazard identification and appropriateness of the risk assessment and risk management of the change;
  - (2) the safe management of risks shared at the interfaces with other sub-systems or other stake-holders involved at the interfaces;
  - (3) the safe integration of the change within its environmental, operational and maintenance context of the railway system;
- (c) The safety requirements identified by the risk assessment are rarely included in the system definition. That makes the ASBO understanding of the change difficult and complicates the independent safety assessment of the correct application of the CSM.

### 3.6.8. **Serious deficiencies in the management of risks shared at the interfaces :**

- (a) On one hand, as all interfaces with the other sub-systems and other internal or external actors are not systematically identified and clearly described in the system definition, they cannot be properly and systematically addressed by the risk assessment.
- (b) On the other hand, communication and contractual arrangements/provisions can exist with the other actors. However, the external actors are not systematically involved in a joint



hazard identification and management of risks shared across the interfaces. Often at the end of the project, the proposer just transfers to those external actors the “safety related application conditions/constraints (SRACs)” they must accept to manage, without being consulted on the appropriateness of those measures.

- (c) When RUs/IMs sub-contract the risk assessment and risk management activities to suppliers or manufacturers, the sub-contractor can be obliged contractually to involve in the risk assessment all the other actors impacted by the change. The problem is that in practice the supplier/manufacturer does not have any control and enforcement power to involve correctly all necessary actors, and to oblige them to take part, in a joint hazard identification and joint management of risks shared across the interfaces with those other actors.
- (d) This raises concerns not only on the capability of external actors to control appropriately the risks under their area of responsibility but also uncertainty with respect to the completeness of the risk identification and safe integration of the change within the environmental, operational and maintenance context of the railway system. This points out a misunderstanding of the overall concept of “safe integration” and its incorrect implementation by the sector.
- (e) In addition to the concerns above, many proposers tend to assign safety related application conditions that go beyond the scope of responsibility and reasonable domain of control by other actors, despite the fact that those later ones are not properly involved in the identification and management of risks shared across the interfaces.

### 3.6.9. **Tendency to wrongly transfer the control, management and acceptance of own risks under the responsibility of other actors :**

- (a) **Sub-contracting** : some RUs and IMs do not carry out themselves the overall system risk assessment and risk management. They sub-contract to suppliers/manufacturers the complete application of the CSM for risk assessment, including the endorsement of the acceptance of risks that fall under the RU/IM area of responsibility. Sub-contracting is not forbidden; but transfer of responsibility to other actors is non-compliant with Article 4 of the Safety Directive 2004/49.

It can happen for example that the sub-contractor (supplier/manufacturer) is required to be responsible for both the identification and acceptance of operational and maintenance risks. This includes for the sub-contractor the obligation to define any necessary operational and maintenance risk control measures which must be exported either to the RU/IM or to any other actor impacted by the shared interfaces.

- (b) **Design errors** : reciprocally some suppliers/manufacturers export abusively to users of their products and sub-systems (i.e. to RUs/IMs) safety related application conditions (SRACs) for mitigating design errors. The side effects of that are constraining operational and maintenance measures for RUs, IMs and ECMs instead of preventive risk control measures through technical improvements of the manufacturer’s design.

### 3.6.10. **Little or no exchange of risks or non-compliances that must be controlled by another actor :**

The entire concept of “informing another actor about uncontrolled risks and non-compliances that fall under its area of responsibility” is not well understood. So, if an actor identifies an uncontrolled risk, or a non-compliance, that can only be controlled/managed by another actor, it does not feel obliged to inform the right actor (or to notify it to the NSA). The associated risk can then remain uncontrolled by that other actor.

### 3.6.11. Misuse of checklists :

- (a) Existing/generic hazard checklists can be used for cross-checking the completeness of the hazard identification and for providing the assurance of an exhaustive and systematic risk management. However, when the proposer is not familiar with the risk based approach, use of such hazard checklists can be counterproductive. Indeed, in such checklists :
  - (1) hazards can be highly aggregated in the checklists without containing detailed sub-hazards, or;
  - (2) hazards can only be at the operational and maintenance levels whereas they are used for the assessment of a technical change at the design/construction stage.
- (b) So, the hazards identified by the application of the CSM and those in the generic hazard checklists can be of a different nature or can have different and incompatible levels of detail. If such generic hazard checklists are not carefully used as supportive material, there is no assurance that the hazards specific to the change are actually identified and properly managed. This is of particular concern if the level of detail of the hazard identification phase is influenced by the quality of the supporting generic hazard checklists.

### 3.6.12. Poor hazard record/log management :

- (a) The concept of hazard management is not understood and not correctly implemented. It is not considered as a useful tool but just as a legal obligation. So, often the hazard record is created at the end of the project. It is thus not updated/maintained from the beginning of the design till the implementation phase;
- (b) Many stakeholders mix up the hazard record tool and risk analysis tools, where the inputs of the hazard record usually come from. Thereby, the hazard record is a simple copy/paste of the safety study (e.g. FEMCA table) with additional columns. Because of that, it contains unnecessarily too much information, which complicates and increases the costs of management of the hazards registered in the hazard record.
- (c) Often, important fields of a common sense hazard record are missing : e.g. the person in charge of implementing the risk control measure, the deadline, the responsible for the verification, the way of verification, the status “CLOSED” or “OPEN”, etc.
- (d) Some actors transfer the risk(s) and safety measures to be implemented by other actors at the interfaces. But they do not mind whether the receiving actor understands the risks and accepts to control them. They do not ask this latter one to acknowledge the awareness of their responsibility for controlling the received risk(s).
- (e) Often, only the safety measures (i.e. exported constraints/conditions) are transferred to the right actors for the risks shared across the interfaces. But the proposer fails to export systematically at the same time the risks that are associated to those measures. As the receiving actor is not aware of the actual reasons for implementing those safety measures, there is a risk that either they are incorrectly implemented or not systematically implemented.
- (f) The hazard record is rarely used during the operation and maintenance of the railway system for monitoring the effectiveness of the identified risk control measures and taking action plans in case of non-compliances. The hazard record is considered as paper or formal work necessary just for the management of the change.

3.6.13. In general, because railway companies compete with each other, there is a lack of sharing of knowledge, experience and examples of application of the CSM between stakeholders.

### 3.7. CSM for risk assessment – CENELEC 50126(-1 and 50126-2) standard(s)

- 3.7.1. The complementarity of the CSM and CENELEC 50126-1 and 50126-2 standards is not widely understood.
- 3.7.2. Some stakeholders are wrongly seeking for differences of the risk assessment method between the CENELEC 50126-1 and 50126-2 standards and the CSM for risk assessment. In practice, in terms of the risk assessment and risk management process, the Agency does not see any difference; there are just small differences in a few definitions and the obligation for the ASBO to be accredited or recognised. The CENELEC ISA is not obliged to be accredited/recognised.
- 3.7.3. **Many ASBOs confirm the Agency view :** compliance with the CENELEC 50126-1 and 50126-2 standards ensures automatically compliance with the CSM if the independent safety assessment requested in CENELEC is carried out by an ASBO accredited/recognised vs. Regulation 402/2013 for the relevant technical area. In other words, the application of the CENELEC 50126-1 and 50126-2 standards is an acceptable means of compliance with the requirements of the CSM if the ISA is replaced by an ASBO competent in the same field.
- 3.7.4. **Critical :** as some companies wrongly separate the application of “CSM-ASBO” and “CENELEC-ISA”, there is potential for duplication of risk assessment and independent assessment or even for gaps in controlling risks at the interfaces. The ASBOs which see a border between the CSM and the CENELEC 50126 standards tend to accept the independent assessment by a “non-accredited/non-recognised” ISA of the correct “demonstration of compliance with the safety requirements”. As the ISAs are not subject to the obligation of accreditation, this creates a problem of trust and mutual recognition of the report of such ASBOs. Obviously, some ASBOs misunderstand point § 3.3 in Annex I of Regulation 402/2013. They include point § 3.3 in Annex I of the CSM in the scope of their assessment only if it is explicitly written in their contract.
- 3.7.5. There is a wide wrong belief that the “CSM & ASBO” are applicable to RUs/IMs for “the safe integration and the assessment of operational requirements” whereas “CENELEC & ISA” are applicable to manufacturers for the design of technical systems.
- 3.7.6. In some countries, the relations between the CSM for risk assessment, the CENELEC 50126 standard and national legislation is not well understood. So, when the proposer is not familiar with the “risk based thinking”, he cannot identify the synergies and complementarities between all those sets of requirements. Consequently, the proposer is not capable to separate the work streams and to coordinate correctly the NOBO, DEBO and ASBO activities. In that case there is a lot of duplication of work and costs between the following independent conformity assessments :
- (a) the CSM for risk assessment requires an independent safety assessment to be done by an ASBO;
  - (b) TSIs can require the compliance with RAMS standards (e.g. CENELEC 50126); that is to be independently checked by a NOBO;
  - (c) national regulations can also require the compliance with RAMS standards; that is to be independently checked by a DEBO, although this is already done by the NOBO;

### 3.8. Lacking expertise on the market – Time for EU strategic decisions

- 3.8.1. Huge lack of experts on the market competent both in risk assessment and railway fields :

- (a) “Vicious circle” between the offer and the demand for risk assessment expertise in railways :  
Considering the sector efforts to justify almost systematically the “non significance” of safety related changes (see section § 3.2. above), the risk assessment process of the CSM is not yet so widely and so often applied. Thereby, the market does not yet perceive a sufficient demand for developing and offering know-how, skills and practical expertise in these fields :

- (1) the technical, operational or organisational railway fields, and simultaneously;
- (2) the risk assessment process and various methods and tools (e.g. PHA, HAZOP, Event Trees, Fault Trees, FMECA, etc.) for effective identification and management of risks;

However, as the offer of experts with combined “know-how, skills and practical expertise” in these two fields is limited, the railway sector cannot recruit competent staff for taking over internally the full responsibility of the risk assessment and risk management of changes. Therefore, due to a continuing lack of competent experts on the market, the proposers tend to further decide that the changes are not significant in order to avoid applying the formal risk assessment process of the CSM. So the cycle is restarted.

- (b) In practice, due to the legal obligation to apply the risk based approach at different levels, the demand for professionals in risk assessment and risk management, with railway knowledge and expertise, is quite high. This is reflected by a high rotation of staff between the NSAs, NOBOs, ASBOs and railway companies.
- (c) The sector is investing efforts in training its staff in the fields of risk assessment and risk management. Own competence and capability in conducting risk assessment is growing slowly. Unfortunately, despite those railway sector efforts the availability of competent resources remains insufficient on the market to satisfy all potential demands.
- (d) In addition to this lack of expertise on the railway market, with the increase of the age of competent and experienced railway employees and their progressive retirement the lack of expertise can only worsen. If nothing is done to mitigate this situation, the sector will continue to struggle with the understanding and correct application of the CSM

3.8.2. The Agency recommends strategic decisions and initiatives to be taken with the EC and Member States to motivate and encourage technical universities across the whole EU to :

- (a) create trainings and risk assessment modules in their educational master programs for future engineers; the Agency could lead and coordinate these activities with universities, and;
- (b) offer on demand the same course to railway engineers currently employed in the railway sector during a few week training.

### 3.9. Suggestions/requests from NSAs, ECM Certification Bodies and ASBOs

3.9.1. Some NSAs, ECM Certification Bodies and ASBOs recommend the following actions to be taken in order to improve the understanding and the use of the CSM for risk assessment. It is to note that some recommendations require changes of legal text which cannot be done without EC mandate and involvement of relevant representative bodies (CER, EIM, UNIFE and other organisations) :

- (a) help with the decision on the significance of a change, for example :
  - (1) provide more examples of application of each criterion in Article 4(2) of the CSM;
  - (2) impose the use of a calibrated matrix for assessing and arriving more systematically at the decision that the change is significant. That can prevent proposers from escaping the obligation to apply the CSM and appoint an ASBO;

- (3) request in legislation that every safety relevant change is significant by default;
  - (4) include in legislation a (non-exhaustive) list of changes which are always significant;
  - (b) better dissemination of roles and responsibilities of the ASBO could help considering it as a benefit and not as a "bureaucratic and unnecessary validation";
  - (c) the NSA should challenge and better control the application of the CSM through the certification and supervision of the RU/IM SMS. Where necessary, the NSA should request more balanced decisions and justifications on the significance of changes;
  - (d) make at least mandatory the assessment by an ASBO of the correctness of the proposer's decision and justifications of the significance of the change. *The Agency underlines that outside the scope of the CSM; it would be redundant with the current NSA/ECM Certification Body role in the certification and supervision of the RU/IM/ECM management system;*
  - (e) give an illustrative example of a Hazard Record/Log;
  - (f) increase the clarity and understandability of the CSM to make it readable by practitioners who must implement it. *The Agency underlines that this cannot compensate the lack of sector competence in risk assessment and "risk thinking";*
  - (g) make available helpful guidance in the relevant EU languages;
  - (h) target dissemination on the CSM to the specific needs of small railway companies;
  - (i) provide the relationship between the CSM and CENELEC 50126 standard and the explanation at what extent compliance with the CENELEC standard allows also to comply with the CSM;
  - (j) make available examples of risk assessment that illustrate the correct application of the different steps of the risk assessment process of the CSM;
- 3.9.2. Some NSAs underline they do not have internally sufficient knowledge and capability to promote alone the CSM for risk assessment. The Agency can offer support to those NSAs.
- 3.9.3. Considering that different interpretation may be given across the EU concerning the management of operational and organisational changes, it is necessary to harmonise further the competence requirements the ASBO has to demonstrate and the actual independent assessment activities.
- 3.9.4. Although many ASBOs report that the guides already issued by the Agency contain sufficient information to carry out correctly the risk assessment, one NSA asks for more guidance concerning the required level of detail for the hazard identification.
- 3.9.5. As the concept of safe integration is not yet correctly understood, the sector is asking for more explanations and guidance.

## 4. Proposed recommendations

- 4.1. Only a small minority of companies (not more than 10 % to 15 % - refer to section § 3.5.3.) actually understands and correctly applies the CSM for risk assessment. So, there is still a very large proportion of stakeholders across the EU who still face serious difficulties with its understanding and correct application. The method is effective but the period of time from its mandatory application seems too short for the companies for being able to "learn by doing".
- 4.2. As the return of experience does not identify any justification for modifying the content of the CSM for risk assessment :

- (a) the Agency does not recommend yet to revise the associated Regulation 402/2013 and its amendment by Regulation 2015/1136;
- (b) the Agency recommends to put in place, in collaboration with the national safety authorities, an appropriate and agreed dissemination programme to increase the railway sector awareness with the risk management concepts (including thus the CSM for risk assessment and also CSM for monitoring) and to help them achieving full compliance with the CSM for risk assessment. *The dissemination programme will have to be developed and agreed separately.*
- 4.3. The Agency concludes also that this first measurement of the railway sector experience with the CSM for risk assessment does not give yet a reliable picture of any potential problem with the requirements of the CSM. In addition to that, the analysis of the results shows that the stakeholders less familiar with the risk assessment and risk management concepts have more difficulties in understanding the CSM compared to those who are advanced in risk management.
- 4.4. Considering that both “risk assessment and monitoring” processes of the RU/IM/ECM management system should actually be used on a recurrent basis, the Agency recommends to :
- (a) have a combined measurement of the return of experience on risk management [i.e. with both the “CSM for risk assessment” (i.e. Regulations 402/2013 and 2015/1136) and “CSM for monitoring” (i.e. Regulation 1078/2012)] – [*Why combining both? → refer to section § 4.7.*], and to;
- (b) redo the collection of the return of experience with these two CSMs at a later stage after the delivery of the dissemination programme proposed in section § 4.2. above. This permits the crosschecking of whether :
- (1) the sector maturity is improving and whether it is “learning by doing”;
  - (2) the dissemination programme is effective and whether a better targeting of additional dissemination or a specific training is necessary.
- The collected information should serve as a solid justification for revising, improving or clarifying problematic legislation, or guidance material, based on objective observations by the users of real weaknesses and problems with the methods.
- 4.5. Indeed, the most mature stakeholders report that the “risk assessment process” and “monitoring process” of the management system cannot be separated. In addition to that, the Agency underlines that the measurement of the effectiveness of these two CSMs and the railway sector experience with their use must not be a “one shot exercise”, in particular knowing that a big number of stakeholders is still immature in “thinking in terms of risk and risk based approach”.
- 4.6. The pitfalls of a “one shot REX measurement” is to reveal problems with these two CSMs, and the supporting guidance material, whereas in practice these two CSMs are not sufficiently used or not well understood. The lack of use of these two CSMs by the sector shall not lead to an unreliable picture of the methods and to misled conclusions that could result in unjustified revisions of the CSM for risk assessment and CSM for monitoring.
- 4.7. Why combining the collection of the REX with the CSMs for risk assessment and for monitoring?**

In order to enable the Agency to fulfil its legal obligations, it is important to collect the EU railway sector experience with these two CSMs at the same time. Indeed, as they constitute two key pillars of the PDCA (Plan-Do-Check-Act/Adjust) cycle of the RU/IM/ECM management system :

- (a) the experience with the use of these two CSMs is available at the same time to NSAs and ECM Certification Bodies through their assessment/certification and supervision/surveillance of the RU/IM/ECM management system;
- (b) the EU legislation requires already the NSAs and ECM Certification Bodies to support the Agency in measuring the railway sector experience with the legislation. Consequently, observing “through the eyes of NSAs and ECM certification bodies”, the Agency can also measure the return of the sector experience with these two CSMs;
- (c) the measurement of the effectiveness of each of these two CSMs is dependent on the correct implementation of the other CSM;
- (d) the Agency can avoid requesting the NSAs and ECM Certification Bodies to provide additional and separate information for each CSM every year.
- (e) a correct synchronisation and cooperation with the NSAs and ECM Certification Bodies enables the Agency to gather the necessary REX information through existing tasks of NSAs and ECM Certification Bodies, without asking them additional work.

As the ASBOs are systematically assessing the correct application of the risk assessment process and the suitability of the results of the CSM for every significant change, the ASBOs are also to be involved in any future survey of the sector experience with the CSM.

The railway sector (RUs, IMs, ECMs and manufacturers) can also be consulted for getting directly their own experience, unfiltered by NSA and/or ECM Certification Body reporting.

## 5. Conclusions

5.1. To collect the return of experience of EU railway stakeholders with Regulation 402/2013 on the CSM for risk assessment, the EU legislation requires the national safety authorities (NSAs) and ECM Certification Bodies to support the Agency. The Agency coordinated with the NSAs, ECM Certification Bodies but also with CSM Assessment Bodies (ASBOs) who are in charge of independently assessing the correct application of the CSM and the suitability of results for every significant change. A summary of all inputs received from the survey is provided in ANNEX A of this report. Chapter 5. summarises the main outcomes of the survey. More details on the analysis can be found in section § 3. above.

5.2. The analysis of the stakeholders’ experience with the CSM shows that :

- (a) it is not possible to provide a common and accurate picture of experience with the use of the CSM for every country and every category of stakeholders in a country. The levels of understanding and implementation of the CSM vary from country to country, from stakeholder to stakeholder in a country, or even from project team to project team in a company.

In general the following three main trends emerge. They are consistent throughout the different questions and represent the experience of RUs, IMs, ECMs and manufacturers :

- (1) **stakeholders who well understood and correctly apply the CSM;**

This is only a small minority of companies (not more than 10 % to 15 % - refer to section § 3.5.3.), usually more mature with the risk management concepts. Usually big manufacturers, infrastructure managers (IMs) and big railway undertakings (RUs) and a part of entities in charge of maintenance (ECMs) fall in this category. **Their experience with the CSM is positive;**

- (2) **stakeholders for whom the understanding and implementation of the CSM were challenging but they are “learning by doing” and they are “continually improving” its use;**
- They represent a very large majority of companies across the whole EU. They still face serious difficulties in understanding and correctly applying the method. Usually small RUs, a part of ECMs, RUs of countries more familiar with the application of rules rather than with risk management and one part of newcomer RUs fall in this category. **Their experience with the CSM is still negative and insufficient to show a reliable picture;**
- (3) **stakeholders who have not (yet) well understood, or have not understood at all, the CSM and who have not correctly applied, or have not applied at all, the CSM.**
- (b) the period since the date of application of the CSM is judged not long enough to enable the stakeholders, less familiar with the risk management concepts, to “learn by doing” and to improve their understanding and the level of compliance with the method;
- (c) only 2 to 5% of all changes are considered significant, independently on whether the countries/companies are familiar with the “rule based” or “risk based thinking”. Most of those 2 to 5% of changes are of “technical nature”. So, the sector has less experience with the risk assessment of operational and organisational changes;
- (d) a large majority of proposers tend thus to classify most of the changes as non-significant in order to avoid the application of the formal risk assessment process of the CSM, which they do not yet understand well and are unsure whether they apply it correctly. Consequently, the lack of experts on the market with “know-how, skills and practical expertise” in both risk assessment and railway fields can only encourage the sector to continue misclassifying changes into non-significant ones;
- (e) due to a poor understanding of the CSM, usually :
- (1) the system definition is incomplete and poorly described;
  - (2) the external actors are not systematically involved in a joint hazard identification and joint management of risks shared across the interfaces with other sub-systems;
  - (3) there is no assurance of completeness of the hazard identification and proper risk management, in particular with respect to the safe integration of the change within the environmental, operational and maintenance context of the railway system;

Section § 3.6. lists the main concerns with respect to the correct application of the CSM.

