

Report on the *return of experience with the use of the (EU) Regulation 1078/2012 on the CSM for monitoring*

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EXECUTIVE SUMMARY

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

The (EU) Regulation 1078/2012 on the CSM for monitoring applies to railway undertakings (RUs), infrastructure managers (IMs) and entities in charge of maintenance (ECMs). 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 and ECM Certification Body 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 and implementation of that CSM differ across the EU :

- Many stakeholders (*especially those more mature with the risk management concepts*), including IMs, RUs and ECMs, have well understood and correctly implemented the method;
- A large number of stakeholders 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 implementing the method. Their experience is still negative or insufficient to show a reliable picture;
- A number of countries or stakeholders have neither understood nor implemented the method yet.

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

Three years of application of the method are too short to “learn by doing” and improve the understanding and the level of compliance. To avoid unjustified amendments of the CSM, it is necessary to gather objective stakeholders’ observations on real weaknesses and problems with the method.

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;
- combine the measurement of the return of experience of both the “CSM for monitoring” (Reg. 1078/2012) and “CSM for risk assessment” (Reg. 402/2013 and 2015/1136) 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 3 years 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

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Table of content

EXECUTIVE SUMMARY	1
Table of content.....	2
List of abbreviations.....	2
1. Why is a Report on the “Return of Experience (REX)” necessary?	3
1.1. Legal obligations.....	3
1.2. Technical arguments - Continual improvement	3
2. Method for collecting the return of experience [REX] with the CSM.....	4
3. Participation rate of NSAs and ECM Certification Bodies to the collection of the return of experience with the CSM for monitoring	4
4. Summary of the NSA and ECM Certification Body answers	5
5. Analysis of the sector experience with the CSM	5
6. Analysis of the effectiveness of the CSM.....	12
7. Proposed recommendations	13
8. Conclusions.....	15
ANNEX A – Summary of the answers to the questionnaire used for gathering the return of experience (REX) with the use of the CSM for monitoring	17
ANNEX B – Questionnaire for the Gathering of Return of Experience (REX) with the use of the CSM for monitoring (Regulation 1078/2012)	32

List of abbreviations

Abbreviation	Meaning
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
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 5⁽¹⁾ of the (EU) Regulation No 1078/2012 on the CSM for monitoring 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 4th 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 monitoring is a harmonised method for the effective management of safety during the operation and maintenance of the railway system. It is a fundamental part of the RU/IM/ECM management system which should identify non-compliances with the application of the processes, procedures and risk control measures of the management system and, where necessary identify and implement, appropriate preventive and/or corrective measures. Thereby, 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⁾ According to Article 5 of Regulation 1078/2012 :

- (a) Article 5(5) : “*the Agency shall collect all information on the experience of the application of this Regulation and, when necessary, shall make recommendations to the Commission with a view to improving this Regulation*”;
- (b) Article 5(6) : “*The national safety authorities shall support the Agency in collecting such information from railway undertakings and infrastructure managers*”;
- (c) Article 5(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*”;
- (d) Article 5(7), “*the Agency shall submit to the Commission... a report analysing the effectiveness of the method and of the experience of railway undertakings, infrastructure managers and entities in charge of maintenance in applying this Regulation*”

- 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 monitoring 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. Method for collecting the return of experience [REX] with the CSM

- 2.1. In order to build a representative overview on the sector experience with the use of the CSM, it is not necessary to consult every individual RU, IM or ECM in the EU. Thereby, in compliance with Article 5(6) and Article 5(3) of the CSM for monitoring, the Agency requested the NSAs and ECM Certification Bodies to provide their inputs on the monitoring activities they can observe during the certification and supervision/surveillance of the RU/IM/ECM management system. To do this :
 - (a) the Agency drafted a supporting questionnaire on the CSM for monitoring;
 - (b) the draft questionnaire was presented at the NSA network meeting of May 2016;
 - (c) the questionnaire was sent for formal review by the NSAs in June 2016;
 - (d) the final questionnaire, updated with the comments, was sent for action to all NSAs and all ECM Certification Bodies in July 2016. The questionnaire is contained in ANNEX B below.

3. Participation rate of NSAs and ECM Certification Bodies to the collection of the return of experience with the CSM for monitoring

- 3.1. Number of consulted NSAs and ECM Certification Bodies :
 - (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 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) 15 accredited ECM Certification Bodies;
 - (3) 7 recognised ECM Certification Bodies.
- 3.2. So, taking into account that 19 NSAs act also as ECM Certification Bodies, the Agency consulted in total 50 different entities [28 NSAs and 22 ECM CB which are not at the same time NSAs].
- 3.3. Among those 50 consulted entities, the 13 entities below actually took part to the scrutiny and provided inputs to the Agency : 12 NSAs and 1 accredited ECM Certification Body. The participation rate is therefore of about 25 % of the consulted entities :
 - (a) Bulgarian NSA, acting also as ECM CB;
 - (b) Croatian NSA, acting also as ECM CB;

- (c) Czech Republic NSA, acting also as ECM CB;
 - (d) Danish NSA, acting also as ECM CB;
 - (e) Estonian NSA;
 - (f) Finnish NSA, acting also as ECM CB;
 - (g) German NSA, acting also as ECM CB;
 - (h) Irish NSA, acting also as ECM CB;
 - (i) Polish NSA, acting also as ECM CB;
 - (j) Quality Austria - Trainings-, Zertifizierungs- und Begutachtungs GmbH
[one accredited Austrian ECM Certification Body];
 - (k) Romanian NSA, acting also as ECM CB;
 - (l) Slovak Republic NSA;
 - (m) Spanish NSA, acting also as ECM CB.
- 3.4. Only one accredited ECM Certification Body among 22 bodies [15 accredited and 7 recognised] took actively part to the collection of the ECM experience with the use of the CSM for monitoring. The other ones did not provide any input.
- 3.5. From the 12 NSAs which participated to the survey, 10 NSAs are also ensuring the role of ECM Certification Body. This means that 11 participating entities provided also the experience of the entities in charge of maintenance of freight wagons with the use of the CSM for monitoring.
- 3.6. The collected results are thus representative of the experience of RUs, IMs and ECMs in the countries from which replies were received.