5.3. The analysis of the effectiveness of the CSM shows that :

- (a) the CSM for risk assessment is effective for achieving the objectives that are set out in Article 1 and Article 15(5) of the associated (EU) Regulation 402/2013.
- Although many companies complain that the risk assessment process is complex and not widely understood, the survey confirms that the CSM is not fundamentally different from practices and risk assessment standards used in the past. Countries and companies familiar with the “risk based thinking” estimate that the whole concept was well-known before the adoption of the CSM. For the CCS sub-system, the CENELEC 50126, 50128 and 50129 standards are based on the same concepts and are common practice for almost 20 years;
- (b) objective justifications are not yet identified which would require an urgent amendment or revision of the CSM for risk assessment;



- (c) finally, the time since the date of application of the CSM is not long enough to enable the stakeholders, less familiar with the risk management concepts, to “learn by doing” and to improve their understanding and the level of compliance with the method.
- 5.4. Therefore, the Agency has not identified any evidence for recommending yet the revision or amendment of the CSM for risk assessment.
- 5.5. However in order to help the sector with the implementation of the CSM, **the Agency recommends** the following :
- (a) to put in place, in collaboration with the national safety authorities, an appropriate dissemination programme to increase the railway sector awareness with the risk management concepts (including both the CSM for risk assessment and CSM for monitoring) in order to help them achieving full compliance with the CSM for risk assessment;
- (b) to take strategic decisions and initiatives with the EC and Member States in terms of education and training in order to (see section § 3.8. above for more details) :
- (1) compensate the current lack of expertise on the market in railway risk assessment, and;
- (2) anticipate the growing loss of railway expertise with a continually increasing number of employees reaching the age of retirement;
- (c) as the effectiveness of the “CSM for risk assessment” (i.e. Regulations 402/2013 and 2015/1136) and the “CSM for monitoring” (i.e. Regulation 1078/2012) depends on the correct implementation of the other CSM, any additional measurement of return of experience needs to combine these two CSMs<sup>(9)</sup>;
- The lack of effective and complete use of these two CSMs by the sector shall not lead to an unreliable picture of the methods and to misled conclusions that could result in unjustified revisions of the CSM for risk assessment and CSM for monitoring;
- (d) with the support of NSAs, ECM Certification Bodies and ASBOs redo the measurement of the effectiveness and experience with these two CSMs at a later stage after the delivery of that dissemination programme;
- (e) the results of such a return of experience should then serve as a solid basis for planning justified improvements or clarifications of legislation, or guidance material, based on objective observations by the users of real weaknesses and problems with the methods, and a better targeting of any necessary additional dissemination or training activity.
- 5.6. The following additional recommends are taken on board by the Agency :
- (a) in the scope of implementation of the 4<sup>th</sup> Railway Package, the Agency monitoring of the NSA activities has to look at how the NSA supervision of the RU/IM SMS verifies that the Change Management Control process of the RU/IM SMS identifies, assesses and properly controls the risks arising from both non-significant and significant changes;
- (b) the Agency has to coordinate with the European Cooperation for accreditation, the national accreditation and recognition bodies and the ASBO Cooperation Group in order to harmonise further the requirements, acknowledgement and supervision of the ASBO competence across the whole EU;

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<sup>(9)</sup> *Why combining the monitoring of the effectiveness of both CSMs? → refer to section § 4.7.*

- (c) considering the lack of cooperation of the ASBO recognition bodies in the establishment of a Peer Evaluation system, and a low number of recognised bodies (except by three countries), put the project in the standby mode, discuss with the EC and decide on next steps forward;
- (d) reflect with the EC on a clear separation of roles and responsibilities between the DEBO and the ASBO to avoid the ASBO reassessing the checks already done by the DEBO.

*The DEBO should know ALL national rules, not just the technical ones. So it should not limit its verification of conformity to Notified National Technical Rules (NNTRs) but should also verify the Notified National Safety Rules (NNSRs);*

- (e) reflect with the NSAs and ECM Certification Bodies on the relevance in the CSM to leave the proposer free choice to appoint another ASBO, rather than the NSA/ECM Certification Body, for the independent assessment of the correct application of the risk assessment process and suitability of results of “operational and organisational changes”. It could automatically be included in the scope of certification and supervision/surveillance of the RU/IM/ECM management system, no matter whether the change is significant or non-significant.

Manufacturers which do not deal with such types of changes are not affected by that recommendation.

## **ANNEX A – Summary of the answers to the questionnaire used for the gathering of return of experience (REX) with the use of the CSM for risk assessment**

- A.1. This annex summarises the inputs of 12 NSAs, 5 ECM Certification Bodies and 21 CSM Assessment Bodies (ASBOs) to the questionnaire in ANNEX B below on the RU, IM, ECM and manufacturer experience with the use of the CSM for risk assessment. The replies are given in relation to the corresponding questions of the questionnaire.
- A.2. Unless necessary for sorting out the results, when the NSAs considered the experience common to all stakeholders the NSAs did not systematically point out the difference in the experience of RUs, IMs and ECMs in their country. The NSAs, ECM certification bodies and ASBOs were asked to provide a representative picture of the overall sector experience with the use and implementation of the CSM.
- A.3. Taking this into account, with the exception of a few questions, in general three main trends emerge from the replies below; they are consistent throughout the different questions and representative of the RU, IM, ECM and manufacturer experience :
- (a) Stakeholders having well understood and correctly implemented the CSM;
  - (b) Stakeholders for whom the understanding and implementation of the CSM were challenging but they are “learning by doing” and they are “continually improving” its use;
  - (c) Stakeholders having not (yet) well understood or not understood at all the CSM and thus having not correctly implemented, or not implemented at all, the CSM.
- A.4. Those trends are usually verified by NSAs and ECM Certification Bodies through the respective Annual Safety Reports RUs and IMs submit to NSAs and, the Annual Maintenance Reports ECMs submit to ECM Certification Bodies.

## Q 1. Significance of the change and type of change

- (a) Are there notified national rules setting out what changes are significant in the country? If yes, which ones?
- (1) In most of EU Member States there are no notified national rules setting out which changes are to be considered as significant. In almost all countries, the criteria in Article 4(2) of the CSM are used to assess the significance of changes.
  - (2) In general, when national rules exist in a country, they relate to changes of Rolling Stock that must be considered as significant. Usually this is the case when a new vehicle authorisation is needed; the NSAs require the application of the CSM for risk assessment and an Independent Safety Assessment Report of an ASBO, regardless the proposer's decision on the significance.
  - (3) As an alternative way to strict national rules, in a few countries, the NSA or the IM give some guidance (in particular for Rolling Stock) how to assess the significance of changes.
- (b) How does the sector assess the significance of the change? If any, what other criteria than those in Article 4(2) of Reg. 402/2013 do they use?
- (1) Other criteria than those in Article 4(2) of the CSM do not seem to be used for the assessment of the significance of changes. Some companies have internal guidance for the assessment of the significance; the guidance is based on the CSM criteria.
  - (2) The experience shows that the large majority of proposers across the entire EU :
    - (i) estimates that the assessment of the significance of the change is complex and difficult;
    - (ii) classifies almost all their changes as non-significant just to avoid applying the CSM for risk assessment and appointing an independent ASBO.

The answers report that only 2 to 5% of changes are considered significant, independently on whether the countries are "rule based" or familiar with the "risk based thinking". Surprisingly, by the application of their SMS procedures a few incumbent railway companies consider almost every safety related change as a significant. The non-significant but safety related changes are also systematically subject to lighter risk assessment with an independently safety assessment by either an ASBO or an ISA.
  - (3) In Germany, the outcomes of the NeGST research project give some guidance for Signalling projects how to assess the significance of changes. It is based on the CENELEC risk acceptability matrix.
- (c) Are some of the 6 criteria in Article 4(2) of Reg. 402/2013 more important than the other ones for deciding that a safety related change is significant? If yes, which ones?
- (1) The decision on the significance of changes is strongly dependent on the previous experience of the people/teams making the assessment of the significance. Consequently, for the same change in the same company or in the same country, different people can arrive at different decisions with proper or poor justifications.
  - (2) In particular, the decisions on the significance of organisational, and often of operational, changes are more difficult than for technical changes.
  - (3) Although quite many replies declare equally important all criteria of the CSM, the most frequently used ones seem to be in order of importance 1°) "failure consequence", 2°) "complexity", 3°) "reversibility" and then when used 4°) "novelty", 5°) "monitoring" and 6°) "additionality". "Additionality" seems even to be used very rarely and just by a few stakeholders.

- (d) *No matter whether a change is significant or not, when the change is safety related, the risks arising from the change must always be controlled to an acceptable level!*

So, what type of documentation justifies the proposer's decisions? In particular, if no risk assessment is made, how is the acceptance of risks arising from those non-significant changes justified?

- (1) The ASBOs do not assess non-significant changes. So, usually they do not have access to proposer's justifications. The NSAs who replied the questionnaire do not have clear information either.
- (2) Just a few replies report that right methods exist in the SMS-es of companies. They seem to be well applied for demonstrating proper risk management for non-significant safety-related changes.
- (3) Otherwise, in general the CSM for risk assessment is misunderstood and badly implemented. The sector does not understand the meaning of "keep adequate documentation to justify the decisions" for non-significant changes. When a justification exists, it is a rough preliminary hazard analysis or a kind of form/table where the 6 criteria of Article 4(2) are covered with a few explanations. There seems not to be really identification and acceptance of risks done during the assessment of the significance. That does not give the assurance of a proper risk management. When risks are controlled to an acceptable level by provisions of the SMS, the link to the relevant SMS processes/procedures is poorly documented.

- (e) If a risk assessment is also made for non-significant safety related changes, which process is used?

There is no information reported which risk assessment process is used for non-significant safety related changes. Companies more familiar with the "risk-based thinking" use the same process for both significant and non-significant changes, i.e. the one in Annex I of the CSM for risk assessment, except that no ASBO is appointed; sometimes an ISA is even contracted for the independent safety assessment. Some other companies have just a high level preliminary risk assessment. For most of the others, the level of documentation is very poor and does not provide the assurance of a proper risk management.

- (f) Is there a difference of risk assessment process and level of detail of the assessment between Technical, Operational and Organisational types of changes? If yes, what are those differences?

- (1) Although a few replies report there is no difference of treatment between technical, operational and organisational changes, in practice the application of the CSM to technical changes seems to be more natural than to operational and organisational ones. The sector has much more experience with risk assessments for technical systems.
- (2) The CSM for risk assessment is even less understood and less applied to operational and organisational types of changes. These later ones are rather subject to use of standards and codes of practice without necessarily having formal documentary evidence of it.
- (3) For technical changes, there are also more quantitative assessments and the level of detail of risk assessments is higher, in particular when an NSA authorisation is necessary (e.g. vehicle or structural sub-system authorisation).

- (g) At what extent does the legal obligation to appoint an assessment body discourage the sector to decide that the change is significant? How could that be solved?

- (1) Appointment of an ASBO discourages a lot of companies in their decision on the significance of changes. Many stakeholders, and in particular those familiar with the "rule based thinking", do not want to make visible their "internal" problems outside their companies. They consider the CSM for risk assessment and the independent assessment by an ASBO as additional "administrative workload and bureaucratic formalism". Both are considered as useless burden, with additional or even very

high costs that require additional time (possibly delaying the entry into service) without actual benefits.

(2) On the contrary, the companies more familiar with the “risk-based thinking” begin to see the benefits of a structured risk assessment approach and the additional assurance provided by an independent pair of eyes. Such companies are more inclined to appoint an ASBO early in the process. The fear of having an independent ASBO involved in the verification of the risk management starts disappearing.

(3) **The NSAs and ASBOs propose the following Improvements :**

- (i) disseminate better the roles and responsibilities of the ASBO could help considering it as a benefit and not as a "bureaucratic and unnecessary validation";
- (ii) provide more examples of application of each criterion in Article 4(2) of the CSM;
- (iii) through the supervision of the proposer’s SMS, the NSA should challenge and better control the application of the CSM and request more balanced decisions on the significance of changes;
- (iv) impose the use of a calibrated matrix for the assessment of the significance of the change;
- (v) request in the legislation that every safety relevant change is considered significant;
- (vi) include in the legislation a (non-exhaustive) list of changes which must be considered significant;
- (vii) make at least mandatory the assessment by an ASBO of the correctness of the proposer’s decision and justifications of the significance of the change;

(h) Who is usually the CSM assessment body for operational and organisational types of significant changes? And how does the mutual recognition function for those types of changes?

(1) *Operational and organisational changes usually affect the allocation of roles and responsibilities throughout the organisational structure of the company, the processes, procedures and working instructions of the RU/IM SMS. This question aimed at checking whether the sector and NSAs avoid the duplication of independent assessments. Indeed, for significant changes, either all SMS arrangements are fully assessed by the NSA or the risk assessment and risk management of the change are independently assessed by an ASBO whose report must then be mutually recognised by the NSA for the upgrade/renew of the SMS Certificate/Authorisation (when the Certificate/Authorisation update/renew is needed).*

(2) In practice, no information is given by most of the replies so that no general rule can be reported. In particular, knowing that only 2 to 5% of changes are significant (where most of them concern technical systems), the sector has a small experience with operational and organisational **significant** changes.

(3) Two NSA states that for operational and organisational changes the NSA plays the role of the ASBO. A few other replies say it is done by an in-house ASBO and mutual recognition is not needed for those changes. This is questionable when, according to Article 10(5) and Article 11(2) of Safety Directive 2004/49/EC, the SMS Certificate/Authorisation needs to be updated/renewed by the NSA. Indeed, according the Article 6(3), in that case the NSA shall mutually recognise the independent safety assessment report of the ASBO.

(4) Knowing that different interpretation may be given across the EU, it is requested to clarify Regulation 402/2013 concerning the competence requirements for the ASBOs in the fields of operational and organisational changes.

## Q 2. Hazard identification and classification

- (a) When does the risk assessment start with respect to the development process of a change? From the beginning of the change management in order to drive proactively the design choices or closer to the end just for having the right paper work and demonstrating right choices were done?
- (1) It is dependent on the change but also on the safety culture of the proposer/applicant. For example, to support vehicle authorisations, usually risk assessments start from the beginning of the design of new vehicles or the modernisation of existing ones. The exceptions are old projects, where risk assessment are added at the end. For many infrastructure projects, the risk assessment (and the ASBO involvement) is done at the end of the project.
  - (2) For the other types of changes, a general trend cannot be seen yet. Both cases, i.e. with early or late risk assessment, and early or late ASBO involvement, are met. It mainly depends on the safety culture of the proposer/applicant who manages the change. Inexperienced personnel and companies (usually smaller railway undertakings) tend to start early the risk assessment but real progress is achieved at the end of the project, probably thanks to a better understanding of both the method and of the advantages provided by it.
  - (3) Many proposers/applicants still perceive the evidence from the CSM as an “add-on” documentation to the usual one in a project. Although some lately improvement is noticeable, usually formal risk assessment process is applied at the end of the project just for building proper paper evidence and for demonstrating the right choices are done. The outcomes of the risk assessment are not largely used for influencing the design choices. It is common practice especially for organisational changes.
  - (4) Although old projects are still having their risk assessments done at the end, the trend is improving slowly. With the increase of safety awareness, the benefits of having a structured and systematic approach for risk assessment, supported by the witnessing report of an independent ASBO, are more and more understood. So risk assessments start being used already from the preliminary concept phases of the project in order to influence proactively the design choices with early identifications of possible problems and the implementation of any necessary preventive/corrective measures that controls the identified risks to an acceptable level.
  - (5) It is to note that some stakeholders are mixing “project risks” (e.g. financial risks, delivery risks, etc.) with the “safety risks”.
- (b) When does the risk assessment finish with respect to the change management?
- (1) It is difficult to draw a clear conclusion from the received answers. Some stakeholders are wrongly mixing the risk assessment with the monitoring of effectiveness of resulting risk control measures during the use of the system under assessment. During that “testing period”, the risk assessment is not considered closed formally.
  - (2) The following non-exhaustive answers are received. Risk assessment finishes :
    - (i) before the change is implemented, which then does not include the “demonstration of compliance with the identified safety requirements”;
    - (ii) just before submitting the file to the NSA, without mentioning in the cases;
    - (iii) following the ASBO report;
    - (iv) following the proposer’s declaration that all identified risks are controlled to an acceptable level;
    - (v) after the demonstration of compliance with the safety requirements;
    - (vi) when the NSA process is finished and the NSA decides that the change is appropriately managed;

- (vii) after a first period of testing during the use of the system under assessment;
- (viii) when the application is submitted to the NSA;
- (ix) when the proposer decides to use the system;
- (x) etc.

The variety of replies clearly indicates an insufficient level of understanding of the CSM for risk assessment by the railway sector.

- (c) Does the system definition of the change permit a comprehensive risk assessment to be done? For example, are the scope, boundaries, interfaces, environmental and any other limitations included and clearly described? Are there parts of a project excluded from the risk assessment, and thus are not subject to independent assessment, without proper justifications? If yes, is it documented?
- (1) The ASBOs estimate that the system definition of significant changes is always an important issue (for non-significant changes, they do not have information). There might be complete parts of the system excluded from the risk assessment and treated separately; that makes the integration and the assessment of risks at the interfaces difficult. The parts of the system excluded from the risk assessment and independent assessment are not always clearly analysed and justified by the proposer.
  - (2) At the beginning of the project, when the ASBO is involved, the system definition is never complete. However, after a few iterations through the risk assessment process, and the outcomes of the ASBO independent safety assessment, the system definition gets improved and can be considered sufficiently detailed and complete to permit the proposer carrying out correctly its risk assessment. This seems to indicate a positive change in the trend; the system definitions start being complete and clear to support a proper risk assessment.
  - (3) A few replies report that the system definition is complete and sufficient to permit a comprehensive risk assessment to be done. In practice, the quality of the system definition depends mainly on the proposer and the change. Usually for CCS sub-systems, the system definition seems to be better documented; it tends to be sufficiently clear and complete. For new projects, it tends also to be complete whereas for existing systems, it is usually missing and incomplete.
  - (4) Often, the system definition is quite poor, concise and insufficiently detailed. In general, the scope and geographical boundaries (where applicable) are well defined especially for technical changes (less for operational and organisational ones). Although the system boundaries and the interfaces are included, they are not well defined. Often, the environmental constraints and the limitations or assumptions for the risk assessment are missing. In most cases, the safety requirements resulting from the risk assessment are not included in the system definition. Consequently, not only the understanding of the change is difficult for the ASBO, but also those lacks do not permit a clear understanding of the change and therefore an exhaustive hazard identification and complete risk management to be done.
  - (5) These deficiencies in the system definition, especially the lack or poor description of interfaces and links with other stakeholders and sub-systems, raise a particular concern with respect to :
    - (i) the safe management of risks shared between the interacting sub-systems and between the different stakeholders involved at the interfaces, and;
    - (ii) the safe integration of those sub-systems and of the roles and responsibilities of the different stakeholders involved at the interfaces;

Thereby, this does not give the assurance that all concerned rail-sector actors systematically cooperate in order to identify and manage jointly the hazards and related safety measures that need to be handled at the interfaces.



- (d) What methods or tools are usually used for the hazard identification? How does the sector ensure it is exhaustive and systematically done? Are (international) standards used for that? Which ones?
- (1) The methods and tools vary not only from proposer to proposer but also depend on the historical practice in the country. Among others, the following tools are reported :
    - (i) ISO 31000 and ISO 31010 standards, national standards (e.g. NS 5814);
    - (ii) manufacturers of CCS equipment use the CENELEC 50126, 50128 and 50129 standards and their guidelines;
    - (iii) team brainstorming and variants of FMEA. FTA and ETA are not used very often;
    - (iv) HAZOP (application guide BS IEC 61882:2001 Hazard and operability studies);
    - (v) in Germany, for vehicles the EN 15380-4 standard and checklists and guidance provided by the NSA (hazard list TeSiP, for trains the “Safety Guideline Vehicle SIFR”);
    - (vi) guidance on FMEA and FMECA techniques provided in EN 60812:2006 standard;
    - (vii) in-house procedures of the RU/IM SMS, including self-developed semi-qualitative and quantitative methods;
    - (viii) methods derived from aviation;
  - (2) Many stakeholders give preference to cross-checking completeness vs. existing/generic hazard checklists and the use of brainstorming and HAZOPs by multidisciplinary teams of experts. Those checklists are then continually updated based on the experience gained on every project. So, the hazard identification is strongly based on the expertise of the safety team in charge of the risk assessment, and thus on their professional judgement. These are often considered as safeguards that give the assurance of an exhaustive and systematic hazard identification and risk management.
  - (3) It is to notice that some ASBOs report not yet having seen any trustful argumentation (from any proposer) that the hazard identification is exhaustive and systematically done. That questions then the control of all potential risks that can arise from a change.
- (e) Are the same resource and time efforts spent for managing all identified hazards/risks? Or is there a focus on the most important ones? How is the risk acceptability demonstrated for the hazards/risks which are not processed further through the risk management?
- (1) This question relates to the processing of risks which are already broadly acceptable. And the replies are based on the assumption that the hazard identification is exhaustive.
  - (2) Usually, the proposers familiar with the “risk based thinking” focus their risk assessment on the most important risks. For the broadly acceptable risks, they track their fulfilment through the development process of the change. Their acceptance is done vs. criteria defined beforehand. On top of that, some of the stakeholders apply the ALARP principle to decrease further the level of residual risk.
  - (3) Many other stakeholders, in particular those familiar with the “rule based thinking”, do not make any distinction. They devote the same resource and time efforts (except for SIL0 and not safety related risks) for the assessment and management of all identified risks, including the already broadly acceptable ones. However, special demonstration of their acceptability is not done.
  - (4) Surprisingly, when CoP’s are used for controlling hazards, there is no further processing than demonstrating the compliance with the requirements of the CoP. But nothing is mentioned concerning the use of the Hazard Record for their management.
  - (5) When explicit risk estimation is used, the same time/effort seems to be spent for the assessment and management of all identified risks.