4. Summary of the NSA and ECM Certification Body answers

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

5. Analysis of the sector experience with the CSM

- 5.1. 25 % of contacted participants took actively part to the collection of the “Return of Experience” on the use of the CSM : 12 NSAs and one accredited ECM Certification Body.
- 5.2. With the exception of a few questions, in general three main trends emerge in the replies in ANNEX A; they are consistent throughout the different questions. As explained in section § 3.5., they are also representative of the experience of RUs, IMs and ECMs (although these later ones are not systematically separated in the replies, unless the experience was actually different) :
- (a) Stakeholders having well understood and correctly implemented the CSM;
 - (b) Stakeholders for whom the understanding and the 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.

5.3. Effectiveness of the CSM for monitoring

- (a) Although in a few countries the RUs report to their NSAs problems⁽²⁾ with the CSM, the analysis of all other inputs on its “Return of Experience” does not identify any apparent problem with the understanding of the requirements in the CSM for monitoring and with their correct and complete implementation;
- (b) On the contrary, at least 30 % of the inputs or 30 % of stakeholders (RUs, IMs and ECMs) have a positive experience with the CSM. Coincidentally, those replies usually match with the countries and stakeholders which are more mature with the risk management concepts. Those stakeholders have a good understanding of the CSM requirements. They have implemented the CSM correctly and completely, as expected and documented in the application guide on the CSM for monitoring :
- (1) Monitoring is usually an integrated part of their management system. In some companies, monitoring is even a common tool for checking the correct application and effectiveness of integrated management systems (e.g. safety and quality);
 - (2) The approach to monitoring is proactive. It is used to prevent dangerous occurrences, in addition to the reactive approach which analyses statistics and investigates accidents and incidents;
 - (3) Their monitoring strategy and monitoring plans are based on the management system documentation;
 - (4) Although it is not yet a largely spread practice, the prioritisation of the monitoring activities to the areas of greatest risk is continually gaining ground. At present, all operational processes, procedures and risk control measures of the management system are monitored equally regardless of whether the activity is of high or low risk;
 - (5) The monitoring strategy and plans use both quantitative and qualitative indicators to :
 - (i) give early warnings (i.e. proactive approach) of any deviation from the expected outcome, or assurance that the expected outcome is achieved as planned;
 - (ii) give information about unwanted outcomes;
 - (iii) support decision making;

For the companies most advanced with risk management, those indicators are defined not only based on technical expertise but also on risk assessments;

⁽²⁾ *In some countries more familiar with the application of rules rather than with the risk management concepts, in general RUs estimate that :*

- (a) *the (EU) Regulation 1078/2012 on the CSM for monitoring is written in a very abstract and theoretical way;*
- (b) *the formal separation of monitoring requirements between Regulations 1078/2012 on the CSM for monitoring and 1158/2010 on the CSM for conformity assessment makes the understanding difficult;*
- (c) *it is difficult to make clearly a difference between the Regulation 1078/2012 on the CSM for monitoring and the Regulation 402/2013 on the CSM for risk assessment.*

All these considerations make difficult an adequate and practical implementation of the monitoring activities. When put together with the lack of resources, RUs face difficulties in understanding and correctly and completely implementing all the requirements of the CSM.

As a paradox, the ECMs in the same countries, which are more mature with the risk management concepts, have realised that the “abstract monitoring process” described in the CSM is not a “European invention” but that comparable monitoring methods can be found in the requirements of many other management systems.

- (6) Enough resources (usually specialised safety people) are allocated to the management and implementation of the monitoring activities. The roles and responsibilities for monitoring are also clearly and correctly understood by the involved staff;
 - (7) According to the monitoring strategy and plans, monitoring data and indicators are collected and analysed to verify that the processes and procedures of the management system are correctly applied and that they achieve the expected outcome;
 - (8) Action plans (with appropriate preventive and/or corrective measures) are defined to correct the identified non-compliances;
 - (9) The effectiveness of the measures in the action plans is verified during the next cycle of the monitoring activities, according to the same monitoring process;
 - (10) Although achieved in different ways (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 monitoring activities are well documented;
 - (11) The results from monitoring activities are subject to reviews by the middle and top management of the company to adjust, where necessary, the monitoring strategy, priorities and plan(s). Results from monitoring serve as a real decision-making tool;
 - (12) *The most mature companies with risk management do not only have integrated “monitoring and management systems” (e.g. combining monitoring of safety and quality) but have also very advanced management systems. The Change Management Control process in the management system combines the use of the “CSM for monitoring” and the “CSM for risk assessment” to define the corrective/preventive measures of the action plans.*
- (c) Based on the experience of this category of stakeholders, there is no sufficient and objective evidence which would show that the CSM for monitoring is not effective for achieving the objectives that are set out in Article 1⁽³⁾ of the (EU) Regulation 1078/2012 on the CSM for monitoring.

5.4. **Feedback common to almost all stakeholders (RUs, IMs and ECMs) :**

- (a) In general, almost all stakeholders (RUs, IMs and ECMs) perceive the CSM for monitoring only as a legal obligation. Although exceptions can be found (e.g. ECMs), usually the stakeholder maturity with the risk management and management system concepts is not yet at a level where they would use the monitoring as an active tool for optimising the company costs and competitiveness. *This shows an immature and insufficient stakeholders’ awareness of the importance of an effective monitoring system.*

⁽³⁾ Point 2 in Article 1 of Regulation 1078/2012 states the following :

“This Regulation shall be used for the following :

- (a) *to check the correct application and the effectiveness of all the processes and procedures in the management system, including the technical, operational and organisational risk control measures ...*
- (b) *to check the correct application of the management system as a whole, and if the management system achieves the expected outcomes; and*
- (c) *to identify and implement appropriate preventive, corrective or both types of measures if any relevant instance of non-compliance to points (a) and (b) is detected.”*

- (b) Similarly, unless required by national legislation, the stakeholders never submit the corrective and/or preventive action plans drawn up by the monitoring process to the “approval” of the NSA or ECM Certification Body. This was the reply that the Agency expected. Usually, the stakeholders (RUs, IMs, ECMs) have to submit to the NSA or ECM Certification Body only the action plans that are related to non-conformities identified during the supervision/surveillance of their management system by the NSA/ECM Certification Body.
- (c) Although the contractors might be requested to communicate various safety documents or safety information (e.g. safety policy, training records for staff, etc.), the stakeholders do not request their contractors to implement the CSM within their organisations. In general, they monitor the safety performance of their contractors, and the correct execution of the contracted tasks. This is usually achieved by dedicated processes imbedded in the RU/IM/ECM management system. When non-conformities are identified, the RU/IM/ECM tracks their correct implementation by the contractor/supplier.
- (d) When non-conformities are identified within the area of responsibility of another actor, it is almost never reported to the NSA/ECM Certification Body, unless it is required by national legislation. The non-conformities are communicated directly to the right stakeholder who shall take the necessary corrective/preventive actions. In exceptional cases (e.g. serious disagreement with a contractor/supplier), the NSA might be involved/contacted to help finding a consensus (arbitration).
- (e) When defects and construction non-conformities or malfunctions of technical equipment are identified, usually they are not communicated to the manufacturer unless specific contractual arrangements are in place with the manufacturer. This is without prejudice to safety. Regardless whether the manufacturer is informed or not, the RU/IM/ECM manages the control of the non-conformities of the technical equipment until the necessary corrective-preventive actions are implemented to keep the railway system safe. In some countries, it is mandatory that all companies report to the NSA the defects and non-conformities of technical equipment which are critical for the railway safety. Then the NSA spreads those non-conformities through the Safety Information System (SIS).
- (f) In general, there is a lack of sharing of knowledge and experience (also) on the CSM for monitoring among the stakeholders because they compete with each other.

5.5. Differences between the stakeholders :

The detailed analysis of the results contained in ANNEX A below does not lead to a common experience of all stakeholders across the EU or even among all stakeholders in the same Member State. The levels of understanding and the difficulties faced with the implementation of the CSM for monitoring vary a lot from country to country and even from company to company in the same country. Some reasons for that 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⁽⁴⁾ 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.

(4) *The main "types of service" are "passenger transport", including/excluding high-speed services, "freight transport", including/excluding dangerous goods services, and "shunting only".*

5.6. Although those differences might justify partially the gradation of the difficulties the stakeholders are facing, the main reason for those differences of understanding and difficulties in correctly implementing the CSM for monitoring is a too short period of time (three years) since the CSM became applicable (7 June 2013).

5.7. For many stakeholders, and in particular for those not yet fully familiar with the risk management, (safety) management system and continuous improvement concepts, three years 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 during the monitoring activities. Those are reasons for differences in the experience and the stakeholders’ maturity with the use of the CSM.

5.8. Most representative classification of the stakeholders on their experience with the CSM :

An accurate classification of all stakeholders across the EU is not possible; the objective of the work was not to get the return of experience of every individual country. It aimed at looking for an overall picture of the situation. It is thus possible that an NSA or an ECM Certification Body does not fully recognise the inputs it provided to the Agency.

(a) The stakeholders which have not (yet) well understood, or have not understood at all the CSM, have not correctly implemented, or not implemented at all, the CSM. That category of stakeholders faces the greatest difficulties with the understanding and the implementation.