- (6) Due to a smaller sector experience with risk assessment of operational and organisational changes, many stakeholders make a poorer assessment and management of those risks. For example, the acceptance of some operational risks is based just on a declaration of the acceptance by an operational staff.
- (f) What influences the level of detail of the hazard identification? Is it dependent on the risk acceptance principle used for controlling the identified hazards?
- (1) The level of detail of the hazard identification is very dependent on the quality and completeness of the system definition.
  - (2) Although the companies familiar with the “risk based thinking” have rather an adequate level of detail of the hazard identification, for most of the other stakeholders the inappropriate level of detail of the hazard identification is not dependent on the used risk acceptance principle.
  - (3) In practice, the majority of stakeholders does not actually understand the minimum level of detail required for the hazard identification with respect to each of the three risk acceptance principles. Usually, when they use CoP’s and Reference Systems, they perform an unnecessarily detailed hazard identification whereas a low level of detail is largely sufficient. This leads to unnecessary additional work and unnecessary additional costs for the risk assessment and risk management of all identified hazards in the Hazard Record.
  - (4) In the countries familiar with the “rule based approach”, the use of detailed (hazard) checklists is even a disaster for many stakeholders when they apply CoP or compare to Similar Reference Systems. The level of detail of the hazard identification is influenced by the quality of (hazard) checklists used as reference table. So, it often happens that the hazard checklists are misused. Sometimes the hazards are highly aggregated in those checklists and do not contain detailed sub-hazards. Sometimes the hazards are identified only at the operational and maintenance stages whereas the change is a technical system, assessed at the design/construction stage. Consequently, there is no assurance that the hazards specific to the change are actually identified and properly managed.
  - (5) In countries familiar with the “risk based thinking”, the level of detail of the hazard identification depends on the knowledge and experience of people in charge of the risk assessment and on the method used for the hazard identification. The cost of formal risk assessment is also the main factor that influences the level of detail of the hazard identification. Wherever a standard or a CoP might be used, the proposer uses it to limit the risk management efforts, without further reflection. Often, the side effect of that is the implementation of constraining operational risk control measures instead of preventive risk control measures through technical improvements just to avoid the associated costs.
  - (6) In countries not familiar with the “risk based thinking” (usually eastern countries), the right level of detail of the hazard identification does not depend on the applied risk acceptance principle. It depends mainly on the good or bad experience and know-how of the company and people in charge of the risk assessment.
  - (7) Almost all replies report that the risk assessment requires more efforts when using explicit risk estimation. So as far as possible, the sector tries to avoid it.
  - (8) One NSA asks for more guidance to be developed regarding the level of detail of the hazard identification.

### Q 3. Identification, control and management of shared risks at interfaces

- (a) How do proposers involve other stakeholders or contractors for the identification, control and management of risks at the interfaces with their activities? Are they involved at all? What tool(s) do they use for that? Have you seen contractual arrangements for that topic?
- (1) Although a few replies point out that the interface management depends on the contractual arrangements between stakeholders and the type of change (technical, operational or organisational), in general, the interface management is not well done at all. Contractual arrangements/provisions exist but they are rare. So, the interface management must improve.
  - (2) Very often, the proposer does not involve at all the other stakeholders in the hazard identification, risk assessment and risk management of risks shared at the interfaces. Only when those stakeholders are within the same company, the proposer involves them in the hazard identification and risk management from the beginning. When they are external, the proposers just inform them at the end of the project about the exported safety constraints those external stakeholders must accept to manage. Most of the time the Hazard Record is the tool used for that.
  - (3) In some eastern countries, the existence of national rules, binding for all involved parties, is considered sufficient. So, the need for involving those other parties in the hazard identification and risk management at the interfaces is not considered as necessary.
  - (4) Often, the identification and management of shared risks at the interfaces is done better for technical changes than for operational or organisational ones. When other stakeholders are involved at the interfaces, brainstorming and coordination meetings are the tools used for that.
  - (5) Only in very few countries, the infrastructure manager systematically involves somehow the other concerned stakeholders in the hazard identification and risk management of interfaces. But the process and tools used for that are not systematic and must be improved.
  - (6) Only some companies familiar with the “risk based thinking” involve correctly all other concerned stakeholders. They also foresee contractual provisions for such cooperation. The Hazard Record is the tool used for that.
  - (7) The most worrying information concerns some RUs and IMs which do not carry out themselves the overall system risk assessment. Contractually, they oblige the supplier/manufacturer to be responsible in charge of all risk assessment and risk management activities. The contract explicitly obliges the supplier/manufacturer to involve in the risk assessment and risk management all other impacted actors. In practice, the supplier/manufacturer does not have any control and enforcement power to involve correctly all necessary stakeholders for the hazard identification and management of risks at the interface.
- (b) Do proposers assign safety requirements to other actors beyond the scope of their responsibility and reasonable domain of control?
- (1) Although the concerned actors are not properly involved in the management of shared risks at the interfaces, many proposers tend to assign safety requirements for the control of risks that go beyond the scope of responsibility and reasonable domain of control by those actors.
  - (2) For example, it happens often that RUs/IMs subcontract entirely to a supplier/manufacturer the complete risk assessment and risk management. This later one is expected to be responsible for the identification and the acceptance of operational and maintenance risks, with the export of any necessary operational and maintenance risk control measures.

- (3) Reciprocally, some suppliers/manufacturers transfer abusively to RUs/IMs risks and associated risk control measures for design errors inherent to their products and sub-systems whereas the RUs/IMs are not capable to control those risks with appropriate operational measures.
  - (4) For companies familiar with the “risk based thinking”, usually only safety related application conditions (SRACs – called also conditions for use) are exported with the formal acknowledgement of the receiving actor that he accepts to control the associated risks.
- (c) How are conflicts between stakeholders managed and solved when agreement cannot be reached between two actors? How is that documented?
- (1) The resolution of conflicts depends mainly on the contractual provisions.
  - (2) Conflicts seem to be rare. But when there is disagreement, the proposer manages the agreement of a solution through bilateral meetings. The conclusions are included in specific forms (if any) or in minutes of meetings, signed by both parties. Where necessary, the initial contract is amended accordingly. In some countries, the NSA might be consulted for a non-binding opinion. Rarely arbitration is done by Courts.
- (d) When an identified risk or non-compliance falls under the responsibility of another actor, how is that managed (transfer of safety measures, exchange of information, etc.)? Who coordinates the exchanges and correct management of the identified hazards?
- (1) Companies familiar with the “risk based thinking” understand quite well the concept. Their safety manager is in charge of the proper management of the identified problems. He notifies the identified risk or non-compliance of a safety measures to the right actor who is responsible for the control of the associated risk or for the implementation of an appropriate risk control measure.
  - (2) Although many replies report that the proposer manages the discovered problems, the Agency rather understands that the entire concept is either not well understood or those who discover problems in the area of responsibility of another actor do not feel obliged to take any action.

#### Q 4. Risk estimation and risk evaluation (i.e. risk acceptance)

- (a) What is the sector experience with the use of the three risk acceptance principles: Codes of Practice, Reference Systems and Explicit risk estimation?
- (1) Although there is a trend to use primarily codes of practice, a general picture cannot be given for whole EU or for all stakeholders in the same country. CoP’s are often used also to justify the non-significance of a change.
  - (2) Many companies, in particular those which do not have internally the necessary safety experts for carrying out the risk assessment face serious difficulties with the CSM as a whole. They do not understand any of the three risk acceptance principles. In countries familiar with the “rule based approach”, some stakeholders misuse the three risk acceptance principles. For example, they use quantitative explicit risk estimation for mechanical systems whereas CoP are rather expected. Comparison with reference systems seems to be the most difficult principle. Only RUs seem to be capable using it.
  - (3) Regardless whether the stakeholders are familiar with the “rule based approach” or “risk based thinking”, preference is systematically given to the use of CoP, followed by the comparison to similar reference systems (although less frequently applied). Explicit risk estimation is rarely used, mainly for innovative solutions or for technical systems. A few replies state that all three risk acceptance principles are equally used, mainly in Eastern countries.

- (4) Some countries try to avoid systematically the use of reference systems and explicit risk estimation due to the lack of experience with those two principles and the difficulty to apply them.
  - (5) The majority of stakeholders estimate that explicit risk estimation requires the highest experience in risk assessment and risk management. For the CCS sub-system, it is the most used risk acceptance principle with the support of CENELEC 50126 to comply with the CSM for risk assessment.
  - (6) In countries familiar with “risk based thinking”, CoP are used first. Explicit risk estimation is used to assess deviations from CoP or reference systems.
- (b) Is there a preference or greater experience with one of those three risk acceptance principles? Why?
- (1) Obviously, CoP occupy the first place for the reasons explained in point (a) above. But it can also be explained by the misunderstanding of the reading of the CSM : *“first mentioned in the CSM means first one which must be applied”*.
  - (2) In addition to that, in the countries familiar with the “rule based approach”, the stakeholders have the least experience with reference systems and explicit risk estimation. As their staff does not know how to apply those two principles, they tend to apply primarily CoP’s.
  - (3) Explicit risk estimation is the least used one because the sector considers it requires the highest safety expertise. Explicit risk estimation is the preferred principle for the CCS sub-system.
- (c) Is an order of priority between the three risk acceptance principles imposed and by whom?
- (1) Although the CSM does not impose any order of priority among the three risk acceptance principles, the stakeholders of countries familiar with the “rule based approach” consider at a large unanimity that the order of priority is the one of their appearance in the CSM, i.e. 1°) CoP, 2°) reference systems and 3°) explicit risk estimation). The other countries which do not consider that the order is imposed by the law follow the same order. They estimate that the complexity of risk assessments increases in the same order.
  - (2) Suppliers/manufacturers apply rather 1°) codes of practice, 2°) explicit risk estimation, 3°) reference systems. However, for innovative technologies (e.g. new electronic systems or software), or when no standards or CoP are available, manufacturers use the explicit risk estimation.
  - (3) The companies familiar with the “risk based thinking” use equally the three risk acceptance principles, depending on the most convenient method for every identified risk or cluster of risks.
- (d) How does the sector decide whether the risk is controlled to an acceptable level for the three risk acceptance principles? Does the sector use CENELEC or other standards? If yes, which ones and what similarities or differences do they find with respect to the CSM?
- (1) When the proposers use CoP and reference systems, they check whether the conditions in the CSM are fulfilled (i.e. their relevance for the identified hazards). Then the risks are considered acceptable. They demonstrate the compliance of the change with the requirements of the CoP or derived from the reference system.
  - (2) In Germany, if the design of vehicles is done following the SIRF model published by the NSA, with the support of the CENELEC 5012xy standards, the risks are considered acceptable.
  - (3) In other countries, manufacturers use the CENELEC 50126, 50128 and 50129 for both the design of vehicles and CCS sub-systems. The CENELEC matrices are used for the acceptance of risks.
  - (4) Otherwise risk acceptance is managed in different ways using :
    - (i) self-developed risk acceptance criteria for explicit risk estimation;

- (ii) for CCS sub-system, the risk matrix (frequency level; severity level) of CENELEC EN 50126:1999 standard is used to derive quantitative criteria. The matrix values of CENELEC are usually taken as such without checking whether they fit the needs of the proposer;
  - (iii) for designing generic components of the CCS sub-system the IEC 61508 standard and THR's (Tolerable Hazard Rate) are used;
  - (iv) semi-quantitative criteria (Risk Priority Numbers - RPNs) defined by expert judgement in the scope of the risk assessment;
  - (v) customer requirements, when they exist;
  - (vi) (a few answers only) qualitative risk assessment and acceptance based on expert judgement;
  - (vii) ALARP is also used by manufacturers;
  - (viii) the false belief that CSM & ASBO are applicable for safe integration and the assessment of operational changes whereas CENELEC & ISA are applicable for the design of technical systems.
- (e) Are there risk acceptance criteria defined by national rules other than those defined in Regulation 2015/1136?
- (1) In general, in the EU there are no national rules for the acceptance of risks. In the countries where the national legislation requires compliance with standards, this is usually vs. CENELEC 50126.
  - (2) Only in Germany the use of the SIRF model (Sicherheitsrichtlinie Fahrzeug), published by the NSA, is recommended for the homologation purposes of vehicles. Risks are assumed acceptable when the vehicle is designed according to the reference TeSiP (Technischer Sicherheitsplan) hazard list and SIRF.
  - (3) In Norway there is a specific rule concerning the prevention of Single Failures leading to catastrophic consequences.
- (f) When applying explicit risk estimation, how is the risk acceptance achieved? Does the sector always quantify the risks? If not, what is the ratio between qualitative and quantitative risk estimations? And what is the sector experience with the use of Regulation 2015/1136 on design targets?
- (1) Only two replies mention a ratio of 90% qualitative vs 10% quantitative risk assessments. Although the other replies do not quote any figure, qualitative risk acceptance, based on expert judgement, seem to be the most often used for the acceptance of risks in explicit risk estimation.
  - (2) In Germany, the SIRF risk graph method is more used for quantitative assessments. The "Safety Guideline Vehicle SIRF" defines the relation between qualitative and quantitative risk estimations. It is also widely used in Germany.
  - (3) In FMEA, semi-quantitative assessments, based on expert judgement and Risk Priority Numbers (RPNs), are used. The RPN must be below a specific level to consider the risk acceptable.
  - (4) With the exception of CCS sub-system, there are not many cases of quantitative risk assessment and of use of CSM DT's from Regulation 2015/1136; the explicit risk estimation is the least used risk acceptance principle. But when such quantitative methods are used, the probability or frequency of occurrence is calculated and balanced to the severity of the consequence to determine the risk acceptance. The return of experience of events can also be used in some countries to determine the acceptable probability or frequency of occurrence of an event.
  - (5) The stakeholders familiar with the "risk based thinking" do not see difference between the quantitative risk assessment vs. CSM DT's and SIL levels set out in CENELEC. The way to demonstrate compliance with each is exactly the same, using FTAs.

- (g) What documentary evidence does the sector provide to demonstrate the applicability of Codes of practice and Similar Reference Systems for the control of risks of the system under assessment?

In case of deviations from a Code of Practice or a Reference System, how is the risk acceptance demonstrated for the deviations?

- (1) Usually, when a CoP or reference system is used for controlling the risks associated to the identified hazards, the conditions in points § 2.3.2 and § 2.4.2 of Annex I of the CSM are verified. As only railway CoP's or well-known standards are used, their relevance is not questioned further. For example appropriateness of CENELEC EN50128 for software is not questionable and EN45545 for controlling risks of fire in a train neither.
  - (2) When the system is similar to an existing one, the safety requirements are derived from the reference system without questioning further the relevance of the reference system. According to the REX inputs, the requirement in point § 2.4.2(a) of Annex I of the CSM (*"the reference system still qualifies for approval in the Member State"*) seems not to be checked
  - (3) When those two risk acceptance principles are used, the proposer complies with all requirements (e.g. provision of any plans, calculations, tests, compliance with processes, etc.) which are required by those principles.
  - (4) For CoP's deviations are assessed using explicit risk estimation. For reference systems, deviations are assessed using CoP's or explicit risk estimation.
- (h) Does the CSM Assessment Body independently assess the correct application of the three risk acceptance principles? Why?
- (1) With the exception of two ASBOs whose answers are unclear, all other ASBOs confirm they do check the correct application and the actual compliance of the change with all requirements contained in CoP's, derived from a reference system or identified by explicit risk estimation.
  - (2) When a part of the system under assessment is already independently assessed by another conformity assessment body, the ASBO does not redo the checks that other body already did.

## Q 5. Demonstration of compliance with the safety requirements

- (a) Is "demonstration of compliance with safety requirements" well understood, implemented and documented? What does the sector actually understand and how does it demonstrate the compliance of the change with the safety requirements derived from the risk assessment?
- (1) In practice, more often, the concept is not well understood, implemented and demonstrated. For some stakeholders, the risk assessment does not identify any safety requirement. It is just paper work. Consequently, there is nothing to be implemented and to comply with.
  - (2) Small railway undertakings, with limited resources, usually do not understand the concept and do not implement it correctly.
  - (3) Big railway undertakings, having more resources, usually understand better the concept of identification of safety requirements, correct implementation and demonstration of compliance. They track the status of correct implementation and compliance using the Hazard Record. Reference to test records, validation tests, calculations, etc. is registered in the Hazard Record.
  - (4) It is to note that the level of understanding, implementation and documentation of the work depends on the company and the team of the company assigned to the project. Consequently, in the same company, some projects correctly demonstrate the implementation of the safety requirements

resulting from the risk assessment. Others projects do not understand what is to be done and how to demonstrate it.

- (5) Countries and companies more familiar with the “risk based thinking” tend to understand correctly the meaning of the requirement. The demonstration is part of the proposer’s verification and validation set of documentary evidence that support the safety case of the change. Usually this is documented in line with CENELEC EN 50126, 50128 and 50129 standards. The hazards, risks, safety requirements and any associated activities are correctly traced in the Hazard Record. The main problem with this category of stakeholders is an uncomplete identification of hazards and thus of associated safety requirements. That might partially be due to an incomplete system definition. Functions, interfaces and any other relevant constraint that are not included or described with a sufficient level of detail cannot be well assessed and controlled.
- (b) Does the sector use CENELEC or other standards for demonstrating compliance with the CSM? If yes, do they find discrepancies between the CSM and the standards? If yes, which ones?
- (1) As many stakeholders are not familiar with the “risk based thinking”, they do not understand and do not have experience with risk assessment. Consequently, they do neither understand the CSM nor the CENELEC standards.
  - (2) Just a few replies say they do not use the CENELEC 50126 and any other standard. All the ASBO answers confirm that the CENELEC 50126 standard is the main and most widely used standard, in particular for CCS sub-systems where the CENELEC 50128 and 50129 are also used.
  - (3) It is even a common practice to apply the CENELEC standards to ensure compliance with the CSM for risk assessment. With the exception of differences in some definitions, the ASBOs have not found any discrepancy between the CSM and the CENELEC 50126 standard. The ASBOs state that compliance with those CENELEC standards ensures automatically compliance with the CSM, except the differences of requirements and demonstration of achievement for the ISA and the ASBO. Some other stakeholders are wrongly seeking for differences of method between CENELEC and the CSM for risk assessment.
  - (4) Manufacturers find unnecessary the CSM for risk assessment. They want to apply the CENELEC standards. For the CCS sub-system, manufacturers prefer using CENELEC and ISA instead of the CSM for risk assessment and the ASBO.
- (c) Are new hazards or inadequate measures found during the demonstration of compliance? What actions are taken for those hazards/inadequate measures?
- (1) The stakeholders not familiar with the “risk based thinking” and with risk assessment declare never finding new hazards or inappropriate risk control measures during the demonstration of compliance with the safety requirements set out by their risk assessment. In practice, most of the time that is not possible. Such a strong statement clearly indicates a poor level of understanding of the risk assessment and risk management concepts by both the proposer and the ASBO they appoint to their project.
  - (2) It is even worrying to record that some ASBOs from some Eastern countries are not aware of it.
  - (3) On the contrary, the stakeholders familiar with the “risk based thinking” confirm that new hazards or non-effective safety measures can be found during the implementation of the change. In that case, the proposer starts a new iteration in the risk assessment process. The hazard is registered in the Hazard Record and managed according to the process of the CSM.
  - (4) Manufacturers detect also hazards and non-effective risk control measures during the demonstration of compliance with the safety requirements derived by their risk assessment. Often manufacturers,



in particular when bound by contractual constraints, tend to export safety related application conditions (SRACs) to users of their products (RUs/IMs) for some of those hazards whereas they would be better controlled by additional risk control measures in the design of their product.

- (d) Is the “demonstration of compliance with safety requirements” independently assessed, and at what extent, by the CSM Assessment Body?
- (1) In general, yes the ASBOs are aware and are assessing the correct implementation by the proposer of the safety requirements defined by the risk assessment. They assess formally the proposer’s evidence of the compliance of the design of the change with the safety requirements.
  - (2) Although they do not have the evidence for the statement, some ASBOs are of the opinion that different practices are in place across the EU. Some ASBOs do correctly perform the independent assessment of the demonstration of compliance with safety requirements. The other ASBOs do not perform almost any assessment of it. According to the same opinion, an indicator of such practices is the very low price proposed by such ASBOs. If these practices prove to be true, it could seriously harm the mutual recognition of the Safety Assessment Report of trustable ASBOs too.
  - (3) Most of the Eastern country ASBOs who took part to the survey are conscious they are responsible for the independent assessment of the entire risk assessment process. That includes the proper consideration of components/products from suppliers, with their ISA reports, that need to be incorporated into the system under assessment.
  - (4) In countries familiar with the “risk based thinking”, the ASBOs are gradually taking over the work of the ISA as there is no difference of working methodology between the two bodies.
  - (5) For the exported safety constraints, the ASBOs underline they are not capable to check they are actually implemented by the receiving actors. The ASBO can only ensure the measures are identified and transferred correctly to the right actor with his acknowledgment. Check of implementation and appropriateness is to be done by the ASBO of the receiving actor.
  - (6) **Critical**: some wrongly separate CSM-ASBO and CENELEC-ISA. Consequently, such ASBOs tend to accept the check of “demonstration of compliance” to be done an ISA. As the ISAs are not subject to the obligation of accreditation, this creates a problem for trust and mutual recognition of the report of such ASBOs. Obviously, some ASBOs misunderstand point § 3.3 in Annex I of Reg. 402/2013. They included it in the scope of their assessment only if it is written in their contract.

## Q 6. Hazard Management

- (a) Is Hazard Management well understood, implemented and documented in a Hazard Record/Log?
- (1) In big railway companies, with sufficient resources, usually the hazard management concept is better understood, implemented and documented in a Hazard Record. In small railway companies, with less resources, usually the whole risk assessment concept is not well understood. So hazard management is not well carried out.
  - (2) In countries familiar with the “rule based approach”, the stakeholders do not understand well the CSM for risk assessment. They prefer working with predefined hazard checklists to help them visually cross checking they do not omit managing hazards. They build the Hazard Record afterwards just for complying with the legal obligation.
  - (3) Other stakeholders understand well the hazard management concept. But they do not use any formal tool and do not have a proper Hazard Record for documenting the activity. It is then questionable how they can be sure that all hazards are actually managed and properly controlled. In addition to that, the Hazard Record does not contain the four mandatory fields of the CSM (hazard;

associated safety measure; assumptions made; reference to used RAP and origin of the hazard). Very often, the Hazard Record is also not regularly updated, although it might exist.

- (4) In general, the quality, completeness and traceability of the hazard management is strongly dependent on the competence of the project team in charge of the risk management. Although the sector is continually getting better, it could still be a quite complicated task for many stakeholders and companies, in particular for companies which do not have integrated management systems. Indeed, stakeholders can be confused because they must comply with different European or national legislation. For examples in relation to environmental, financial, security and health at work, internal standards, etc., the companies must create several types of registers and records resulting from those various risk control methods. They can easily get lost with all those obligations.
  - (5) In countries familiar with the “risk based thinking”, some stakeholders do not understand either, and do not implement correctly, the concept of hazard management. Often, the hazard record is created at the end of the project. It is thus not updated and maintained from the beginning of the design and implementation phase. In addition to that, very often, the hazard record is simply a copy/paste of the risk assessment study (e.g. an FMEA table) with additional columns.
  - (6) In general, the robustness of the Hazard Record management depends on :
    - (i) the familiarity of the company with the “risk based or rule based thinking”;
    - (ii) the age and the experience in risk management of the company;
    - (iii) the size of the company (enough resources assigned to risk management or lack of resources);
    - (iv) the culture and know-how in development and management of Hazard Records (e.g. manufacturers and stakeholders involved in the design and approval of vehicles have greater experience);
  - (7) There are different structures of the Hazard Record : from records covering all activities of the organisation (in the case of big companies managing a greater number of threats) to Hazard Record built just for the change.
  - (8) The sector would like to have an example of Hazard Log.
- (b) What type of information is registered in Hazard Records/Logs?
- (1) As a rather general observation, many stakeholders mix the Hazard Record and the risk analyses that shall be used to populate the Hazard Record. Thereby, the Hazard Record is a simple copy/paste of the safety study (e.g. FEMCA table). It contains therefore too much information. That increases the costs and complicates the management of the registered hazards.
  - (2) With a few exceptions, more or less the stakeholders who have a Hazard Record, this latter one contains the minimum information requested by the CSM. All identified hazards, origin of hazards, selected risk acceptance principles and actor in charge of controlling each hazard.
  - (3) Only the stakeholders who are experienced with the “risk based thinking” are aware that the Hazard Record can be far more complex and complete than just the minimum fields required by the CSM. It depends on the specificities of every project, the number of stakeholders involved at the interfaces and the complexity of the change.
  - (4) Companies not familiar with the “risk based thinking” do not understand the concept and requirements of hazard management. They use the Hazard Record as a cross-checking document which contains a list of all dangerous events recorded from the past experience, rather than the hazards identified by the risk assessment of the change. Consequently, there is no evidence of completeness of the used list of hazards.

- (5) Concerning additional information, it is dependent on the company and the needs for which the Hazard Record is used for. It can contain for example :
- (i) at least the hazards, their origin and risk control measures;
  - (ii) hazard scenario, consequence at subsystem level, consequence at system level, gravity of damage, number of persons involved, exposition time, probability of damage coming to effect, avoidance possibility, SIL-Level, acceptance criterion, documentation needed to close the hazard, result/status.
- Agency comment :** this proves a serious lack of understanding of the aim of a Hazard Record, as it seems to be a copy of an FMECA table. Those fields are usually the columns of an FEMCA rather than information contained in a Hazard Record. For example, the following additional information is expected to be found : the person in charge of implementing the risk control measure, deadline, responsible for verification, way of verification, status CLOSED or OPEN, etc.;
- (iii) etc.
- (6) Usually the Hazard Records do not contain information on the “assumptions made during the risk assessment” and do not track the progress in monitoring the risks associated with identified hazards. Sometimes hazards are mixed with the sources of the hazards. Sometimes the actor(s) in charge of management of the hazard are not the adequate ones who actually can control them. Sometimes all three risk acceptance principles are indicated to be used for the same hazard whereas in practice only one or two are used. Also reference is made to a generic Hazard Record where information are aggregated or standardised rather than having a Hazard Record for the change.
- (c) What type of tools does the sector use for the hazard management, i.e. for registering, tracing to the risk assessment studies, managing and tracking the identified hazards and risks, including those at the interfaces, until they are controlled to an acceptable level?
- (1) When Hazard Records exist, the means to fulfil the requirements are various. It is not always well harmonised through the company teams and the SMS procedures. It depends on the project team and can vary from/to :
    - (i) no common tool used;
    - (ii) spread Excel sheets/tables are the most broadly used means (usually by smaller companies);
    - (iii) dedicated bought specific IT tools (usually bigger companies and manufacturers);
    - (iv) specific self-generated applications (e.g. based on MS Office Access tool);
    - (v) web based tools that can be shared with the stakeholders involved at the interfaces;
    - (vi) simple paper records;
    - (vii) templates based on SIRF/EN50126/EN50129.
  - (2) Usually big RUs/IMs have dedicated IT tools for registering any relevant information and for managing properly the Hazard Record. Mature companies have a harmonised Hazard Record template as part of their SMS.
- (d) Are the hazards related to the area of responsibility of another actor managed differently? Why? And, is the acceptance of the transferred risk by the receiving actor documented and registered?
- (1) A significant number of replies state that the stakeholders do not have experience with Hazard Record management.
  - (2) When Hazard Records exist and are actually used, in general the hazards that are related to the area of responsibility of another actor are not managed differently than the hazards under their own area of responsibility.

- (3) The small railway companies, and those not familiar with the “risk based thinking”, are a little bit lost when dealing with hazards that must be transferred to another actor. This is even more complicated when they use existing hazard checklists instead of identifying the specific hazards for the change. They face difficulties in sorting out the hazards that fall under their own area of responsibility from those that are in the scope of work and responsibility of another actor. Despite those difficulties, the sector is improving gradually with the management of risks transferred either internally within the same company or to external stakeholders involved at the interfaces.
  - (4) Big railway companies, and those familiar with the “risk based thinking”, manage all hazards, including the ones transferred to other actors, in the same way. They trace correctly the transferred information with the evidence of the acceptance of the transferred hazard by the receiving actor.
  - (5) Usually, almost all actors who properly transfer hazards and safety measures to another actor also trace properly the acknowledgement of the acceptance of responsibility by the receiving actor.
  - (6) A few stakeholders just transfer the identified risk(s) but do not mind whether the receiving actor accepts it. They do not ask this latter one to acknowledge that they are aware of their responsibility for controlling the received risk(s).
  - (7) Some ASBOs involved in the present survey are worried they cannot go and check that the receiving actor actually controls the transferred risk. They are just capable to check that the receiving actor acknowledges the reception of the hazard and associated safety measure.
- (e) How does the sector use the Hazard Records/Logs during the operation and maintenance of the railway system?
- (1) As the ASBO work finishes with the delivery of the independent safety assessment report, the ASBOs do not have any information on that. A few ASBOs rightly report that based on their experience with operators and maintainers, the Hazard Record is not used during operation and maintenance. It is paper or formal work just necessary during the management of the change. ASBOs estimate, Hazard Records should be taken into account more, as they are a fundamental tool during operation and maintenance for monitoring purposes and for the management of the action plans in case of identification of non-compliances. But that is out of the ASBO scope and must be assessed by the auditors of the SMS, i.e. NSAs.
  - (2) The NSAs who answered the questionnaire do not provide almost any information about it. Just one NSA mentions that RUs/IMs and ECMs must consider Hazard Records while developing their “Maintenance and Operation Plans”. But the NSAs do not tell anything on how they check this neither during the SMS certification nor during its supervision.

## Q 7. Documentary evidence from the application of the risk management process

- (a) How are the tasks and activities (i.e. roles, responsibilities and necessary cooperation) of the different actors involved in the risk management documented? Is the organisation of the risk management documented at all and by whom? Are roles and responsibilities of everyone clearly understood by all involved actors?
- (1) Point § 5.2 in Annex I of the CSM for risk assessment requires the proposer to include in the evidence of the correct application of the CSM "*a description of the organisation and the experts appointed to carry out the risk assessment process*". This seems to be very rarely done. So, very often the description of the organisation and of the management of the change are missing. Or, because risk assessment is performed at the end of the project, backdated “cosmetic documents” are built sometimes just to fulfil the legal requirements.

- (2) The railway sector does not seem to understand the purpose of the legal obligation and the benefits for the independent assessment activities. Thereby, the roles and responsibilities of everyone are not clearly understood by all involved actors. This is of particular concern when dealing with the exhaustive identification and the proper management of the risks shared between several actors at the interfaces.
  - (3) Other actors find the definition of roles and responsibilities at a very high level sufficient as it is already defined in the legislation. They do not find necessary providing additional details for the specific project/change. This makes difficult the understanding by the ASBO of the organisation and the way the change is managed. Similarly, when CENELEC standards are used, the functional roles are copied from CENELEC without further detail at the level of the specific change.
  - (4) Although some stakeholders are convinced that their documentation is clear, in practice very often the overall document on the organisation of the change and the experts appointed for carrying out the risk assessment is missing. So, every involved party/actor does not clearly understand the respective roles and responsibilities of everyone on the project and how the risk assessment and risk management are done.
  - (5) Usually, for RUs/IMs, the organisation, the roles and responsibilities of everyone and the way the risk management is carried out is spread through many documents of either the project or company SMS. In practice, these are usually general/generic organigrams. The information is rarely integrated in a specific document which details who does what for the specific change.
  - (6) Companies familiar with the “risk based thinking”, and manufacturers, understand the CSM requirement. They document clearly the organisation of the project, at least in the report of the risk management activities. The description is anyway requested by the ASBO as part of its independent assessment. For big projects, the planned activities, tasks, and responsibilities are usually specified in a Safety Plan, developed according to the CENELEC guidelines. If the project does not contain a safety plan, it is detailed in the successive versions of the safety case, or of the overall document tracing the history of the risk management activities since the beginning of the project. In case of insufficient explanation, the point is maintained open during the independent safety assessment as long as it is not solved by the proposer/applicant.
- (b) What evidence does the sector have for the risk assessment and risk management activities? Are at least all requirements in point 5.2 in Annex I of Regulation 402/2013 met? What is the overall quality of this evidence?
- (1) The quality, structuring and completeness of the evidence generated by the risk assessment and risk management activities are generally low, with a few exceptions. This is due to a lack of understanding, experience and knowledge of the risk concepts. The ASBOs are nevertheless observing a continual improvement as the sector experience is slowly growing through a better understanding, application and implementation of the CSM.
  - (2) Although the proposers produce documentary evidence from risk assessment and risk management activities, currently well-structured documentation is usually missing. The useful information is spread and to be searched through various documents resulting from the risk assessment and risk management activities.
  - (3) Often a safety case is produced following the recommendations of the standard CENELEC EN 50129 standard. The quality and content of the safety case vary a lot from company to company, and even from project to project in the same company, depending on the team assigned to the project.
  - (4) The companies not yet familiar with the “risk based thinking” do not really understand the purpose of a safety case. So, the quality of the documentary evidence is poor. Such companies are not

- interested in spending too much time for producing paper work. They try to fulfil the requirements with minimum efforts only because it is required by the CSM.
- (5) The companies more familiar with the “risk based thinking” are aware of the benefits of a well-structured risk assessment and risk management documentation. The quality of their documentation is better. Usually their risk management report or safety case is based on the recommendations of the CENELEC 50129 standard. So all evidence listed in point § 5.2 in Annex I of Regulation 402/2013 is usually contained within. Although it still needs improvement, usually the overall quality seems acceptable in particular for big or complex projects/companies.
- (6) In some Eastern countries, the ASBOs report that :
- (i) the risk assessment and risk management process are totally misunderstood. Consequently, the evidences provided is very general and does not related to the specific change under assessment. The proposer identifies too general and high level railway hazards at the beginning of the risk assessment process but they are not linked to the particular change/system;
  - (ii) the requirements of point § 5.2. in Annex I of Regulation 402/2013 are not fully met. Especially the specific “list of necessary safety requirements to be fulfilled” for the change is difficult to be elaborated. Consequently, the evidence and demonstration of compliance with all the necessary safety requirements is missing. A description of the organisation and the experts appointed to carry out the risk assessment process is always presented but, during the independent safety assessment of the risk assessment, the ASBO discovers that it is only paper; the relevant employees are not aware of what they are supposed to do on the project. Because the initial system definition does not exist, or it is incomplete or contains errors, the safety related conditions for the system integration, operation or maintenance are not identified and documented;
  - (iii) it is not possible to assess the quality of the evidence because there is no such evidence.
- (c) Is every step of the risk management process in Annex I and the flowchart of Reg. 402/2013 clearly documented? Does the structure indicate a correct understanding of the method? Or on the contrary, there is lack of structured documentation and too much confusing paper work?
- (1) Once more, the degree of matching of the documentary evidence and risk assessment activities with the steps of the process specified in the CSM varies. The extent of compliance depends mainly on the expertise of the staff assigned to risk assessment, the benefits expected by the proposer, the country, the organisation or the company.
  - (2) Despite the Regulation 352/2009 on the CSM for risk assessment is applicable since 2010, the CSM is still very new and not well understood by many countries and many stakeholders. In 2018, many organisations still apply the method for the very first time. The outcomes from the risk management are very general. The identified safety requirements are unclear and not properly linked to the hazards/risks they are controlling. As they are not always registered in the Hazard Record, their correct management cannot be demonstrated transparently. Often, the outcomes sound more useless paper work, or a cosmetic presentation vs. the requirements of the CSM, rather than an attempt to identify and control the risks that can arise from the change.
  - (3) To help with a correct implementation of the method, the sector is asking the Agency to make available supportive examples that illustrate the correct application of the different steps of the risk assessment process in the CSM.
  - (4) **Paradoxically, many ASBOs report that the guides already issued by Agency contain sufficient information to carry out correctly the risk assessment.**

- (5) In the countries where the stakeholders are more familiar with the “risk based thinking”, the quality of the documentary evidence is improving with the increase of their experience with the understanding, application and implementation of the CSM. The overall report from the risk management, or the safety cases, are becoming better structured. It enables to follow up more easily the progress through the different steps of the risk assessment process of the CSM.
- (6) The companies familiar with the “risk based thinking” are capable to trace consistently their risk assessment activities with respect to every step of the process in the CSM. That proves that the CSM is understandable. The problem for the other stakeholders is more the lack of competence in risk assessment of the staff in charge of application of the CSM rather than a lack of clarity of the CSM.
- (d) Does the documentary evidence clearly state the assumptions for the risk assessment (e.g. scope, boundaries, interfaces, environmental, operational and any other limitations/conditions) which need to be checked for the mutual recognition of the risk assessment?
- (1) The extent to which the assumptions and conditions of the risk assessment (e.g. scope, boundaries, interfaces, environmental, operational and any other limitations/conditions) are clearly documented varies with the organisation/company. It is strongly dependent on the experience with the risk assessment and the interest perceived from it. It is clearly another point for improvement.
- (2) Surprisingly, the experts who are good in risk assessment are quite poor in putting it in words in formal documents.
- (3) In companies familiar with the “risk based thinking”, although deficiencies can be observed, generally the level of documentation is acceptable. In particular, when the CENELEC 50126 and 50129 standards are used, the documentation of the assumptions and conditions for use are better documented as a part of the safety report or safety case.
- (4) For the others companies, not familiar with the “risk based thinking”, those assumptions and conditions for use are not always clear, complete and enough documented. The least well-documented assumptions and constraints are for the “interfaces” and “safety integration”. For example, a new line project can be split into several projects (infrastructure, energy, CCS, etc.); each sub-project could have a risk assessment, but often the risk assessment at the boundaries and interfaces is poor. This makes difficult the system safe integration and does not enable the mutual recognition of the results from the risk assessments of the different involved parts.
- (5) Another weakness is a non-centralised management of all assumptions and conditions resulting from the risk assessment. These can be well-documented in various reports/outcomes from the risk assessment. But, they are not always registered in the Hazard Record. Also, the points § 2.1.2(f) and (g) in Annex I of the CSM for risk assessment are missing : “(f) existing safety measures and, after the necessary relevant iterations, definition of the safety requirements identified by the risk assessment process” and, “(g) assumptions that determine the limits for the risk assessment”.

## Q 8. Independent assessment and safety assessment report

- (a) Is there a notified national rule specifying who is the assessment body? If not, how does the sector select/appoint the assessment body? What influences at most the selection of the assessment body?
- (1) Only two countries report there is a national rule specifying who shall be the ASBO. But the rules are not given. Otherwise, in the other countries, there are no such national rules. The proposers decide which ASBO they want to selected from the ERADIS database.

- (2) The proposers use the ERADIS database for selecting the accredited or recognised ASBOs. ERADIS shows the fields of competence of every. Some countries do not have domestic ASBOs; they appoint accredited or recognised ASBOs from other countries.
  - (3) The most important criteria that influence the choice of the ASBO are : the cost of the independent assessment, sometimes the technical knowledge and often the knowledge of the ASBO from previous projects. When in some countries the risk assessment and risk management are sub-contracted to a supplier, often the supplier appoints the ASBO.
- (b) What influences the choice of the assessment body? Does it matter if the body has already been involved within the project, e.g. advising other stakeholders/contractors of the project, before they are appointed as assessment body for the purposes of the CSM?
- (1) Various factors influence the choice of the ASBO :
    - (i) the language in which the documents and correspondence must be written and produced. In some countries there is no domestic ASBO. In Slovenia, Croatia and Romania currently NSA is the only ASBO recognised in those states. But the sector is free to use competent ASBOs from abroad;
    - (ii) in public companies, the selection of an ASBO is done through a tender procedure. Consequently, when all required criteria are fulfilled on the paper, the price is the factor that drives the decision;
    - (iii) for private companies, not bound by public tendering, the price, experience, relationship with the ASBO and time for the independent assessments are the key factors. However, although the experience from previous projects is considered, in countries or companies not familiar with the “risk based thinking”, the price is the determining factor;
    - (iv) in Germany, proposers give preference to ASBOs familiar with the safety process and assessments of functional safety according to the SIRF model (NSA guide). This means almost systematically German ASBOs;
    - (v) in countries and companies familiar with the “risk based thinking”, the selection of the ASBO is done on the basis of its reputation, prestige, experience and previous references.
  - (2) One NSA reports that for his country, his feeling is that often the same parties are always involved. The railway and ASBO market is small; they know each other. Companies usually choose those ASBOs that have been working with them in previous projects because those ASBOs are familiar with their methodology, point of view, procedures, etc.
  - (3) With the exception of Romanian NSA acting as ASBO, all other ASBOs are well aware they cannot provide consultancy services regarding the rail system/subsystem being assessed. The Romanian NSA RO is unclear with respect to what guidance it offers to the sector. It mentions providing support of the best possible compliance with the requirements of the CSM. The Agency assumes these are general recommendations rather than proposals of action plans and risk control measures for closing the identified non-compliances.
  - (4) General observation : the railway sector is reluctant to work with ASBOs. Usually, they appoint an ASBO only because it is a legal obligation.
- (c) At what moment of the development process of the change does the proposer appoint the assessment body and when does this body start its work? Does it have the opportunity to challenge the proposer's choices from the beginning of the process or it comes when the risk assessment is done?
- (1) The moment at which the ASBO starts the independent assessment of a significant change depends on the proposer's perception of the benefits brought by this activity :