(b) **IMs and big RUs**, in general in the countries where the railway sector is more mature with the risk management concepts :

- (1) In general, they demonstrate a better understanding and more correct implementation of the requirements in the CSM for monitoring;
- (2) Usually, the monitoring process is an integrated part of their management system which is used to check the correct application and the effectiveness of the provisions of the management system;
- (3) Monitoring is planned in a proactive way, based on the provisions in their management system;
- (4) Both qualitative and quantitative indicators are used; they are preferably set up based on risk assessments and risk registers, although technical expertise may also be used;
- (5) Some companies already prioritise monitoring to areas of greatest risk based either on results from risk assessments or on the experience gained during previous monitoring activities. Some other companies which do not yet prioritise, and which for the moment monitor equally all operational processes, procedures and risk control measures of the management system, are progressively moving also towards prioritisation;
- (6) Monitoring activities are better documented and traced with respect to the operational processes and procedures of the management system;
- (7) Enough resources are allocated to monitoring activities. They are usually under the responsibility of a Safety Department in the company;
- (8) Action plans are defined with appropriate corrective and preventive measures. In general the effectiveness of those measures is also actually verified;
- (9) Since 2013, the understanding of the CSM, the monitoring strategy, priorities and plans improved based on the results and experience gained through the monitoring activities;

(c) ECMs :

- (1) In general, ECMs have a good understanding of the CSM; they are largely compliant with the CSM. However findings are made on an ongoing basis by their certification body;
- (2) Monitoring is also an integrated part of the management system. Some ECMs report nevertheless that the redundancy of monitoring requirements in Regulation 1078/2012 on the CSM for monitoring and the ECM Regulation 445/2011 is a safeguard against separate implementations of monitoring activities for the needs of both legal texts;
- (3) Monitoring is planned in a proactive way, based on the provisions in their management system;
- (4) Monitoring focusses to areas of greatest risks based on the results and the experience gained through previous monitoring activities;
- (5) Although initially most of ECMs perceived the CSM just as a legal obligation, with the improvement of their understanding of the CSM, they are slowly realising that an effective monitoring can also bring economic advantages (optimise both the monitoring and maintenance costs);
- (6) Enough resources are allocated to monitoring activities. Usually, a Safety Manager is responsible for coordinating and managing the monitoring activities in the company;
- (7) Monitoring activities are documented and traceable with respect to operational processes and procedures of the management system. But there is room for improvement;
- (8) Action plans are defined with appropriate corrective and preventive measures. In general the effectiveness of those measures is also actually verified;
- (9) Since 2013, the understanding of the CSM, the monitoring strategy, priorities and plans improved slightly based on the results and the experience gained through the monitoring activities;

(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 correctly implement it;
- (2) Usually the monitoring process is separate from the management system. It is not systematically used to check the correct application and the effectiveness of the operational processes, procedures and risk control measures of the management system. But they intend to integrate the monitoring process as a part of their management system;
- (3) Those who already check the correct application of the provisions within their management system give less focus on checking the effectiveness of those provisions;
- (4) Usually the monitoring strategy is based on the experience gained through previous monitoring activities rather than on the documentation of the management system;
- (5) In countries more familiar with application of rules rather than with risk management, RUs estimate that the CSM is written in a very abstract and theoretical way which leads to difficulties in understanding and correctly implementing the CSM. They would prefer that the monitoring requirements are entirely integrated into the general requirements of the CSM for conformity assessment (i.e. Regulation 1158/2010). They have also difficulties in prioritising the monitoring to areas of greatest risks;

- (6) Monitoring is still reactive/lagging, mainly due to a short experience (CSM is applicable since 7 June 2013). Often, it is limited to corrective actions rather than being proactive and preventing incidents or accidents. There is a tendency to finding out the root causes via accident/incident investigations to develop the monitoring strategy and move towards a proactive approach. However, there are signs of establishment of proactive/leading monitoring strategies;
- (7) Although the monitoring seems not prioritised but covers all processes and procedures of the management system, they are improving based on the experience gained during previous monitoring activities;
- (8) Although both qualitative and quantitative indicators are used; preference is given to qualitative indicators. They are defined based mainly on technical expertise rather than on risk assessments;
- (9) Resources for monitoring are tight but for some companies not to the extent of not being able to comply with the CSM and the company monitoring objectives. For the others, there is a lack of resources for implementing a continuous monitoring;
- (10) For many small companies, the monitoring is under the single responsibility of a Safety Manager (i.e. one person);
- (11) Action plans are defined with appropriate corrective and preventive measures. However, in general the effectiveness of those measures is rarely verified. Sometimes, those action plans are not formally documented;
- (12) The monitoring activities are not so well documented and can hardly be traced to the operational processes and procedures of the management system. There is thus room for improvement;
- (13) A three year period is too short to measure a visible improvement of maturity with the CSM for monitoring.

5.9. **Differences between big and small companies in understanding and implementing the CSM :**

Although big companies can afford allocating more resources to monitoring 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 and high ambitions and high needs in terms of monitoring activities throughout the company;
- (2) They allocate sufficient resources to monitoring 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) Big companies usually have better and proactive monitoring systems, with defined objectives. However, being dispersed (e.g. a central company with regional units), they are facing different challenges due to the complexity of their organisations and more complex management systems. So, they are still at a very early stage of implementation of the CSM and need still to improve;

(b) **Small companies :**

- (1) Usually small companies have less complex organisational structures, more modest ambitions and generally smaller needs for monitoring activities;

- (2) Frequently, small companies face more problems regarding the resources they are capable to allocate to the monitoring activities :
 - (i) they face a workload which is difficult to deal with because usually the same staff is responsible also for other activities within the company;
 - (ii) for some small companies, monitoring activities are thus limited to periodic risk assessments, inspections, audits and management reviews;
 - (iii) some small companies have rather reactive strategies : they are learning from the results of monitoring. They rely on finding out the root causes via accident and incident investigations to develop their monitoring strategy and move towards a preventive approach;
- (3) For the ECMs, usually the size of the company is of minor relevance. The most important parameter is the management commitment in allocating the necessary staff and financial resources for the establishment of an effective monitoring system;
- (4) Finally, companies where risks are high (e.g. transport of dangerous goods) pay more attention to monitoring. Their monitoring process is relatively more extensive.

5.10. **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) 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 abstract and theoretical requirements of the CSM into a practical safety organisation;
 - (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;
- (b) In some countries more mature with risk management, big differences in knowledge, understanding and implementation of the CSM have not been observed;
- (c) Big companies can afford allocating more resources to monitoring activities whereas small companies have less resources for monitoring.

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

6. **Analysis of the effectiveness of the CSM**

6.1. As indicated in section § 5.3., a category of stakeholders, in general those more mature with risk management, has well understood the CSM and has implemented the method correctly. The return of experience of those stakeholders on the effectiveness of the CSM is positive.

6.2. Concerning the other categories of stakeholders in section § 5.2., in general less advanced with risk management concepts, it results that :

- (a) for a big majority of stakeholders, a three year period of application of the CSM is not long enough to be able to understand well the CSM requirements, to implement them correctly,

- to “learn by doing” and to improve the deficiencies discovered during the monitoring activities;
- (b) the main problem is the lack of understanding of the CSM and the difficulty to make a link between the requirements of the CSM and their internal operational processes, procedures and risk control measures they have put in place in their management system for controlling the safety of their business;
 - (c) therefore, there is no yet objective evidence showing that the CSM for monitoring is not effective.
- 6.3. The inputs collected from NSAs and ECM Certification bodies report a few stakeholders who are very mature with the risk management, (safety) management system and continuous improvement concepts :
- (a) they have very advanced, optimised and integrated “management systems” (e.g. one system for safety and quality management) where the monitoring activities are an integrated part of the management system for all areas of the management system;
 - (b) they consider the monitoring of the management system as not separable from the risk assessment and risk management process;
 - (c) the Change Management Control process of their management system is based on a continual and combined use of the “CSM for monitoring” and the “CSM for risk assessment” for setting up the corrective/preventive measures of the action plans;
 - (d) in order to manage effectively the instances of non-compliances identified by the monitoring activities, they have setup a strong link between :
 - (1) the “risk assessment and management” processes, and;
 - (2) the monitoring activities and the action plans resulting from monitoring activities
 - (e) the corrective and/or preventive measures of the action plans are systematically based on risk assessments of the changes necessary for correcting the identified non-compliances;
 - (f) those companies regularly assess their respective action plans and apply the risk management processes to ensure that the action plans are up to date and reflect the actual situation within the management system of the company;
 - (g) they start realising that monitoring can be used as an active tool for optimising the company costs and the business competitiveness.
- 6.4. Based on the analysis in section § 5. above of the railway sector experience with the use of the CSM for monitoring, and of its effectiveness in section § 6., it can be concluded that the method is effective for achieving the objectives that are set out in its Article 1⁽³⁾.

7. Proposed recommendations

- 7.1. Although many stakeholders have actually understood the CSM for monitoring and correctly implemented the method, there is still a large number of stakeholders across the EU who still face difficulties with its understanding and correct implementation. The method is effective but three years since the date of application is a too short period of time for being able to “learn by doing”.
- 7.2. As the return of experience does not identify any justification for modifying the content of the CSM for monitoring :

- (a) the Agency does not recommend yet to revise the associated Regulation 1078/2012;
- (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 CSM for monitoring) and to help them achieving full compliance with the CSM for monitoring. *The dissemination programme will have to be developed and agreed separately.*
- 7.3. The Agency concludes also that this first measurement of the railway sector experience with the CSM for monitoring 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 with the understanding of the CSM for monitoring compared to those who are very advanced with risk management : refer to section § 6.3.
- 7.4. Consequently, given that both “monitoring and risk assessment” 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 monitoring” (i.e. Regulation 1078/2012) and “CSM for risk assessment” (i.e. Regulations 402/2013 and 2015/1136)] – [Why combining both? → refer to section § 7.7.], and to;
- (b) redo the collection of the return of experience with these two CSMs not later than 3 years after the delivery of the dissemination programme proposed in section § 7.2. 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 can 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.
- 7.5. Indeed, the most mature stakeholders report that the “monitoring process” and “risk assessment 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 immature in “thinking in terms of risk and risk based approach”.
- 7.6. 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 mislead conclusions that could result in unjustified revisions of the CSM for monitoring and CSM for risk assessment.
- 7.7. Why combining the collection of the REX with the CSMs for monitoring and risk assessment?**
- 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 NSA and ECM certification body eyes”, the Agency can also measure the return of the sector experience with these two CSMs;
- (c) the measurement of 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 thus the Agency to gather the necessary REX information through existing tasks of NSAs and ECM Certification Bodies, without asking them additional work.