- (i) Stakeholders familiar with the “risk based thinking” appoint the ASBO at an early stage of the change management. They estimate that an early involvement of ASBO is beneficial for a better design of the change.
    - (ii) Stakeholders not familiar with the “risk based thinking” (usually in Eastern countries, but it happens also in other countries) are usually appointing the ASBO at the end of the process just to get the confirmation that the risk assessment is correctly done. Consequently, bad design choices cannot always be modified/challenged due to the advanced status of the project. The ASBO has just the possibility to agree or disagree with the proposer, but without any change being made to the system under assessment.
  - (2) In both cases, the ASBOs challenge the proposer’s choices.
  - (3) The ASBOs strive to change that practice, but without real success. A possible action for improving this bad practice could be a higher check by the NSA of the management of changes during the supervision activities of the RU/IM SMS.
  - (4) Worrying information : some ASBOs from Western countries believe acceptable to start the independent assessment only when the proposer’s documentation is almost finalised. Those bodies estimate this sequencing important in order to guarantee the independence of the ASBO; they estimate the ASBO should not be influencing the proposer’s design choices. Obviously those ASBOs confuse “giving recommendations to the proposer” and “challenging the processes used and the appropriateness of risk control measures”.
  - (5) That belief is shared by the Romanian NSA who acts as ASBO. The Romanian NSA agrees that the proposer should appoint the ASBO when the risk management process is finished and documented. The proposer is to remain the only one responsible for the results of the process. If the ASBO is involved from the start of the project, there is a risk to break its independence.
- (d) Have you ever seen the replacement of an assessment body by another one before the end of a project? If yes, what were the justifications? Did the new one get the results from the previous body?
- (1) The intention of this question is to check whether proposers try to hide problems discovered by the ASBO in case agreement cannot be reached.
  - (2) A few replies report that it can happen. The reason for changing the ASBO during the project was that the proposer found the ASBO conclusions not good. Other possible justifications for changing the ASBO are quite broad : risk to break the project deadlines, procedures for independent assessment too deep, excessive workload not permitting to manage and complete the assessment on time, etc. Bound by confidentiality commitments, the first ASBO is not allowed to communicate its observations to the new ASBO without the proposer’s permission.
  - (3) The other replies report that it almost never happens. It has just been seen with some ISAs. But it was not due to disagreement between the ASBO and the proposer. The reason for changing the ISA was an insufficient competence of the ISA who was not open for other approaches than those familiar to him; it was asking for answers to fundamental questions. This is obviously against the role of a conformity assessment body who shall never give solutions but point out to the problems.
- (e) Are there in-house assessment bodies? If yes, for what types of projects are they usually involved?
- (1) Type A ASBO who took part to the survey do not have the answer to this question. According to some ASBOs, some CCS manufacturers use in-house ASBOs, usually for generic and specific applications.
  - (2) Just A few NSAs provided reply to the question. Most of the involved NSAs report not being aware which type of ASBO is appointed for the independent assessment of significant changes. This then

- questions the extent to which those NSAs actually include the risk assessment process in the scope of their supervision activities of the RU/IM SMS.
- (3) The in-house ASBOs report they have far better knowledge of the in-house organisation of the risk management and the capabilities of the proposer. They estimate having in general a better competence than external bodies concerning the content of the change.
  - (4) However, in-house ASBOs are more often used for assessing minor changes. In cases of big or more complex changes, for liability reasons, the proposers prefer to appoint an external ASBO (i.e. type A one).
  - (5) It to note that quite many ASBOs estimate that type C ASBOs are not allowed by Regulation 402/2013. They estimate type C ASBOs are not independent and not impartial. Obviously those ASBOs misunderstand the CSM.
- (f) Who is the assessment body for (operational and organisational) changes brought to the (safety) management system?
- (1) *Operational and organisational changes usually affect the allocation of roles and responsibilities throughout the organisational structure of the company, the processes, procedures and working instructions of the RU/IM SMS. This question aimed at checking whether the sector and NSAs avoid the duplication of independent assessments. Indeed, for significant changes, either all SMS arrangements are fully assessed by the NSA or the risk assessment and risk management of the change are independently assessed by an ASBO whose report must then be mutually recognised by the NSA for the upgrade/renew of the SMS Certificate/Authorisation (when the update/renew is needed).*
  - (2) In practice, no information is given by most of the replies so that no general rule can be reported. In particular, knowing that only 2 to 5% of changes are significant (where most of them concern technical systems), the sector has a small experience with operational and organisational significant changes.
  - (3) The ASBOs do not know how this is done. It seems that the independent assessment of operational and organisational changes is done often by an in-house ASBO. In practice, the sector is very focused on technical changes, and other types of changes are not analysed so deeply.
  - (4) As the NSA do neither know the answer to this question, the Agency wonders at which extent those NSAs actually include the risk assessment operational and organisational changes in the scope of their supervision activities of the RU/IM SMS.
- (g) How many assessment bodies are usually involved on a project? For which reasons?
- (1) In practice, a general statement cannot be given as every single project can be structured differently.
  - (2) Although one ASBO is usually involved in a project, there could be more than one, if for example the appointed ASBO does not have the competence in all fields of the change to be assessed. There can also be several ASBOs if the change affects several subsystems or the overall railway system. If the project is divided into multiple lots, different ASBOs can be assigned to the individual lots. In case of changes at interfaces or complex changes involving several ASBOs, collaboration between the different ASBOs is necessary.
  - (3) For big projects, there can be an ASBO for the overall system. It has to take into account the reports from the different ASBOs appointed for the different subsystems/components. The overall ASBO also independently assesses the proposer's safe integration of the outcomes from the risk assessments of the sub-systems/components.

- (4) Usually sub-contractors have their own ASBO because it is easier for them to manage their scope of work.
- (h) How does the sector manage the interfaces between the different conformity assessment bodies who might be involved in the same project (NSA, NOBO, DEBO, Assessment Body/Bodies, etc.)?
- (1) The level of understanding and the way this is organised depend on the stakeholder experience, but also on the project team in charge of the management of those activities. The NSAs and ASBOs are of the same opinion : the proposer/applicant is responsible for coordinating the relationships between the different conformity assessment bodies (NOBO, DEBO, ASBO) involved in the project. The NSAs estimate that they shall always operate separately from those three types of bodies.
  - (2) Many stakeholders do not well understand how to coordinate the roles and responsibilities of the different conformity assessment bodies in a project. There are contradictory expectations. Some stakeholders estimate that the NOBO is the overarching body responsible for the coordination of various work streams, including the report from the ASBO. They expect the NOBO to take in charge all activities and if there is a need, the NOBO is to engage other bodies. On the contrary, other stakeholders have the opposite understanding, i.e. that an ASBO is to be appointed at the system level in order to assess the proposer's coordination of the outcomes from the NOBO, DEBO and any other ASBO appointed at a sub-system/component level. Obviously these are two non-compatible viewpoints.
  - (3) Companies familiar with the concept of "conformity assessment" have usually a manager in charge of coordination of the different bodies involved in the project. This is defined at the beginning of the project; the work is then split between the different actors. When possible (i.e. there is no contradictory national rule and the body is qualified for all roles), the proposer prefers to allocate all conformity assessments to the same company (i.e. tasks of NOBO, DEBO and ASBO). The proposer can also request the ASBO, NOBO and DEBO to coordinate between themselves and to agree on who will assess what, and who will accept what, in order to avoid the duplication of independent assessments.
- (i) For significant changes, do proposers systematically write a "Proposer's Declaration" as this is required in Article 16 of Regulation 402/2013?
- (1) As the proposers produce the declaration in Article 16 of Regulation 402/2013 after the ASBO Report, all ASBOs do not know whether it is done systematically. Surprisingly some NSA are not aware either. Once more, this then questions the extent to which those NSAs actually include the risk assessment process in the scope of their supervision activities of the RU/IM SMS.
  - (2) Other replies report a rate of 50%-50%. So, in some countries, there is a "Proposer's Declaration" according to Regulation 402/2013. In other countries, the "Proposer's Declaration" is not produced. Some NSAs even report that it is not required by the national law. Obviously, this is a breach of a legal requirement; national legislation cannot supersede an EU law. ASBOs are nevertheless teaching proposers about their obligation to have a "Proposer's Declaration". It is starting slowly to become a common practice, at least for significant changes. But it is not a point that is assessed by ASBOs.
- (j) Does the sector usually agree with the observations of the CSM Assessment Body? If not, do they correctly justify and document the parts of the safety assessment report for which they disagree?
- (1) The level of agreement with the ASBO observations depends on the culture of the considered country.
  - (2) In countries familiar with the "risk based thinking", the most frequent practice is that the proposers fully agree with the ASBO conclusions. As the ASBO is usually appointed from the beginning of the

project, during the successive iterations of the risk assessment, the proposer has time to address properly the identified non-compliances. So, there are almost no open issues in the final ASBO assessment report. Where the stakeholders disagree with the ASBO, the proposer correctly justifies and documents the parts of the safety assessment report for which it disagrees. Occasionally, some NSAs can have issues with the acceptability of the proposer's justifications.

- (3) In countries which are not familiar with the "risk based thinking" (usually Eastern countries), It seems more natural to ignore the ASBOs conclusions. That is due to the fact that the proposers appoint the ASBO at the end of the project. So, the proposers do not have the time to implement any corrective actions. Usually, the proposers do not document at all the part of the safety report they disagree with.
  - (4) It is to note that some incumbent railways tend to limit the scope of independent safety assessment. But at the same time they do not want the ASBO to make clear the limitations and the implications in the independent safety assessment report. They want to benefit of mutual recognition for a much broader scope than what the ASBO is actually allowed to assess through the scope of independent assessment contractually narrowed in the contract.
- (k) What is the overall experience with the use of CSM Assessment Bodies in your country? Are Assessment Bodies from your country appointed or are bodies from other countries also contracted? What are the reasons for those decisions?
- (1) In countries where there are no domestic ASBOs, only foreign organisation can be appointed. Otherwise, the proposer is free to choose ASBOs from inside the country and from other countries provided they are accredited/recognised for the relevant field(s).
  - (2) It is nevertheless to note that some NSAs do not accept the accreditation/recognition of foreign ASBOs if, in addition of being registered as an accredited/recognised ASBO in the right field, those ASBOs cannot demonstrate to the NSA that they have also the knowledge of national regulations and normative documents used in the railway sector of the Country. This is a national requirement added by the NSA on top of Regulation 765/2008 on the functioning of the accreditation and which was judged not necessary during the drafting of Regulation 402/2013. The Agency opinion is that national legislation cannot supersede Regulation 402/2013 without applying the provisions in Article 8 of Directive 2004/49.
  - (3) Although the proposers/applicants are free to appoint whatever accredited or recognised ASBO registered in the ERADIS database, usually they prefer working with domestic ASBOs. The language of the documentation and for communicating with the proposer is the most constraining factor. This is also one reason why many foreign ASBOs have branches in other EU countries with local experts who know the language and particularities of the system and techniques in use in the country. This is more common practice with infrastructure projects. Spain usually works with national accredited ASBOs. German proposers/applicants prefer working with German ASBOs.
  - (4) In Slovenia, Croatia and Romania the NSA is recognised by the Ministry to act as ASBO. There are no cases reported so far where ASBOs from other countries were appointed. But the sector is free to select without any limitation accredited/recognised ASBOs from abroad. As explained above, the reason is the language in which the documents and correspondence take place.
- (l) Is there a difference of quality of independent assessment between Assessment Bodies and in particular between the accredited and recognised ones? If yes, what are those differences?
- (1) As the NSAs are involved in the authorisations of placing into service vehicles and structural sub-systems, and thus have access to ASBO reports, they were expected to answer the question. Unfortunately, the Agency did not receive answers in the difference.

- (2) Concerning the ASBOs, as there was no exchange of experience so far the ASBOs are not directly aware about differences of quality between the two categories of ASBOs. Nevertheless, the situation is changing since the ASBO Cooperation Group has started in 2017.
- (3) No matter whether they are accredited or recognised, the quality of independent assessment of some ASBOs is judged insufficient by NSAs and peers who have to mutually accept independent safety assessment reports.
- (4) Accredited ASBOs estimate being subject to a rigorous and regular supervision by their National Accreditation Body (at least one audit per year for controlling the application of their procedures). They are not sure all Recognition Bodies carry out systematically similar supervision of recognised ASBOs.
- (5) Requirements for recognition in Germany seem to be much higher (e.g. concerning technical competence) than the requirements applied for the ASBO accreditation or recognition in other countries.
- (6) Agency recommendation : monitor in future the performance of ASBOs.

#### Q 9. Overall sector understanding of the CSM and of Risk Management Concepts

- (a) Is the CSM for risk assessment well understood and correctly implemented? What main difference(s) has it introduced in the sector for the assessment, control and management of risks arising from their activities?
- (1) The method is well understood by the safety teams created by some RUs/IMs. It is less appreciated by other organisational teams of companies which must take part to risk assessments. So, in the majority of countries, and in many companies, most of the staff, including often the top management, considers the CSM for risk assessment as unnecessary bureaucratic burden. They implement it for complying with legal requirements and not because they are convinced it brings added value for the company.
  - (2) The opinion of the ASBOs is that the underlying problem of that situation is the lack of correct procedure for managing safely changes through a formal risk assessment procedure in the SMS of railway companies.
  - (3) In Eastern countries, many stakeholders totally misunderstand the method. With their current level of maturity, they do not apply the method in a proactive way but just for producing the formal paper required by the law for putting the structural sub-systems into service. In practice, the results of the risk assessment process are absolutely useless and do not match the particularities of the change under assessment.
  - (4) In the countries more familiar with the “rule based thinking”, in general the sector is facing serious difficulties with the understanding, application and implementation of the CSM for risk assessment. It is still considered too abstract. Most of the stakeholders do not understand why they must apply it and how to apply it.
  - (5) In the countries familiar with the “risk based thinking”, the picture is more positive. The CSM is considered as a cornerstone that changed the approach to risk control. Compared to the classical “rule based approach” where things are done without knowing why, “thinking in terms of risk” is a new concept for the systematic identification of risks, of appropriate risk control measures and control of the actual implementation of those risk control measures.
  - (6) Although the sector experience is getting better, in small railway undertakings there is still a lack of competent staff in the fields of risk assessment and risk management. As those companies perform a

limited number of changes, they cannot afford having a permanent safety staff only in charge of the risk assessment and risk management activities.

- (7) The CSM for risk assessment has introduced the following major differences :
- (i) a formal and systematic top down methodology for risk assessment and risk management. The obligation to identify hazards/risks and to link them to the risk control measures make the proposer understanding why he is taking actions (i.e. prevent known problems to happen instead of applying blindly mandatory rules);
  - (ii) it has triggered in railway companies the creation of dedicated departments/teams in charge of documented risk assessment and risk management;
  - (iii) the formal risk assessment process must start from beginning of the change management, i.e. from the concept and down to the implementation and verification phase of the change management;
  - (iv) the demonstration of achievement of the safety requirements for all types of changes and also for all structural sub-system, i.e. not only for the CCS sub-system through compliance with the CENELEC 50126, 50128 and 50129 standards;
  - (v) the application of the CENELEC standards was voluntary (unless requested by national legislation) whereas the use of the CSM for risk assessment is mandatory;
  - (vi) mandatory appointment and opinion of an independent assessment body for all significant changes, not only for technical ones from the CCS field;
  - (vii) the use of Codes of Practice (e.g. standards) and comparison to similar reference systems is allowed equally to explicit risk estimation;
- (8) Countries and companies familiar with the “risk based thinking” estimate the CSM is not fundamentally different from the practices and standards in use before the adoption of the CSM. For the CCS sub-system, where the CENELEC 50126; 50128 and 50129 standards are common practice, the whole concept is already well-known.
- (9) Although the sector understanding of the method is slowly improving while applying it, there is still a long way to go. The efforts must continue at all levels (Agency, NSAs, railway sector) to improve further its understanding, application and implementation. The method is not yet correctly applied everywhere and by everyone. For example, for CCS sub-systems, it is usually better implemented; for infrastructure, operational and organisational changes, the sector still needs time and experience to improve.
- (b) Is this level of understanding reflected in a description of tasks and responsibilities of the different actors involved within the risk management activities? Who is coordinating all those activities?
- (1) As reported in Question 7(a), the description of tasks, roles and responsibilities of the different actors involved within the risk management activities is not well done and does not reflect the actual situation. It is always not clear to ASBOs who coordinates the risk management activities, in particular for complex projects where several actors are involved.
  - (2) Sometimes NSAs and ASBOs observe the reluctance of some parts of organisations to accept the roles and responsibilities concerning the risk assessment and risk management assigned to them.
  - (3) In countries and companies familiar with the “risk based thinking”, usually CENELEC 5012x standards or proper QMS procedures are used. So the activities and roles of everyone are well described. The coordination is done by safety/quality manager of the proposer.
  - (4) In big railway companies, usually a safety manager of the proposer coordinates the risk management activities. The quality of the documentation and the description of the activities is continually improving in the companies which apply the CSM more frequently.

- (5) It is astonishing that some NSAs declare coordinating themselves the risk assessment and risk management activities of the proposer.
  - (6) Also, as previously mentioned some incumbent railways usually subcontract all risk assessment and risk management activities, including the acceptance of risks and of the change, to the main supplier or main contractor.
- (c) What differences do you observe between big and small railway companies?
- (1) Although it is not possible to give a general statement based on the size of the company, some general trends can be distinguished between big and small companies.
  - (2) Big railway companies :
    - (i) they can afford having a permanent department, with a sufficient number of resources, in charge of the safe management of changes and applying the risk assessment and risk management procedures of the company. In principle, this should be in place in every big company;
    - (ii) as they implement a higher number of significant changes, they have a higher opportunity to “learn by doing”;
    - (iii) they have a higher knowledge of the risk concepts. So, they understand better the CSM for risk assessment and apply it better;
    - (iv) they are more familiar with the “process thinking” and with the concept of systematic top-down approach to risk management;
    - (v) nevertheless, they perceive the obligation to apply the CSM (e.g. for vehicle authorisations) as unnecessary bureaucracy with additional efforts, costs and delays bringing in practice additional project risks and uncertainties. If they would have the choice, they would rather not to apply the method;
  - (3) Small railway companies :
    - (i) they take longer to react to changes of legislation and thus need more time to adapt;
    - (ii) they cannot afford having permanent staff responsible only for the safe management of changes and the associated risk assessment and risk management activities;
    - (iii) as they cannot all have own competent staff, often they sub-contract the application of the CSM for risk assessment to external companies;
    - (iv) as they do not make many changes, they do not have a lot of significant ones. So they have less the possibility to “learn by doing”;
    - (v) some of them, even if safety related changes are non-significant, they apply the CSM and want to have a safety report from the ASBO;
    - (vi) they are more flexible and are able to implement smarter solutions. So, maybe they tend to better capture the essence of the CSM for risk assessment. Even "small" companies can quite often carry out the risk assessment in a very comprehensive manner with very good results;
    - (vii) in case of deficiencies, they tend to solve the problems instead of debating on them;
    - (viii) usually the risk assessment and risk management activities are carried out directly by the operational staff;
    - (ix) usually they consider the CSM for risk assessment as a legal obligation with additional constraints which generates additional efforts/costs without necessarily helping them;
  - (4) The NSAs are asking for dissemination on the CSM for risk assessment targeted to the needs of small companies.
- (d) What differences do you observe between former incumbent and newcomer railway companies?

- (1) The following main differences between former incumbent and newcomer railway companies can be made :
  - (2) Former incumbent railway companies :
    - (i) they are more resistant to change and to the application of new methods, in particular if they feel it requires more resource. They prefer to continue thinking in former processes and solutions;
    - (ii) however, they have more resources and railway experience for applying the CSM for risk assessment, even if they do not completely understand the necessity of doing it;
    - (iii) they have more rigid ways of thinking, managing, solving issues, etc. usually based on the CENELEC 5012x guidelines. So they consider the CSM as unnecessary duplication of CENELEC (which is well understood);
  - (3) Newcomer railway companies :
    - (i) as they have often a very flat organisation, they have rarely staff who is competent in risk assessment and risk management;
    - (ii) when necessary, often they hire externally supporting staff or sub-contract completely the application of the CSM for risk assessment;
    - (iii) they are flexible and can change easier their way of thinking in a more constructive way. They tend to be proactive and implement the CSM for staying on the market;
    - (iv) they are capable adapting faster to the terminology used in the CSM.
- (e) Is the application of the CSM considered as a useful proactive tool for optimising the company business costs, or on the contrary seen just as a legal obligation with additional constraints, generating additional efforts/costs (more work, need of additional staff and more paper)? If it is negatively perceived, how were the risk assessments done and documented before the existence of the CSM?
- (1) None reports that the CSM for risk assessment is valued and applied to reduce/optimize the costs of the safety management
  - (2) Companies familiar with the “risk based thinking” and ASBOs are of the opinion there is no difference between the documentation required by the CSM for risk assessment and the documentation produced in the past. The documentation is just created differently.
  - (3) The perception of the usefulness of the CSM for risk assessment depends on the person to whom the question is asked in a company. There are project teams (in particular safety staff) which consider the CSM as a useful proactive tool for identifying proactively possible risks and for putting in place timely risk control measures. But there are also many teams/staff in the same companies who perceive the CSM negatively and unnecessary legal obligation, especially because of the independent safety assessment by an ASBO. Similarly, some companies see advantages and opportunities in applying the CSM but they regret the increase of costs for implementing it. Other companies do not see any reason and benefit for applying the CSM.
  - (4) Although some companies and some staff can find some benefits in applying the CSM, almost all stakeholders see it just as legal obligation with additional efforts/costs. If they would have the choice, most of them would never apply voluntarily the CSM for risk assessment.
  - (5) Concerning manufacturers, before the existence of the CENELEC standards, there was no culture of written safety documents. Then with the introduction of the CENELEC 50126, 50128 and 50129 standards, mainly the CCS sub-system was formally developed and documented in compliance with those standards. For the other sub-systems, the risk management was not carried out formally; the



safety of the design was mainly based on the experience of designers, their “way of carrying out the work” and compliance with well-known rules and standards.