8. Conclusions

- 8.1. To comply with the legislation, with the support of national safety authorities (NSAs) and ECM Certification Bodies, the Agency collected the return of experience of EU railway stakeholders on the (EU) Regulation 1078/2012 on the CSM for monitoring. The inputs are contained in ANNEX A.
- 8.2. The analysis of the stakeholders’ experience with the CSM shows that :
 - (a) it is not possible to provide a common and accurate picture for every country and every category of stakeholders in a country. There are different levels of understanding and different levels of implementation of the requirements from the CSM;
 - (b) many stakeholders, and in particular the ones more mature with the risk management concepts, have actually well understood and correctly implemented the method. Usually infrastructure managers (IMs), big railway undertakings (RUs) and many entities in charge of maintenance (ECMs) fall in this category. Their experience with the CSM is positive;
 - (c) nevertheless, there is still a large number of stakeholders across the EU who still face serious difficulties in understanding and correctly implementing the method. Usually small RUs, a part of ECMs, the 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;
 - (d) there is a number of countries or stakeholders who have not understood at all the CSM for monitoring and who have not implemented it;
 - (e) the experience varies also from country to country, as well as from stakeholder to stakeholder in the same country.
- 8.3. In general the following three main trends emerge in the replies. They are consistent throughout the different questions and they represent the experience of RUs, IMs and ECMs :
 - (a) stakeholders who have well understood and correctly implemented the CSM;
 - (b) stakeholders for whom the understanding and the implementation of the CSM were challenging but they are “learning by doing” and they are “continually improving” its use;

- (c) stakeholders who have not (yet) well understood, or have not understood at all, the CSM and who have not correctly implemented, or have not implemented at all, the CSM.

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

- (a) the CSM for monitoring is effective for achieving the objectives that are set out in Article 1 of the associated (EU) Regulation 1078/2012;
- (b) objective justifications are not yet identified which would require an urgent amendment or revision of the CSM for monitoring;
- (c) finally, a three year period of time since the date of application of the CSM is too short 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.

8.5. Therefore, the Agency has not identified any evidence for recommending yet the revision or amendment of the CSM for monitoring.

8.6. However, the Agency recommends :

- (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 monitoring;
- (b) as the effectiveness of each CSM depends on the correct implementation of the other CSM, any additional measurement of the return of experience needs to combine both the “CSM for monitoring” (i.e. Regulation 1078/2012) and “CSM for risk assessment” (i.e. Regulations 402/2013 and 2015/1136) – [*Why combining both? → refer to section § 7.7.*].

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 mislead conclusions that could result in unjustified revisions of the CSM for monitoring and CSM for risk assessment;

- (c) with the support of NSAs and ECM Certification Bodies, redo the measurement of effectiveness and experience with these two CSMs not later than 3 years after the delivery of that dissemination programme.
- (d) the results of such a return of experience can 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.

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

- A.1. This annex summarises the inputs of 12 NSAs and one ECM Certification Body to the questionnaire in ANNEX B below on the RU, IM and ECM experience with the use of the CSM for monitoring. 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 NSA and ECM certification body 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 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.
- A.5. ^(Q 1) **General RU, IM and ECM understanding of Regulation 1078/2012 on the CSM for monitoring :**
- (a) Understanding and correct implementation :**
- (1) Stakeholders (RUs, IMs, ECMs) having well understood and correctly implemented the CSM :
 - (i) Usually, IMs are those stakeholders who demonstrate a better understanding and implementation of the CSM;
 - (ii) ECMs are also largely compliant with the CSM, however findings are made on an ongoing basis in this area by both the ECM Certification Body surveillance in respect of freight wagons and also the NSA in respect of other types of ECMs in general;
 - (iii) in countries where the railway sector is more mature with risk management and the NSA is strong in supervision :
 - ↳ the overall picture is that both RUs and IMs do understand the substance of the CSM for monitoring. They are using monitoring for the evaluation of the effectiveness of their SMS and as an ongoing tool to take safety decisions;
 - ↳ the needs for monitoring through the SMS can be tracked back longer than 2013. But the entry into force of the CSM for monitoring seems to contribute to an increased focus of the companies on prioritising and describing more formally the monitoring activities and on a better documentation;
 - ↳ the use of action plans for achieving continual improvements is common and a well anchored practice in all companies;

- (iv) some replies report full compliance with the monitoring process in Article 3(2) of Regulation 1078/2012; others do not provide any further explanations;
 - (2) Stakeholders (RUs, IMs, ECMs) for whom the understanding and implementation of the CSM were challenging but are “learning by doing” and “continually improving” :
 - (i) although the understanding of the CSM requirements was a challenge, the stakeholders strengthened their awareness during the implementation of the associated provisions put in place in their (safety/maintenance) management system. The application of the CSM leads thus to (corrective) action plans that are being/going to be implemented;
 - (ii) for others, the CSM seems understood, but the implementation is progressing stepwise through the different layers of the organisational structures of companies. So, various levels of compliance with the CSM requirements subsist.
 - (3) Stakeholders (RUs, IMs and ECMs) having not (yet) well understood or not understood at all the CSM and thus having not correctly implemented the CSM :
 - (i) In countries more familiar with application of rules rather than with risk management, contrary to the IMs, RUs estimate that Regulation 1078/2012 is written in a very abstract way. This leads to difficulties in understanding and, put together with the lack of resources, to incorrect or incomplete implementation. Some RUs also have difficulties to make clearly a difference between the CSM for monitoring (i.e. Regulation 1078/2012) and the CSM for risk assessment (i.e. Regulation 402/2013);
 - (ii) Concerning ECMs certified according to ECM Regulation 445/2011, some of them estimate that due to redundancy of requirements for monitoring between the CSM and Annex III of the ECM Regulation 445/2011, the CSM for monitoring is wrongly implemented. Generally :
 - ↳ those ECMs are not aware of the CSM for monitoring and thus focus on the compliance with the monitoring requirements in Annex III of the ECM Regulation 445/2011, or;
 - ↳ when they are aware of the CSM for monitoring, they focus on monitoring only the sub-contractors;
 - (iii) Stakeholders not directly supervised by the NSA (e.g. suppliers) do not completely understand their monitoring obligations;
 - (4) Some stakeholders report that the knowledge and experience with the CSM for monitoring are not shared because often companies are in competition. They expect the “NSA to organise trainings/workshops on the CSM for monitoring in order to exchange experience”. Some NSAs have taken actions in that direction.
- (b) Used for checking the correct application and the effectiveness of the operational processes, procedures and risk control measures of the management system :**
- (1) Stakeholders (RUs, IMs, ECMs) having well understood and correctly implemented the CSM :
 - (i) all companies are using the CSM to check the correct application and the effectiveness of the operational processes, procedures and risk control measures of the management system;