(6) In the countries familiar with the “rule based thinking”, rules were applied in the past. Usually, there was no risk assessment documentation before the existence of the CSM. The application of the CSM is considered as useful tool for solving liability issues. Some companies perceive the CSM negatively because of the costs for producing the required documentation. Usually those companies do not have “generic safety plans”, “generic safety cases”, etc. that can be reused as a reference or basis for developing a structured documentation specific to a project.

(f) How does the CSM fit within the overall Change Management Process of the stakeholder (safety) management system when modifying operational and organisational procedures/processes or when considering technical changes?

Although the CSM for risk assessment is part of the RU/IM SMS, it is not yet widely applied for assessing modifications of operational and organisational procedures/processes of the SMS. The method is mainly used for assessing technical significant changes.

(g) Is there a link between the CSM for risk assessment and the monitoring activities required through the CSM for monitoring (Regulation 1078/2012) of the stakeholder (safety) management system?

The SMS of RUs/IMs contains procedures for risk assessment, risk management (i.e. Regulation 402/2013) and risk monitoring (i.e. Regulation 1078/2012). However, those procedures are considered and applied separately. Usually, they are not yet totally perceived as two interrelated processes of the SMS, except in companies very mature in “risk based thinking”. In practice, processes related to Regulation 1078/2012 shall be used to monitor the effectiveness of the risk control measures identified and implemented following the application of Regulation 402/2013.

(h) Does the sector check through the periodic internal audits of their management system the consistent use of risk assessment, and in general of the CSM for risk assessment, for the management of all safety related changes? What is the frequency of those internal audits?

(1) The ASBOs cannot know this information. The NSAs do not tell almost anything. Some NSAs even say it is not their role to check that the RUs/IMs monitor internally the consistent application of the CSM in their company.

(2) Those NSAs who include in their supervision activities of the Management System of RUs/IMs/ECMs ask them action plans for including in their internal monitoring plans the verification of the correct implementation of the CSM for risk assessment through the company.

(3) In-house ASBOs confirm they monitor the use of the CSM in their company, probably because they are involved in monitoring functions. But they do not give any information concerning the frequency of those audits.

(i) How does the sector ensure that the risk assessment and risk management activities are carried out by competent staff? Are enough (competent) resources allocated to risk assessment and risk management activities? What difficulties do they face?

(1) The competence of the staff in charge of the risk management is usually checked through the ASBO assessment (point § 1.1.2 in Annex I of the CSM). The expert experience in the railway field is of prime importance. Difficulties usually arise from an insufficient practical experience in applying risk assessment techniques and tools, as well as in managing risks.

(2) The railway staff has a good technical and operational knowledge of the railway system. But their staff is not familiar with the “risk based and process thinking”. As they do not have the necessary

experience and knowledge in the field of risk assessment, additional teams are created for the safe management of changes and for conducting the risk assessment activities. The companies put a lot of efforts in training their staff on risk assessment and risk management techniques. So competence and capability in conducting risk assessment is growing slowly, but resources are still missing. The difficulty is to find qualified and competent experts in both the railways and risk assessment discipline. When experienced staff is not available in the company, external support is used.

- (3) As the mandatory use of the risk based approach is relatively recent in the railway sector, there is a high demand on the market for professionals of risk assessment and risk management. This is reflected by a high rotation of staff between the NSAs, ASBOs and railway companies. This can be a problem for the independence if on the same project the same person is occupied at different posts in different companies at different time intervals.
- (j) Do companies report transparently to the NSA (to the ECM certification body for ECMs) in the annual reports or do the NSAs (ECM certification bodies for ECMs) form a picture through the regular supervision activities of the management system? What kind of information is reported to you in their annual reports on their experience with the CSM?
- (1) The ASBOs do not have this information. The NSAs and ECM Certification Bodies do not explain whether they collect information through the supervision activities of the management system or through the annual reports from the sector.
- (2) The visibility for ECMs is very poor. Their annual reports contain the number of changes, a short description, the classification “significant/non-significant” of the change, the type of the change (organisational, operational or technical, or a mix).
- (3) The RU/IM annual reports to the NSA contain the information requested by Directive 2004/49 and some predefined information requested by the NSA. The RUs/IMs seldom report experiences with the CSM for risk assessment. The reported information is variable, from detailed to very limited.
- (k) Does the sector correctly understand the concept of “safe integration” of the change within the environmental, operational and maintenance context in which it will actually be used?
- This means, do the risk assessments correctly identify, analyse and mitigate also the risks at the interfaces with the external world and do they export systematically all necessary application conditions that are to be verified during the operation and maintenance of the change within the full environmental, operational and maintenance context?
- (1) The concept of “safe integration” is the most complex to understand and to be practically implemented by the application of the CSM for risk assessment.
- (2) So, the understanding of the concept of “safe integration” varies in function of the company or project team in the company. Although in some companies communication exists between the involved parties, there is a lot of room for improvement. Currently, the more frequent practice is a great lack of cooperation with the other actors, even inside the same company. Risks related to other parties are often being ignored. This raises uncertainty with respect to the safe integration of the different sub-systems and components together. However, gradually the sector starts understanding it better and better through continual applications of the CSM. So, the interfaces of the system under assessment with other systems that form the global railway system, and the interfaces between all involved actors, are getting better taken into account.
- (3) As the concept of safe integration is not yet correctly understood, the sector is asking for more explanations and guidance.

- (l) Have you ever observed that the application of the CSM has led to requirements contradictory to those laid down in a TSI?

Either the current applications of the CSM for risk assessment have never identified a requirement contradictory to a TSI. Or, the NSAs and ASBOs who took part to the survey have not been informed about it.

- (m) Are the results of risk assessments systematically submitted to NSA (to the ECM certification body for ECMs) for agreement before their implementation?
- (1) No, the results from risk assessments are never submitted to the NSAs and ECM Certification Bodies for agreement.
  - (2) Only the risk assessments of projects which require an authorisation from the NSA (e.g. vehicle authorisations, a new infrastructure or new operational conditions) are submitted to the NSA. In that case, the NSA is provided with any necessary independent assessment reports of a NOBO, DEBO and ASBO. In other cases, the risk assessment and risk acceptance are managed by the proposers/applicants.
  - (3) The NSAs and ECM Certification Bodies can have a look at a risk assessment only during the annual supervision activities.
  - (4) The case of Slovenian, Croatian and Romanian NSAs is specific. As they are recognised by their Ministry to act as ASBO, those NSAs under the ASBO function systematically assess independently the correct application of the whole risk assessment process and the suitability of the results from that process.

## Q 10. Confidence in Quality level of risk assessments and Mutual Recognition

- (a) When a system has already been accepted according to the Risk Management process of the CSM, do you mutually recognise the safety assessment report of the CSM Assessment Body and the results from the risk assessment? If you do not mutually recognise them, what additional evidence do you request for the mutual recognition of an extended use of the same system?
- (1) The ASBOs check if the assessed change fits the actual project. Usually they recognise the independent safety assessment report of other ASBOs. They also check in the ERADIS database that those ASBOs are accredited/recognised.
  - (2) The NSAs who replied the questionnaire, report that they accept the reports of ASBOs that are accredited/recognised vs. the requirements of the CSM. They also check in the ERADIS database that the ASBOs are accredited/recognised.
  - (3) There was no case reported where additional demonstrations were requested by an ASBO or an NSA.
- (b) Does the application of the CSM provide the assurance that the risks are properly identified and adequately managed? And therefore, does it actually facilitate mutual recognition and access to the railway market? If not, what are the reasons for that?
- (1) The belief that the application of the CSM provides the assurance that the risks are properly identified and adequately managed is shared between those who trust the method and those who are not yet convinced by it.
  - (2) A large majority of stakeholders still believes that the risk management process is totally misunderstood. So it is premature to consider that risks are properly identified and adequately managed. The railway sector does not use largely the “proactive approach” to safety management through risk assessment and risk management. The rule based approach continues to be largely

- used. If something is not addressed by a rule, the “reactive approach” (following an incident or an accident) is used to define appropriate measures for preventing similar events to happen in future.
- (3) The companies familiar with the “risk based thinking” agree that when the CSM is well applied, and independently assessed by a competent ASBO (although an ASBO can also overlook a non-compliance), it should facilitate the mutual recognition. In practice, the sector maturity with the understanding, application and implementation of the method is not yet sufficient to make it possible.
- (4) Due to an incomplete system definition and a rather poor interface management, there is no guarantee of the completeness of the hazard identification and of an appropriate control of all risks. When brainstorming is used for the hazard identification, there is no trust that the method is systematic and actually permits the identification of all reasonable risks. However, progressively a consistent application of the CSM for risk assessment by qualified and experienced staff should permit to harmonise the different approaches used in the past for managing the safe design, operation and maintenance of railways.
- (5) A barrier to mutual recognition is the lack of harmonised risk acceptance criteria, in particular for operational and organisational risk control measures where human interventions are required to keep the railway system safe. For example, concerning the mutual recognition in Germany, there is a risk that the requirements from the SIRF model (Safety Guideline for Rolling Stock) are higher than the risk acceptance criteria used in other EU Member States.
- (6) The following areas for improvement are proposed :
- (i) increase the clarity and understandability of the CSM for risk assessment to make it readable by practitioners who must implement it;
  - (ii) make available helpful guidance in the relevant EU languages;
  - (iii) help with the decision on the significance of a change;
  - (iv) etc.
- (c) Has the CSM fostered also the exchange of safety-relevant information between different actors within the rail sector and does it facilitate the management of safety across the different interfaces which may exist within this sector?
- (1) The opinion about the improved exchange of safety relevant information between actors is shared. 50% of replies agree that the CSM introduces a systematic process for the exchange of safety relevant information at the interfaces between the different involved sub-systems and actors. 50% of replies do not agree with that point of view.
  - (2) The companies mature with the “risk based thinking” agree that the exchanges of safety relevant information is fostered between the manufacturer, the operator and the entity in charge of maintenance. For those projects that have a great technical complexity, the answer is also positive.
  - (3) The other proposers/applicants usually consider that the CSM is a tool that must be applied to produce the necessary paper in order to obtain authorisations from an NSA.
- (d) Is the CSM becoming a harmonised tool for Risk Management and for the assessment of the impact of changes on the railway safety level, the systematic identification of the necessary safety requirements to be fulfilled and the formal demonstration of their achievement?
- (1) Again, the opinion of the sector is shared between those who consider the CSM as a harmonised and appropriate tool for risk management and those who estimate that more time is needed to apply the method, gain experience (i.e. “learning by doing”) and reach a sufficient level of maturity. Nevertheless, all agree that there are large differences in the way risks are accepted. And all agree

- there is a lack of harmonised risk acceptance criteria. This is considered as a burden for effective mutual recognition and cross border operations.
- (2) The companies familiar with the “risk based thinking” agree that for the moment, the application of the CSM is not perfect. They also share the concern on the assurance of a systematic identification of hazards and appropriate risk control. But they believe that the CSM is actually becoming a harmonised tool for risk assessment and risk management. The CSM is the key tool for triggering a cultural change in railways and to manage the railway risks in a harmonised way across the whole European Union.
- (3) The companies familiar with the “rule based thinking” consider that the CSM contains very high level requirements that make it not applicable. The sector understanding of the risk management recommended by the CENELEC standards is better understood and considered more systematic too. Consequently, they consider the CSM as an inappropriate tool for the risk management, in particular because it is mandatory only for significant changes. All other changes that are safety-relevant but not significant are not addressed by the CSM. They consider also that the CSM is not appropriate for the assessment and management of risks associated with technical systems. They prefer to use the CENELEC 50126, 50128 and 50129 standards as the only harmonised tool.
- (e) Is there a measurable difference in the understanding and an improvement of use of the CSM between 2010 (when Regulation 352/2009, first version of the CSM became mandatory), 2015 (application of Reg. 402/2013) and 2018, i.e. almost 10 years after its first date of application?
- (1) A general statement cannot be given yet. Regulation 352/2009 was quite rarely used. The experience varies in function of the countries and the different companies in those countries. Some replies report that the main differences are not measurable, except that the introduction of the independent ASBO has automatically led to a drastic decrease of the number of significant changes. The sector wants to avoid appointing an ASBO.
- (2) Other stakeholders are becoming more and more familiar with the CSM; they are continually “learning by doing”. In the last 2-3 years, there is a visible improvement of the safety culture of main RUs and IMs. The awareness of roles of all actors involved across the interfaces is also getting better understood; they are getting involved in the assessment of the shared risks at the interfaces. As the method is getting better understood, it starts being used more frequently. Those stakeholders are also getting more familiar with ASBOs, they are preferred to ISAs. However, although the situation is improving, they acknowledge there is a lot of room for improvement.
- (3) A few voices agree that the longer the method is used, the more the understanding and use of the CSM should improve. However, they underline that such a fundamental change of methodology to railway safety management requires a much longer period of time to get familiar with the “risk concept and thinking in terms of processes and risks”. The railway sector has a high inertia and needs time to switch from their own methods well established since tens of years.
- (f) What activities has the NSA undertaken for promoting and improving the sector understanding and correct application of the CSM for risk assessment? If no actions are taken, what are the reasons?
- (1) The ASBOs do not have the answer to this question.
- (2) Depending on the country, the following types of activities are undertaken by the NSA :
- (i) writing guidelines on how to use the CSM for risk assessment and CSM for monitoring;
  - (ii) discussions with the stakeholders during the supervision activities;
  - (iii) organisation of workshops on the risk based approach and SMS certification and auditing;
  - (iv) meetings with the stakeholders on specific themes;

- (v) organisation of “panel of experts meetings”;
  - (vi) participation to forums with ASBOs (the NSA acts as secretariat for the meetings);
  - (vii) NSA Annual Safety Conferences;
  - (viii) Increase the pressure on the companies for applying the CSM, especially the newcomers. But the effect is minor;
  - (ix) etc.
- (3) Some NSAs underline they are not having internally sufficient knowledge to be capable to promote alone the CSM for risk assessment.
- (g) Do you supervise the application of the CSM separately from the annual reports received from RUs/IMs/ECMs? If yes, please describe the method you use and the types of checks you do.
- (1) The ASBOs do not have the answers to this question.
  - (2) The majority of involved NSAs report they are collecting the sector experience with the CSM for risk assessment only through the Annual Reports from RUs and IMs.
  - (3) Some NSAs report they include in their supervision activities of the RU/IM SMS the check of the management and risk assessment of changes.
  - (4) Some NSAs explicitly say not supervising the application of the CSM for risk assessment by the railway sector.
- (h) Where applicable, at what extent do you include the check of correct and comprehensive application of the CSM within the supervision/surveillance activities of the stakeholders? What is the frequency of those checks?
- (1) The ASBOs do not have the answers to this question.
  - (2) The NSAs which include in the supervision activities the application of the CSM for risk assessment do it at least once a year.
  - (3) The other involved NSAs report they do not systematically supervise every year the correct application of the CSM for risk assessment.
- (i) Does the NSA often require additional checks and risk analyses because it is easy to demonstrate the existence of substantial risk to safety due to gaps in the risk assessments? What are the reasons?
- (1) The ASBOs do not have the answers to this question.
  - (2) Yes, sometimes the NSAs can ask for additional assessments or justifications when the submitted explanations/justifications are unclear. For example :
    - (i) poor justifications for the deviations with respect to codes of practice;
    - (ii) lack or unclear descriptions of the organisation and distribution of responsibilities of the risk assessment and risk management activities;
    - (iii) poor justification on how the criteria on the significance are applied and why the change can be considered non-significant;
    - (iv) there is no proposer’s declaration as required by Article 16 in the CSM;
    - (v) hazards considered improbable without proper justifications.
  - (3) Otherwise, the NSAs do not ask for additional assessments and demonstrations when a significant change is already independently assessed by an accredited/recognised ASBO.

- (j) Similarly do NoBos face difficulties in accepting the “Proposer’s Declaration” based on documented and justified doubts concerning the assumptions made or the appropriateness of the results from the risk assessments? What are the reasons?
- (1) The ASBOs do not have the answers to this question.
  - (2) The NSAs have not cross checked it with NOBOs.
- (k) Is there duplication of work observed between the different conformity assessment bodies (NSA, NoBos, DeBos, CSM Assessment Bodies) that might be involved on a project? What are the reasons?
- (1) There was some duplication of work in the past. That was due to some NNTRs and the way of working of some NSAs (double checks by NSAs).
  - (2) In some countries, as the boundaries are clearly defined between the scopes of work of the NOBO, DEBO, ASBO and NSA, there is no duplications of assessments by those different bodies.
  - (3) In other countries, the NSA is often acting as the second ASBO/NOBO/DEBO because this is expected by the citizens from a public authority (political pressure after some serious accidents). So the NSA requires often extra information.
  - (4) In some countries, the relations between the CSM for risk assessment, the CENELEC 50126 standard and national legislation is not well understood. So, when the proposer is not familiar with the “risk based thinking”, he cannot identify the synergies and complementarities between all those two sets of requirements. Consequently, the proposer is not capable to separate the work streams and coordinate correctly the NOBO, DEBO and ASBO. In that case there is a lot of duplication of work between the following independent conformity assessments :
    - (i) the CSM for risk assessment requires an independent safety assessment to be done by an ASBO;
    - (ii) TSIs can require the compliance with RAMS standards (e.g. CENELEC 50126); that is to be independently checked by NOBO;
    - (iii) national regulations can also require the compliance with RAMS standards; that is to be independently checked by the DEBO, although this is already done by the NOBO;
  - (5) To avoid the multiplications of independent conformity assessments by different bodies, proposers prefer to hire on single conformity assessment body which can fulfil the roles of a NOBO, DEBO and/or ASBO, by having all accreditations/recognitions.
- (l) Do you accept during the certification of the management system the accreditation or recognition of an RU/IM/ECM as a proof of its ability to act as CSM Assessment Body? Why?
- (1) This question is not addressed to ASBOs.
  - (2) The situation has not yet been met, at least in the countries whose NSAs replied the questionnaire.
- (m) Are there in your country assessment bodies which fall under the scope of Article 12 of Regulation 402/2013? If yes, which criteria do you accept to relax? Are they often given contracts?
- There are just one or two exceptions where relaxed criteria according to Article 12 of the CSM can be used for the ASBO. But the details are not given reported.

## Q 11. Questions addressed to the CSM Assessment Body on its experience with the CSM

- (a) What documents does the assessment body request to the proposer in order to understand the change under assessment?

- (1) Obviously the ASBOs have not understood the difference between the documents needed to understand the change to be assessed and the proposer's documentation necessary to plan the independent assessment activities. There is thus a duplication of answers between the points (a) and (b) of this question.
  - (2) A common answer cannot be given. It depends on every ASBO. The ASBOs have provided following answers to the question :
    - (i) it depends on the proposer's structure of the project documentation. Each proposer has its own set of documents. So, the ASBO asks for all documents necessary to understand thoroughly the change and the risk management process;
    - (ii) at least the system definition of the change modification, including the operational and organisational context;
    - (iii) the system definition of the change, the impacts of the change on the railway system, the organisation of the change management and the strategy to demonstrate the compliance with the CSM for risk assessment;
    - (iv) the safety plan, the description of the quality and safety management, the system definition, the hazard analysis, the risk analysis, the specified safety requirements, the demonstration of the correct application of codes of practice, reference systems, explicit risk evaluation, any other evidence of safety validation (including validation/test documents, assessment reports, etc.);
    - (v) etc.
  - (3) If additional clarifications are needed, the ASBOs asks the proposer for additional documentation or information. If necessary, a meeting could take place with the proposer/applicant.
- (b) What documentation does the assessment body consider to plan its independent assessment activities?
- (1) Obviously the ASBOs have not understood the difference between the documents needed to understand the change to be assessed and the proposer's documentation necessary to plan the independent assessment activities. There is thus a duplication of answers between the points (a) and (b) of this question.
  - (2) A common answer cannot be given to this question. It depends on every ASBO. The ASBOs have provided following answers to the question :
    - (i) ASBO 1 : the system definition and the outcomes of the risk assessment;
    - (ii) ASBO 2 : all evidence that can be derived from the flowchart in the Annex I to Regulation 402/2013;
    - (iii) ASBO 3 : the safety process, significance analysis, system definition, hazard list, risk analysis, safety case, Hazard Log with a detailed description of the decisions taken, evidence to show that each hazard is controlled, e.g. independent third party assessment reports for brake, axle, software, etc.;
    - (iv) ASBO 4 : the following documents :
      - ✂ the change management procedure (RU/IM/ECM);
      - ✂ the risk management procedure (RU/IM/ECM);
      - ✂ the other procedures relevant for the scope of the change (HR, maintenance, MMS, etc.);
      - ✂ the assessment report;
      - ✂ the evidence of meeting safety requirements (lists, statements, test results, etc.);
      - ✂ sometimes design drawings, project concepts, tender requirements;
      - ✂ the Hazard Record;



- ↵ etc.
- (v) ASBO 5 : the system definition of the changes, the safety case, when available, description of the safety organisation and of the management of the safety analyses, the hazard management, the results from the risk assessment;
- (vi) ASBO 6 : at least, the system definition, in accordance with the provisions of point § 2.1.2 in Annex I to the CSM for risk assessment;
- (vii) ASBO 7 : the following documents :
  - ↵ the exhaustive system definition of the change;
  - ↵ the affected interfaces;
  - ↵ the safety organisation in charge of application of the CSM for this change;
  - ↵ the strategy to integrate the change inside the railway system;
  - ↵ the safety strategy to demonstrate the compliance with Regulation 402/2013;
  - ↵ the evidence from the application of the risk management process, including the information about the safety management system and quality management system that are applied for the change;
  - ↵ all documentation from the development process of the change : documentation on the design, manufacturing, installation, verification, validation, test and commissioning;
  - ↵ the Hazard Log (Hazard Record);
- (viii) ASBO 8 : the exhaustive system definition, the safety plan, the exhaustive impact analyses (especially in case of changes within sub-systems/components), etc. Those documents are referenced in the ASBO assessment plan;
- (ix) ASBO 9 : the following documents :
  - ↵ the system definition;
  - ↵ the project plan;
  - ↵ the organisation;
  - ↵ the competencies of the staff involved in the change;
  - ↵ the Hazard Log;
  - ↵ the process manuals/descriptions related to the change;
  - ↵ the tendering documentation regarding the change;
- (x) ASBO 10 : the following documents :
  - ↵ the preliminary assessment of the impact of the change;
  - ↵ the project description from the proposer;
  - ↵ the project organisation and project time schedule;
- (xi) ASBO 11 : one or more document/s containing at least the following items :
  - ↵ the change definition, including :
    - ⇒ the change description;
    - ⇒ the change objectives;
    - ⇒ the change boundaries;
    - ⇒ the interaction points;
    - ⇒ the environmental conditions;
    - ⇒ the existing safety measures;
    - ⇒ the assumptions to define limits for the risk assessment;
  - ↵ the analysis of the significance of the change;

- ↪ the definition, evidences and results of the risk management process (if the change is significant);
- ↪ the organisation adopted to carry out the risk assessment process;
- ↪ the evidence of compliance with all necessary safety requirements;
- ↪ the Hazard Log;

(xii) etc.