- (ii) in countries where the railway sector (RUs, IMs, and ECMs) is more mature with risk management, internal reporting systems are well established in addition to sample internal auditing. They aim at checking the correct application and the effectiveness of the provisions in the management system;
 - (iii) in countries more familiar with application of rules rather than with risk management, contrary to the IMs, this is confirmed only for some big RUs;
- (2) Stakeholders who are still learning by doing : there is room for improvement :
- (i) In some countries, the monitoring focuses mostly on checking the correct implementation of operational processes and procedures of the management system. But, the monitoring activities give less focus on checking their effectiveness;
 - (ii) The processes and procedures of the management system seem to be monitored. Only a few RUs include also the check of effectiveness of risk control measures identified through risk assessments;
 - (iii) In some countries, the majority of RUs and IMs do not perform what is expected;
 - (iv) Sometimes, there is no proper analysis of usefulness of the monitoring activities or of the collected information. Consequently, monitoring seems to be reactive and limited to corrective actions rather than being proactive and preventing incidents or accidents;
- (3) Stakeholders (RUs, IMs and ECMs) having not (yet) well understood or not understood at all the CSM and thus having not correctly implemented the CSM :

The monitoring does not actually check the correct application and the effectiveness of the operational processes, procedures and risk control measures of the management system;

(c) Use of qualitative and quantitative indicators :

- (1) With the exception of those stakeholders who have not well understood and correctly implemented the CSM, almost all replies confirm the use of both qualitative and quantitative indicators, in particular by IMs and ECMs. Examples of qualitative and quantitative indicators are given in the replies;
- (2) Just a few replies report that it depends on the company. Usually, they are largely used only by big RUs;
- (3) One reply reports they are practically never used;

(d) Balance between the use of qualitative and quantitative indicators :

- (1) As it is dependent on the company, it is difficult to give a global overview. However, the majority of replies reports that the quantitative indicators are more commonly used, for example “key safety indicators”, in particular in countries and by stakeholders more advanced with the concept of risk management;
- (2) Some replies report a balance between Qualitative and Quantitative of 50% - 50 %, others of 25 % - 75 %, others a range from 20 % to 70 % for qualitative indicators;
- (3) Countries and stakeholders less familiar with the concept of risk management, seem to be more in favour of qualitative indicators;
- (4) Some countries do not have (objective) data available, since the method is not correctly implemented, or they do not have information for all types of stakeholders; the sector is still learning by doing and improving;

(e) Way the monitoring indicators are defined :

- (1) Although the setting of qualitative and quantitative indicators is based on both technical expertise and outcomes of risk assessments, technical expertise of the company seems to be predominant, in particular in countries and by stakeholders less familiar with the concept of risk management;
- (2) Use of technical expertise seems to be privileged for defining monitoring indicators in the field of Rolling Stock maintenance;
- (3) Big companies, as well as countries and stakeholders more advanced with the concept of risk management, seem to define the monitoring indicators mostly based on risk assessments, occurrence reporting on accidents and incidents, and risk registers that reflect the organisational and asset based risks;

(f) Documentary evidence of monitoring activities - Level of detail and traceability with respect to the management system :

- (1) As point 7 in the Annex of the CSM sets the minimum requirements, there is a lot of flexibility. Every company has its own system, specific to the size, complexity and management system of the company, for documenting the monitoring activities. The more mature the management system is the better the documentary evidence and traceability are. The following is reported from countries or companies more mature in monitoring activities :
 - (i) Some quite advanced companies use a “live” IT databases to log in detail the identified non-compliances and statistics, e.g. on accidents and incidents, including the responsible employee and structural unit with the description of its role within the implementation of the measures of the action plans;
 - (ii) Other companies use meeting minutes, risk register (databases) and other tracking sheets for reporting internally to the various layers of the organisational structure of the company;
 - (iii) Audits are documented in audit reports and audit findings are tracked until they are fully closed;
 - (iv) Written notes, identified non-conformities or non-compliances, observations, and action plans are produced. Regular reviews are held to track the progress with the implementation of the measures in the action plans. This documentary evidence is recorded and can be traced through quality system provisions (compliant with the ISO 9001 standard for some companies) to the management system;
 - (v) There is progression towards more appropriate traceability vs. the management system prescriptions;
- (2) Some replies report that the sector is learning by doing. There is thus room for improvement. The development of the documentary evidence is continually improving;
- (3) The level of details depends on the non-compliances identified during the previous monitoring cycle (inspections/audits);
- (4) Companies that do not understand the CSM do not have appropriate documentation as they have not implemented the CSM correctly;

A.6. (Q2) Variations of strategies used for monitoring the company safety performance :

(a) Monitoring is an integrated part of the management system used to check the effectiveness of the company processes and procedures in achieving the planned safety performance or, on the contrary, it is separate from the management system :