- (c) Are usually proposer's quality and safety management systems assessed and certified by another Conformity Assessment Body? If not, how do you assess them?
- (1) This depends on whether the proposer/applicant is an RU, IM, ECM or a supplier (e.g. a manufacturer. As RUs, IMs and ECMs (at least for freight wagons) are submitted to the obligation to have a Certified Management System in place, those actors always have a certified Management System. Some manufacturers also have a certified QMS. So the ASBO does not reassess the already certified management systems of those stakeholders.
  - (2) For other actors not having a certified management system, the ASBO includes the QMS/SMS scopes in the assessment of the application of the CSM for risk assessment. The objective is to assess the proposer's intentions in terms of quality and safety management activities to be done for the change. Depending on the type and complexity of the change, the ASBO checks relevant parts of standards such as the ISO 9001 and CENELEC 5012x, taken as reference to verify that the proposer covers the key points (e.g. competence management of the involved staff, configuration management, traceability, reviews/verification, validation, systematic approach to detect and handle hazards, etc.). Then the evidence of the correct use and application of those activities are assessed (by means of document inspection and/or audits).
- (d) When do you usually start and finish the independent assessment with respect to the planning, design and implementation of the change by the proposer? Do you challenge the proposer's design choices along the whole development process of a change or do you simply confirm those decisions?
- (1) The moment at which the ASBO starts and finishes its assessment, and the ASBO freedom to actually challenge the proposer's choices, vary on the country, the safety culture in the country and of the stakeholder in the considered country.
  - (2) Although the independent safety assessment is expected to start as early as possible, during the planning phases of the change, in practice in some countries (especially Eastern ones) the ASBO is appointed systematically very late at the end of the risk assessment process. At that moment, the design choices are already frozen, the design is done and validated; very rarely it is acceptable from the project point of view to implement "last minute modifications" in the design. Consequently, those ASBOs do not really have the possibility to influence the taken proposer's design choices; they can agree or disagree with the proposer's justifications of the non-conformities. Even when the ASBOs are involved too late in the project, they assess each phase of the process and identify the non-conformities of the design choices when they can cause a safety issue. Usually, when the design cannot be changed, the proposer performs additional risk analyses and exports safety related application conditions to justify the acceptance of the non-conformities. The ASBOs finish the assessment when all raised issues are closed and the ASBO report is delivered.
  - (3) The starting time and the extent at which the ASBO can influence the choices can also vary depending on the ASBO scope of work and moment of the assessment written by the proposer/applicant in the contract. The proposer/applicant can also decide whether he wants intermediate checks to be done or only an assessment of the final documentation.

- (4) Some ASBOs report they do not influence the design choices as this is usually done according to standards, norms, approvals, etc. Those ASBOs rather challenge the proposer on a proper hazard identification and the allocation of appropriate risk control measures, in particular for the interfaces (both internal and external).
- (5) Usually, the companies familiar with the “risk based thinking” request the ASBO to start the independent assessment from the very beginning of the project, before the design starts. They expect the ASBO to accompany the risk assessment of the change and follow the design, review the decisions and assess the compliance with CSM requirements. The assessment finishes when all documents are reviewed, the change is implemented and the ASBO considers the proposer’s evidence sufficient for complying with the CSM.
- (6) **Note** : in some countries, when big investments are made, the end customer can request an ASBO to carry out a prequalification safety assessment report on the supplier’s capability to honour its contractual commitments. So, the independent assessment can sometimes start before the actual project exists. Sometimes it is obvious that the proposer’s choices, or the interactions with other involved actors, are compromising the safety and the feasibility of the intended change.
- (e) Does the assessment body perform a complete and thorough review of all outputs and does it check all details and all results of the proposer’s risk assessment?
- (1) In Eastern countries and countries familiar with the “rule based thinking”, usually the ASBOs assess exhaustively all outcomes from the risk assessment.
- (2) Other ASBOs can also make an exhaustive assessment of all the outcomes of the risk assessment process. However, when the independent assessment of the proposer’s quality and safety processes show trust, some of those ASBOs can decide to perform a sampling assessment. In both cases, the ASBOs assess the suitability of the application of the risk management process and also the suitability of the results from the process.
- (3) Other ASBOs explain that the extent of the review of the outcomes depends on the change and the proposer’s processes. The whole risk assessment process is reviewed thoroughly. However, the application of the risk management process is reviewed with a progressive or step wise approach. If the ASBOs verify by sampling that the proposer applies correctly a documented, systematic and process based methodology for project and risk management, they carry out a thorough assessment of a vertical slice of the outcomes from the risk assessment. They document the criteria for selecting the samples and vertical slice (e.g. grouping of types of risks, covering a percentage of each type of risk depending on the consequences of the risk, etc.). If the assessment identifies non-compliances, the ASBOs inform and request the proposer to review again the application of his processes and the evidence from the risk assessment. Alternatively, if contractually agreed with the proposer, the ASBOs can widen the sample further and perform a full review of all outcomes of the proposer’s risk assessment.
- (4) Finally, other ASBOs explain it depends on the volume and size of the project. If the project is small (or medium), usually the ASBOs review and check every single document resulting from the risk assessment. For bigger projects, when the proposer has a QMS, every document from the risk assessment does not need to be checked; only the most important ones are independently assessed. This sample assessment is based on the trust into the company QMS.
- (f) If not, what is the assessment body working method for assessing the conformity of the proposer’s risk assessment with the CSM and the suitability of the results to form an opinion on whether the change can fulfil its safety requirements?

- (1) The ASBOs of the “rule based thinking” countries verify phrase-by-phrase the compliance with the requirements in Annex I of the CSM. But all ASBOs carry out a “clause by clause evaluation” (CBC-EVA), as referenced in Annex I of Regulation 402/2013, using a question/answer evaluation form (FOR-EVA).
- (2) When every outcome is not assessed, or cannot be assessed (big projects), then the working method is sampling through the risk assessment process and review and audit of the documentation of the selected samples.
- (g) Is the independent assessment based on document reviews only or on additional activities? Please describe.
- (1) The manner the independent assessment is done depends on every ASBO.
- (2) Some ASBOs predominantly carry out assessments and reviews of documents. But that can be complemented by interviews of the proposer’s staff through inspections and audits.
- (3) Audits and witnessing tests can be performed also when the review of the proposer’s risk assessment documents does not provide enough evidence, sufficient justifications or it is necessary to gain more confidence in the proposer’s competence or correct application of all processes. The working method is described in the ASBO assessment plan.
- (4) A few ASBOs usually consider sufficient to base their professional judgement on a review of the proposer’s risk assessment documentation, in particular when the NSA acts as ASBO, without interviewing or auditing the proposer’s staff. Probably the NSA is misled by the experience of certification of the RU/IM SMS which is just paper assessment.
- (5) An ASBO reports performing the following activities :
- (i) document reviews of :
- ✂ the risk management process and outcomes from the process;
  - ✂ the design documentation;
  - ✂ the validation protocols;
  - ✂ the test reports;
  - ✂ the implementation records;
  - ✂ the commissioning reports;
  - ✂ the project meeting protocols;
- (ii) participation as observer in the risk assessment process;
- (iii) participation as observer in the design validation process;
- (iv) participation as observer in some safety/technical project meetings;
- (v) factory and site visits;
- (6) Where necessary, ASBOs can attend driving and witnessing tests in order to better understand the operational and environmental context, as well as potential gaps in the analysis and control of shared risks at the interfaces.
- (h) How does the assessment body prioritise the assessment activities, or focus on specific areas, and on what basis? And in particular how does it ensure that the assessed outcomes of the risk assessment are representative of the quality and robustness of the overall results?
- (1) In some Eastern countries and countries familiar with the “rule based thinking”, the ASBOs check systematically 100% of the outcomes of the proposer’s risk assessment. There is no sampling technique nor vertical slice assessment applied.

- (2) The other ASBOs do prioritise their independent safety assessment activities. The prioritisation depends on the risks associated to the change, the project planning and the organisation of the project. Based on the ASBO expert/professional judgement, prioritisation is done on the key areas that can affect the correctness of the final results from the risk assessment. This is done by :
- (i) understanding the change and, based on the ASBO experience, determine the impacts and risks of the change independently from the proposer's analysis;
  - (ii) assessing the proposer's analysis and contrasting it with the ASBO opinion;
  - (iii) prioritising risks with a high impact on the safety;
  - (iv) choosing sampling criteria that are suitable to the risk identification and that adapt to the intermediate assessment outcomes from a stepwise approach to the final ASBO report.
- (3) Although the ASBOs try to assess all the outcomes of the risk assessment, depending on the change, they can focus the thorough assessment on the outcomes associated with risks of highest criticality. So in practice, they apply sampling.
- (i) What parameters or characteristics of the change influence the type and extent of independent assessment?
- (1) As reported above, in some Eastern countries and countries familiar with the "rule based thinking", the ASBOs check systematically 100% of the outcomes of the proposer's risk assessment. There is no sampling technique nor vertical slice assessment applied.
  - (2) For the other ASBO who do not thoroughly assess 100% of the outcomes of the proposer's risk assessment, different parameters are taken into account for targeting their thorough independent safety assessment activities :
    - (i) the complexity of the change and the degree of innovation and experience of the proposer;
    - (ii) the existence of reports from other conformity assessment bodies (ASBO, NSA, NoBo, DeBo, etc.);
    - (iii) the interfaces with other sub-systems, the novelty, and safety implications;
    - (iv) the difficulties for integrating the change into the railway system;
    - (v) various parameters :
      - ↔ scope of assessment agreed with the proposer;
      - ↔ type of the change (new system, small change);
      - ↔ safety impact : identified risks and consequences;
      - ↔ QMS and SMS background and processes applied in the risk assessment;
      - ↔ competence and experience of the proposer.
- (j) How does the assessment body arrive at the conviction that the proposer's risk assessment process is robust enough, captures (i.e. identifies), understands, analyses and mitigates all reasonably foreseeable hazards to an acceptable level?
- (1) Although all ASBOs have different practices, all of them use their know-how and experience to arrive at the expert judgement on the suitability of the application of the risk assessment process and of the suitability of the results from that process.
  - (2) In some Eastern countries and countries familiar with the "rule based thinking", the ASBOs check systematically 100% of the outcomes of the proposer's risk assessment. There is no sampling technique nor vertical slice assessment applied. As they perform a complete and thorough review of all outputs, they check all the details and all results of the proposer's risk assessment.
  - (3) Other ASBOs explain that, based on their professional experience and judgement, the independent assessment retraces the evidence of the proposer's risk management vs. the requirements and steps

of the process of CSM. This includes the assessment of the competence of the risk assessment team, the used processes, the documentation and results. Correctness, completeness, traceability of the risk management process and its results.

- (4) Other ASBOs build their conviction by :
- (i) understanding the change under assessment and the risk management processes and outcomes;
  - (ii) getting the evidence of the application of a systematic approach for the identification and management of risks by the proposer;
  - (iii) getting the evidence of the proposer's knowledge and competence;
  - (iv) assessing as thoroughly as necessary the proposer's risk management activities and documentation in a stepwise approach.
- (k) Does it happen that the assessment body gives recommendations to the proposer on how to close the identified issues and non-compliances? If yes, give examples of such recommendations
- (1) For some ASBOs, it is not clear from their replies what type of advice they provide to the proposer.
  - (2) In some countries familiar with the "rule based thinking", some ASBOs seem to give recommendations to the proposer; the others ones do not. Here are examples of recommendations :
    - (i) request of additional barriers for protecting level crossings against shortcuts by pedestrians due to new track layout leading to long detours;
    - (ii) stop deeper risk analyses when the limits requested by the CSM are already reached. The ASBOs consider the related section of the CSM very difficult with the current wording and thus difficult to understand. More than that, the ASBOs estimate not being allowed to advice;
    - (iii) recommendations that can improve the organisation but which is not a "non-compliance" with respect to the CSM for risk assessment;
  - (3) From those short explanation, it is difficult to state whether the recommendations are general type advices or whether they endanger the ASBO independence and impartiality.
  - (4) In Eastern countries and countries familiar with the "risk based thinking", the ASBOs identify the non-compliances and justify why they are not acceptable. Then, the proposer/applicant is responsible for solving the non-compliances. The ASBOs are aware that they are not allowed to provide consultancy services regarding the design choices, the risk assessment and risk control measures for the railway system/sub-system under assessment. The ASBOs take care that the advices do not compromise their independence and impartiality of the independent assessment of the action plan(s). In practice, very often during the independent assessment and the discussions with the proposer, the proposer finds alone the action plan(s) he can implement for closing/solving the identified non-compliances.
  - (5) When the ASBOs provide advices, these are general and neutral suggestions usually in an intermediate version of the ASBO safety assessment report. These can for example suggest the proposer to :
    - (i) use automatic tools for the configuration and traceability management;
    - (ii) standardise the internal quality and safety processes instead of implementing ad-hoc solutions for every new project;
    - (iii) structure the information and the architecture of the documentation;
    - (iv) nominate a person responsible for implementing a safety action plan when weaknesses are found concerning the project organisation;
    - (v) set the time milestones for implementing the action plan(s);

- (vi) consider the use of modern CAD technology instead of hand drawn circuit diagrams for extending the lifetime and maintainability of the old “relay based interlocking system”.
- (l) How does the assessment body document its working methods and strategy?
- (1) There is no standardised way to document the ASBO working method and assessment strategy. Although the CSM for risk assessment and the ISO/IEC 17020:2012 standard referenced therein identify clearly the ASBO tasks and type of methods to be used, freedom is left to the ASBO for the details. The ASBOs acknowledge there are no "cooking recipes" on how to do the ASBO work!
  - (2) The ISO/IEC 17020 standard requires the inspection body to have procedures for inspection methods and inspection report templates which guarantee a minimum content of documentation. So the assessment outcomes are documented in the Safety Assessment Report. This report either contains the ASBO inspection plan or gives reference to an external ASBO document that details the ASBO assessment plan.
  - (3) The ASBOs trace the history of the results of the independent assessments activities in an overview listing that is updated during the project. At the end of the project, the overview listing is included in the ASBO final assessment report and shows the different versions of all intermediate reports. Here are some examples of the ASBO documents concerning the working method and the independent assessment strategy
    - (i) audit/assessment plan, List of Open Points (LOP), audit report, test witnessing reports, final assessment report;
    - (ii) record of the list of all proposer’s documents that are assessed and the result of the ASBO assessment of each document;
    - (iii) monitoring and record with all the observations, non-compliances, doubts and issues raised by the ASBO assessment team;
    - (iv) the general assessment strategy is included in a specific assessment procedure of the company. Any part of the strategy procedure that needs to be highlighted is included in the ASBO assessment report;
    - (v) templates for the assessment report.
- (m) What is the intensity of reporting of issues and non-compliances to the proposer and through which communication channels? At what frequency?
- (1) The frequency of the reporting of non-compliances to the proposer and the communication means used for that vary with the project, the ASBO and the working method of every ASBO. There is no frequency defined.
  - (2) Some proposers tend to set the frequency of ASBO visits and reporting in the contract. In that case, usually 1 or 2 ASBO intermediate safety assessment reports are produced during a project of a 1 to 2 year duration. The ASBOs consider this frequency of independent assessment visits and reporting most of the time insufficient for identifying possible weaknesses in the application of the risk assessment process and to permit the proposer taking on time corrective actions.
  - (3) Reporting of non-compliances to the proposer is always done in a written form. But clarifications can be provided through phone calls, e-mail, or direct meetings as soon as possible to permit the proposer addressing the issues on time. So, contact with the proposer is constantly maintained (telephone, e-mail, etc.).
  - (4) The frequency of visits and reporting of non-compliance to the proposer depend on the complexity of the change, on the volume of evidences to be assessed, on the number of findings and on the proposer’s ability to correct the non-compliances.

- (5) Some ASBOs estimate necessary to communicate once per week or every second week in some cases; in other cases they have almost a daily communication, especially closer to the deadline of the project. Probably those ASBOs tend to assess in detail all the outcomes of the proposer's risk assessment.
  - (6) In general, the ASBOs expect the frequency of visits and reporting to be fixed with the proposer at the beginning of the assessment, depending on the change complexity and the project milestones.
  - (7) In general, the communication between the ASBO and the proposer takes place until all open/unclear questions/issues are addressed by the proposer.
- (n) Is the independent assessment process transparent and systematically documented to permit the mutual recognition of the independent Safety Assessment Report?
- (1) All ASBOs document to a certain extent their methodology for assessing the compliance of the proposer's risk assessment process with the requirements of the CSM for risk assessment. This is part of the assessment plan they usually include or reference in the final safety assessment report; it supports the mutual recognition of the ASBO report. The assessment plan and ASBO reports are also used as evidence during the ASBO annual surveillance by their National Accreditation or Recognition Body.
  - (2) However, the ASBOs are not eager to share with their competitors (i.e. other ASBOs) all the details of their independent assessment methodology. On the contrary, they willingly agree to share it with the European Union Agency for Railways.
  - (3) It is to note that sometimes ASBOs observe that the scope and limits of an Independent Safety Assessment Report of other ASBOs are not clear. Consequently, as the independent assessment process is not very transparent and systematic, mutual recognition is made difficult.
- (o) How does the assessment body track the issues it raises on the proposer's risk management activities? And how does it document the history status of those issues until a satisfactory resolution by the proposer?
- (1) There is not one single way for an ASBO to keep a history log with all findings and non-compliances identified and closed from the beginning until the end of the development of a change/project. A different form and level of granularity of information can be recorded by the ASBO in a "Logbook of Open Items" to identify, characterise and follow up the closing of the raised issues. The way it is done in practice depends on the project, the ASBO working method and used templates. There can be for example :
    - (i) simply several versions of the assessment report sent to the proposer;
    - (ii) observation reports with a "List of Open Points" containing the relevant details, including the document history until the satisfactory resolution by the proposer and the evidence of it;
    - (iii) tables or a database to store and track the issues communicated to the proposer; those issues are classified with their status and supporting evidence that the issue is properly addressed by the proposer;
    - (iv) a "List of Non-Conformities" (LNC) with the proposer's action plans;
    - (v) an Open Item List (OIL) shared regularly with the proposed by E-Mail or Share Point. The history status is listed in the OIL (for all issues raised by the ASBO and all answers / solutions / resolutions by the proposer);
    - (vi) etc.
  - (2) If a finding or non-compliance is not properly addressed by the proposer, it is clearly reported in the ASBO final independent safety assessment report.



- (p) What is the type of structure of the independent Safety Assessment Report? What additional information to the one defined in Annex III of Regulation 402/2013 do you include in the report?
- (1) For most of the ASBOs the report complies with the basic structure defined in Annex III of Regulation 402/2013. Sometimes, the report can also include the basic contractual information, the list of the assessed documents, the ASBO evaluation team, the proposer's team, etc. The ASBOs also document the scope and the limits of the independent assessment to make it transparent to a second assessor who could be asked to take the results into account. They include any information needed to make their work transparent to a second assessor, to avoid subjective statements.
  - (2) In Austria and Germany, the NSA has provided a template for the ASBO Report. That template is used by the ASBOs. For small projects, the assessment plan is incorporated in the assessment report.
  - (3) Similarly, the internal assessment procedure of some accredited ASBOs contains a template for the Independent Safety Assessment Report. Here are possible structures of the report :
    - (i) ASBO 1 :
      - ↗ introduction;
      - ↗ background;
      - ↗ scope;
      - ↗ references (containing the list of assessed documents);
      - ↗ system description;
      - ↗ system situation;
      - ↗ CSM assessment;
      - ↗ transferred risk, safety conditions, recommendation, others;
      - ↗ conclusions;
    - (ii) ASBO 2 :
      - ↗ description of the task (assessment scope);
      - ↗ basis of the assessment (norms, standards, regulations);
      - ↗ item under assessment (clear identification of the change under assessment);
      - ↗ assessed documents;
      - ↗ assessment methodology (including the reference to assessment plan);
      - ↗ assessment results (including of the non-compliances and recommendations, if applicable; safety related application conditions, exported constraints, restrictions of use or any other limitations);
      - ↗ conclusions;
      - ↗ Annexes containing, for example the references to the issued technical notes or table where the issues have been logged and managed, extract of exported constraints, etc.
    - (iii) ASBO 3 :
      - ↗ abbreviations and definitions;
      - ↗ reference documents;
      - ↗ reviewed documents;
      - ↗ identification of the assessment body;
      - ↗ purpose of the independent assessment;
      - ↗ independent evaluation plan;
      - ↗ scope of the independent assessment / restrictions;
      - ↗ activities;
      - ↗ results;
      - ↗ conclusion;

- ↵ Appendix 1 1 Received documents;
- ↵ Appendix 2 2 Non-conformities and recommendations;

(iv) ASBO 4 :

- ↵ ASBO identification;
- ↵ application unit;
- ↵ independent assessment plan;
- ↵ scope of independent assessment;
- ↵ system description;
- ↵ results of individual stages of risk assessment :
  - ⇒ assessment team;
  - ⇒ definition of the system;
  - ⇒ hazards identification and classification;
  - ⇒ analysis of the meaning of change;
  - ⇒ applied methods and procedures;
  - ⇒ quarter of risk;
  - ⇒ safety requirements;
  - ⇒ risk management;
  - ⇒ derogations, replacements or exclusions with regard to the agreed procedures (if applicable);
- ↵ results of independent assessment;
- ↵ conclusions from independent assessment;
- ↵ related documents;

(v) ASBO 5 :

- ↵ background
- ↵ object;
- ↵ scope (including the definition of the scope of the independent assessment as well as its limitations);
- ↵ references (standards and documentation assessed and generated);
- ↵ description of the change :
  - ⇒ definition;
  - ⇒ interface;
  - ⇒ safety considerations;
- ↵ assessment methodology (including the reference to the independent assessment plan);
- ↵ safety assessment (including the results of the independent assessment for every step and section in Annex I of the CSM);
- ↵ assessment of the proposer's risk management :
  - ⇒ assessment of the system definition;
  - ⇒ assessment of the risk analysis including the hazard identification;
  - ⇒ assessment of the risk evaluation, including the use of the acceptance principles;
  - ⇒ assessment of the demonstration of compliance with safety requirements;
  - ⇒ assessment of the hazard management, including the exchange of information;
  - ⇒ assessment of the evidences from the application of the risk management process;
- ↵ conclusions (including any identified cases of non-compliances)

(vi) ASBO 6 :

- ↵ summary :
  - ⇒ scope of work;
  - ⇒ competence, independence and impartiality;
  - ⇒ definition of the scope and limitations of the assessment;
  - ⇒ assessment plan;
  - ⇒ external consultants related to this assessment;
  - ⇒ sub-contractors related to this assessment;
  - ⇒ previous assessments;
- ↵ safety assessment conclusion;
- ↵ compliance with the safety requirements/risk management process :
  - ⇒ compliance with the safety requirements;
  - ⇒ risk management;
  - ⇒ demonstration of compliance with the safety requirements :
    - ☞ hazard management;
    - ☞ hazard records – part of the infrastructure safety management system;
- ↵ requirements;
- ↵ communication and deliveries;
- ↵ non-conformities and comments;
- ↵ confidentiality;
- ↵ disagreement management;
- ↵ referred documents;

(vii) ASBO 7 :

The structure of the report in Annex III of Regulation 402/2013 is used, complemented with points from the CENELEC EN 50126, EN 50128 and EN 50129 standards used as a means of compliance with the CSM for risk assessment. The following additional information is also included to the safety assessment report :

- ↵ system definition;
- ↵ information about the initial documentation and the final one :
  - ⇒ identifies the major changes made by the proposer;
  - ⇒ identifies the system engineers and/or designers;
- ↵ safety related actions - traceability and justifications;
- ↵ the system related safety inspections and their results;
- ↵ exported safety related actions and open safety related application conditions.

(viii) ASBO 8 : more or less the structure and content as defined in Annex III of Regulation 402/2013

- ↵ identification of the assessment body;
- ↵ assessment plan;
- ↵ definition of the scope of the independent assessment as well as of its limitations;
- ↵ results of the assessment, with the detail of the activities done and the cases of non-compliance
- ↵ conclusions of the assessment

## ANNEX B : Questionnaire

### *Gathering of Return of Experience (REX) with the use of the CSM for risk assessment (Regulations 402/2013 and 2015/1136)*

#### **LEGAL BASIS - OBJECTIVES**

*This questionnaire is the first step to address the requirements set out in Article 18 of Regulation 402/2013 on the CSM for risk assessment on national safety authorities, certification bodies of entities in charge of maintenance of freight wagons and the European Union Agency for Railways.*

*The objective is to gather with the support of NSAs and ECM certification bodies the experience of the EU railway sector with the understanding, implementation and effectiveness of Regulations 402/2013 and 2015/1136. Although the CSM Assessment Bodies are not obliged to take part in this survey, the Agency would like to consult them on the information they observe through their independently assessment activities of the correct application of the CSM. The NSA, ECM certification body and CSM Assessment Body replies should help building a representative picture on the return of experience and identifying, where necessary, areas for improvement of the legal text or of the associated application guideline.*

*The Agency will analyse all received inputs. It will draft a report and share it with the NSA Network, ECM certification body Co-operation and CSM Assessment Body Co-operation. The purpose is to collect, if any, their remaining suggestions and opinions, to identify together recommendations (e.g. if applicable, necessary action plans) and to agree on the content of the final report on the experience with the CSM.*

*The Agency will send the final report with the agreed recommendations to the European Commission.*

*It is not essential to provide a reply on the experience of every railway undertaking, every infrastructure manager and every entity in charge of maintenance. The NSA, ECM certification body and CSM Assessment Body may provide a representative picture of the overall sector experience with the use and implementation of that Regulation. **If the NSA, ECM certification body and CSM Assessment Body does not have a reply to some of the questions, they can skip the question(s).** In the country where the NSA acts as ECM certification body, the NSA should also provide the experience of the entities in charge of maintenance of freight wagons with Regulations 402/2013 and 2015/1136.*

***Replies to this questionnaire are to be returned to the Agency by at latest 31 March 2018.***

*There is no imposed form or template for replying the questions. The NSAs, ECM certification bodies and CSM Assessment Bodies are free to return their replies in the most convenient form for them provided they point out the question and sub-question numbers the replies are referred to. One possibility could be to use this file with the answers below the question.*

## QUESTIONNAIRE

**Remarks :** NSA should include also the experience of entities in charge of maintenance :

- (1) For the ECMs which are in the scope of Regulation 445/2011, if the NSA acts as ECM certification body.
- (2) For the other ECMs which do not fall under the scope of Regulation 445/2011.

### Q 1. Significance of the change and type of change

- (a) Are there notified national rules setting out what changes are significant in the country? If yes, which ones?
- (b) How does the sector assess the significance of the change? If any, what other criteria than those in Article 4(2) of Reg. 402/2013 do they use?
- (c) Are some of the 6 criteria in Article 4(2) of Reg. 402/2013 more important than the other ones for deciding that a safety related change is significant? If yes, which ones?
- (d) *No matter whether a change is significant or not, when the change is safety related, the risks arising from the change must always be controlled to an acceptable level!*  
So, what type of documentation justifies the proposer's decisions? In particular, if no risk assessment is made, how is the acceptance of risks arising from those non-significant changes justified?
- (e) If a risk assessment is also made for non-significant safety related changes, which process is used?
- (f) Is there a difference of risk assessment process and level of detail of the assessment between Technical, Operational and Organisational types of changes? If yes, what are those differences?
- (g) At what extent does the legal obligation to appoint an assessment body discourage the sector to decide that the change is significant? How could that be solved?
- (h) Who is usually the CSM assessment body for operational and organisational types of significant changes? And how does the mutual recognition function for those types of changes?

### Q 2. Hazard identification and classification

- (a) When does the risk assessment start with respect to the development process of a change? From the beginning of the change management in order to drive proactively the design choices or closer to the end just for having the right paper work and demonstrating right choices were done?
- (b) When does the risk assessment finish with respect to the change management?
- (c) Does the system definition of the change permit a comprehensive risk assessment to be done? For example, are the scope, boundaries, interfaces, environmental and any other limitations included and clearly described? Are there parts of a project excluded from the risk assessment, and thus are not subject to independent assessment, without proper justifications? If yes, is it documented?
- (d) What methods or tools are usually used for the hazard identification? How does the sector ensure it is exhaustive and systematically done? Are (international) standards used for that? Which ones?
- (e) Are the same resource and time efforts spent for managing all identified hazards/risks? Or is there a focus on the most important ones? How is the risk acceptability demonstrated for the hazards/risks which are not processed further through the risk management?
- (f) What influences the level of detail of the hazard identification? Is it dependent on the risk acceptance principle used for controlling the identified hazards?

### Q 3. Identification, control and management of shared risks at interfaces

- (a) How do proposers involve other stakeholders or contractors for the identification, control and management of risks at the interfaces with their activities? Are they involved at all? What tool(s) do they use for that? Have you seen contractual arrangements for that topic?
- (b) Do proposers assign safety requirements to other actors beyond the scope of their responsibility and reasonable domain of control?
- (c) How are conflicts between stakeholders managed and solved when agreement cannot be reached between two actors? How is that documented?
- (d) When an identified risk or non-compliance falls under the responsibility of another actor, how is that managed (transfer of safety measures, exchange of information, etc.)? Who coordinates the exchanges and correct management of the identified hazards?

### Q 4. Risk estimation and risk evaluation (i.e. risk acceptance)

- (a) What is the sector experience with the use of the three risk acceptance principles: Codes of Practice, Reference Systems and Explicit risk estimation?
- (b) Is there a preference or greater experience with one of those three risk acceptance principles? Why?
- (c) Is an order of priority between the three risk acceptance principles imposed and by whom?
- (d) How does the sector decide whether the risk is controlled to an acceptable level for the three risk acceptance principles? Does the sector use CENELEC or other standards? If yes, which ones and what similarities or differences do they find with respect to the CSM?
- (e) Are there risk acceptance criteria defined by national rules other than those defined in Regulation 2015/1136?
- (f) When applying explicit risk estimation, how is the risk acceptance achieved? Does the sector always quantify the risks? If not, what is the ratio between qualitative and quantitative risk estimations? And what is the sector experience with the use of Regulation 2015/1136 on design targets?
- (g) What documentary evidence does the sector provide to demonstrate the applicability of Codes of practice and Similar Reference Systems for the control of risks of the system under assessment? In case of deviations from a Code of Practice or a Reference System, how is the risk acceptance demonstrated for the deviations?
- (h) Does the CSM Assessment Body independently assess the correct application of the three risk acceptance principles? Why?

### Q 5. Demonstration of compliance with the safety requirements

- (a) Is “demonstration of compliance with safety requirements” well understood, implemented and documented? What does the sector actually understand and how does it demonstrate the compliance of the change with the safety requirements derived from the risk assessment?
- (b) Does the sector use CENELEC or other standards for demonstrating compliance with the CSM? If yes, do they find discrepancies between the CSM and the standards? If yes, which ones?
- (c) Are new hazards or inadequate measures found during the demonstration of compliance? What actions are taken for those hazards/inadequate measures?
- (d) Is the “demonstration of compliance with safety requirements” independently assessed, and at what extent, by the CSM Assessment Body?

## Q 6. Hazard Management

- (a) Is Hazard Management well understood, implemented and documented in a Hazard Record/Log?
- (b) What type of information is registered in Hazard Records/Logs?
- (c) What type of tools does the sector use for the hazard management, i.e. for registering, tracing to the risk assessment studies, managing and tracking the identified hazards and risks, including those at the interfaces, until they are controlled to an acceptable level?
- (d) Are the hazards related to the area of responsibility of another actor managed differently? Why? And, is the acceptance of the transferred risk by the receiving actor documented and registered?
- (e) How does the sector use the Hazard Records/Logs during the operation and maintenance of the railway system?

## Q 7. Documentary evidence from the application of the risk management process

- (a) How are the tasks and activities (i.e. roles, responsibilities and necessary cooperation) of the different actors involved in the risk management documented? Is the organisation of the risk management documented at all and by whom? Are roles and responsibilities of everyone clearly understood by all involved actors?
- (b) What evidence does the sector have for the risk assessment and risk management activities? Are at least all requirements in point 5.2 in Annex I of Regulation 402/2013 met? What is the overall quality of this evidence?
- (c) Is every step of the risk management process in Annex I and the flowchart of Reg. 402/2013 clearly documented? Does the structure indicate a correct understanding of the method? Or on the contrary, there is lack of structured documentation and too much confusing paper work?
- (d) Does the documentary evidence clearly state the assumptions for the risk assessment (e.g. scope, boundaries, interfaces, environmental, operational and any other limitations/conditions) which need to be checked for the mutual recognition of the risk assessment?

## Q 8. Independent assessment and safety assessment report

- (a) Is there a notified national rule specifying who is the assessment body? If not, how does the sector select/appoint the assessment body? What influences at most the selection of the assessment body?
- (b) What influences the choice of the assessment body? Does it matter if the body has already been involved within the project, e.g. advising other stakeholders/contractors of the project, before they are appointed as assessment body for the purposes of the CSM?
- (c) At what moment of the development process of the change does the proposer appoint the assessment body and when does this body start its work? Does it have the opportunity to challenge the proposer's choices from the beginning of the process or it comes when the risk assessment is done?
- (d) Have you ever seen the replacement of an assessment body by another one before the end of a project? If yes, what were the justifications? Did the new one get the results from the previous body?
- (e) Are there in-house assessment bodies? If yes, for what types of projects are they usually involved?
- (f) Who is the assessment body for (operational and organisational) changes brought to the (safety) management system?
- (g) How many assessment bodies are usually involved on a project? For which reasons?
- (h) How does the sector manage the interfaces between the different conformity assessment bodies who might be involved in the same project (NSA, NOBO, DEBO, Assessment Body/Bodies, etc.)?

- (i) For significant changes, do proposers systematically write a “Proposer’s Declaration” as this is required in Article 16 of Regulation 402/2013?
- (j) Does the sector usually agree with the observations of the CSM Assessment Body? If not, do they correctly justify and document the parts of the safety assessment report for which they disagree?
- (k) What is the overall experience with the use of CSM Assessment Bodies in your country? Are Assessment Bodies from your country appointed or are bodies from other countries also contracted? What are the reasons for those decisions?
- (l) Is there a difference of quality of independent assessment between Assessment Bodies and in particular between the accredited and recognised ones? If yes, what are those differences?

### Q 9. Overall sector understanding of the CSM and of Risk Management Concepts

- (a) Is the CSM for risk assessment well understood and correctly implemented? What main difference(s) has it introduced in the sector for the assessment, control and management of risks arising from their activities?
- (b) Is this level of understanding reflected in a description of tasks and responsibilities of the different actors involved within the risk management activities? Who is coordinating all those activities?
- (c) What differences do you observe between big and small railway companies?
- (d) What differences do you observe between former incumbent and newcomer railway companies?
- (e) Is the application of the CSM considered as a useful proactive tool for optimising the company business costs, or on the contrary seen just as a legal obligation with additional constraints, generating additional efforts/costs (more work, need of additional staff and more paper)? If it is negatively perceived, how were the risk assessments done and documented before the existence of the CSM?
- (f) How does the CSM fit within the overall Change Management Process of the stakeholder (safety) management system when modifying operational and organisational procedures/processes or when considering technical changes?
- (g) Is there a link between the CSM for risk assessment and the monitoring activities required through the CSM for monitoring (Regulation 1078/2012) of the stakeholder (safety) management system?
- (h) Does the sector check through the periodic internal audits of their management system the consistent use of risk assessment, and in general of the CSM for risk assessment, for the management of all safety related changes? What is the frequency of those internal audits?
- (i) How does the sector ensure that the risk assessment and risk management activities are carried out by competent staff? Are enough (competent) resources allocated to risk assessment and risk management activities? What difficulties do they face?
- (j) Do companies report transparently to the NSA (to the ECM certification body for ECMs) in the annual reports or do the NSAs (ECM certification bodies for ECMs) form a picture through the regular supervision activities of the management system? What kind of information is reported to you in their annual reports on their experience with the CSM?
- (k) Does the sector correctly understand the concept of “safe integration” of the change within the environmental, operational and maintenance context in which it will actually be used?

This means, do the risk assessments correctly identify, analyse and mitigate also the risks at the interfaces with the external world and do they export systematically all necessary application conditions that are to be verified during the operation and maintenance of the change within the full environmental, operational and maintenance context?



- (l) Have you ever observed that the application of the CSM has led to requirements contradictory to those laid down in a TSI?
- (m) Are the results of risk assessments systematically submitted to NSA (to the ECM certification body for ECMs) for agreement before their implementation?

## Q 10. Confidence in Quality level of risk assessments and Mutual Recognition

- (a) When a system has already been accepted according to the Risk Management process of the CSM, do you mutually recognise the safety assessment report of the CSM Assessment Body and the results from the risk assessment? If you do not mutually recognise them, what additional evidence do you request for the mutual recognition of an extended use of the same system?
- (b) Does the application of the CSM provide the assurance that the risks are properly identified and adequately managed? And therefore, does it actually facilitate mutual recognition and access to the railway market? If not, what are the reasons for that?
- (c) Has the CSM fostered also the exchange of safety-relevant information between different actors within the rail sector and does it facilitate the management of safety across the different interfaces which may exist within this sector?
- (d) Is the CSM becoming a harmonised tool for Risk Management and for the assessment of the impact of changes on the railway safety level, the systematic identification of the necessary safety requirements to be fulfilled and the formal demonstration of their achievement?
- (e) Is there a measurable difference in the understanding and an improvement of use of the CSM between 2010 (when Regulation 352/2009, first version of the CSM became mandatory), 2015 (application of Reg. 402/2013) and 2018, i.e. almost 10 years after its first date of application?
- (f) What activities has the NSA undertaken for promoting and improving the sector understanding and correct application of the CSM for risk assessment? If no actions are taken, what are the reasons?
- (g) Do you supervise the application of the CSM separately from the annual reports received from RUs/IMs/ECMs? If yes, please describe the method you use and the types of checks you do.
- (h) Where applicable, at what extent do you include the check of correct and comprehensive application of the CSM within the supervision/surveillance activities of the stakeholders? What is the frequency of those checks?
- (i) Does the NSA often require additional checks and risk analyses because it is easy to demonstrate the existence of substantial risk to safety due to gaps in the risk assessments? What are the reasons?
- (j) Similarly do NoBos face difficulties in accepting the “Proposer’s Declaration” based on documented and justified doubts concerning the assumptions made or the appropriateness of the results from the risk assessments? What are the reasons?
- (k) Is there duplication of work observed between the different conformity assessment bodies (NSA, NoBos, DeBos, CSM Assessment Bodies) that might be involved on a project? What are the reasons?
- (l) Do you accept during the certification of the management system the accreditation or recognition of an RU/IM/ECM as a proof of its ability to act as CSM Assessment Body? Why?
- (m) Are there in your country assessment bodies which fall under the scope of Article 12 of Regulation 402/2013? If yes, which criteria do you accept to relax? Are they often given contracts?

## Q 11. Questions addressed to the CSM Assessment Body on its experience with the CSM

- (a) What documents does the assessment body request to the proposer in order to understand the change under assessment?
- (b) What documentation does the assessment body consider to plan its independent assessment activities?
- (c) Are usually proposer's quality and safety management systems assessed and certified by another Conformity Assessment Body? If not, how do you assess them?
- (d) When do you usually start and finish the independent assessment with respect to the planning, design and implementation of the change by the proposer? Do you challenge the proposer's design choices along the whole development process of a change or do you simply confirm those decisions?
- (e) Does the assessment body perform a complete and thorough review of all outputs and does it check all details and all results of the proposer's risk assessment?
- (f) If not, what is the assessment body working method for assessing the conformity of the proposer's risk assessment with the CSM and the suitability of the results to form an opinion on whether the change can fulfil its safety requirements?
- (g) Is the independent assessment based on document reviews only or on additional activities? Please describe.
- (h) How does the assessment body prioritise the assessment activities, or focus on specific areas, and on what basis? And in particular how does it ensure that the assessed outcomes of the risk assessment are representative of the quality and robustness of the overall results?
- (i) What parameters or characteristics of the change influence the type and extent of independent assessment?
- (j) How does the assessment body arrive at the conviction that the proposer's risk assessment process is robust enough, captures (i.e. identifies), understands, analyses and mitigates all reasonably foreseeable hazards to an acceptable level?
- (k) Does it happen that the assessment body gives recommendations to the proposer on how to close the identified issues and non-compliances? If yes, give examples of such recommendations
- (l) How does the assessment body document its working methods and strategy?
- (m) What is the intensity of reporting of issues and non-compliances to the proposer and through which communication channels? At what frequency?
- (n) Is the independent assessment process transparent and systematically documented to permit the mutual recognition of the independent Safety Assessment Report?
- (o) How does the assessment body track the issues it raises on the proposer's risk management activities? And how does it document the history status of those issues until a satisfactory resolution by the proposer?
- (p) What is the type of structure of the independent Safety Assessment Report? What additional information to the one defined in Annex III of Regulation 402/2013 do you include in the report?