- (1) Stakeholders (RUs, IMs, ECMs) having well understood and correctly implemented the CSM :
 - (i) In countries where the railway sector is more mature with risk management, to a large extent monitoring is entirely imbedded within the organisations' combined or integrated management systems (e.g. a single management system where ISO 9001 and Reg. 1078/2012 are integrated);
 - (ii) In countries more familiar with application of rules rather than with risk management, for the IMs and certified ECMs the monitoring is also an integrated part of the management system. For certified ECMs, the redundancy of monitoring requirements between Regulations 1078/2012 and 445/2011 prevents separate implementations of the monitoring activities;
 - (iii) Some countries not yet entirely familiar with risk management report also that monitoring is part of the management system, although some companies have procedures dedicated to monitoring;
- (2) Stakeholders still learning by doing and improving the implementation of the CSM intend to integrate their monitoring activities into their management systems;
- (3) Stakeholders having not (yet) well understood or not understood at all the CSM, have not yet correctly implemented the CSM :
 - (i) Those stakeholders intend to incorporate the monitoring activities as part of the management system;
 - (ii) In some countries more familiar with the application of rules, the RUs estimate that the formal separation of monitoring requirements between Regulations 1078/2012 and 1158/2010 makes the understanding difficult. Their opinion is that Regulation 1078/2012 is written in a very abstract and theoretical way. It does not support an adequate and practical implementation of monitoring activities. In those countries, the RUs think that it would be good/advantageous to integrate the monitoring requirements into the general requirements of the SMS;

(b) Basis used for the development of the monitoring strategy :

- (1) Stakeholders (RUs, IMs, ECMs) having well understood and correctly implemented the CSM :
 - (i) The monitoring strategy is developed based on the company documentation describing the processes, procedures and risk control measures of the management system, as well as on the results of internal and external audits (e.g. non-compliances identified by the NSA or ECM Certification Body during regular supervision/surveillance activities);
 - (ii) In countries where the railway sector is more mature with risk management, the monitoring strategy is also based on the analysis of accident or incident trends, where relevant data from statistics, results of risk assessments, internal audits of the entire management system and management reviews. The internal monitoring

audits do not target 100 % of the processes and procedures of the management system; they are risk oriented and focus to the areas with the greatest risks.

It is to note that in some of those countries, although for most of the companies the managers have more or less well defined thoughts about the approach to monitoring, only a few companies have actually an explicit or written strategy for monitoring. The reasons for the lack of an overall formalised monitoring strategy are partly due to the need for a comprehensive knowledge of all the operational activities of the company by the company management and partly the traditional areas of focus for monitoring, i.e. incidents, accidents and internal audits on processes and procedures;

- (2) Stakeholders who are still learning by doing are continually improving the implementation of the CSM. They are improving their monitoring strategy based on the gained experience;
 - (3) Stakeholders having not (yet) well understood or not understood at all the CSM, have not yet correctly implemented the CSM :
 - (i) They usually do not have a proactive and preventive system in place. Monitoring is mainly reactive; corrective measures are taken to avoid the occurrence of similar accidents/incidents in future;
 - (ii) In countries more familiar with the application of rules, the RUs have difficulties in defining their monitoring strategy;
- (c) Monitoring strategy : prioritisation/focus on the areas of greatest risk or monitoring with the same efforts of all operational processes, procedures and risk control measures of the management system :**

- (1) Stakeholders (RUs, IMs, ECMs) having well understood and correctly implemented the CSM :
 - (i) Some stakeholders, or some countries, do not prioritise. They monitor equally all operational processes, procedures and risk control measures of the management system, regardless of whether the activity is of high or low risk. However, in some companies or countries, the risk based approach and the targeting to areas of greatest risk is gaining ground;
 - (ii) Others, usually IMs and ECMs, focus the monitoring to areas of greatest risk. This prioritisation is based on the results and experience of previous monitoring cycles. The monitoring frequency depends on risk severity, e.g. high operational speed;
- (2) Stakeholders who are still learning by doing are continually improving the implementation of the CSM.

Although the monitoring seems not to be prioritised but covers all processes, procedures and risk control measures of the management system, in practice those stakeholders are improving their understanding and implementation of the CSM based on the gained experience. Monitoring is carried out in two steps :

- (i) A one year monitoring exercise covering all provisions of the management system;
 - (ii) Then monitoring focusses on areas with a higher level of risk;
- (3) Stakeholders having not (yet) well understood or not understood at all the CSM :

- (i) In countries more familiar with the application of rules, the RUs have difficulties in prioritising the monitoring to areas of greatest risk. They monitor equally all operational processes, procedures and risk control measures of the management system are monitored equally;
- (ii) Efforts were made to try prioritising the monitoring to areas of greater risk but all processes and procedures with high level of risk are not necessarily identified. There are thus gaps in the monitoring activities.
- (iii) Some companies emphasise more on occupational health and safety provisions;
- (iv) Others have not yet correctly implemented the CSM and focus the monitoring just to sub-contracted activities;

(d) Proactive/leading, reactive/lagging or both approaches to monitoring :

- (1) Stakeholders (RUs, IMs, ECMs) having well understood and correctly implemented the CSM :

In addition to the reactive monitoring approach which investigates accidents, incidents and other dangerous occurrences, to identify the reasons and setup action plans preventing them to happen again in future, monitoring is essentially proactive or leading intended to prevent the occurrence of such dangerous situations. This is also the experience of IMs and ECMs in the countries more familiar with the application of rules;

- (2) Stakeholders who are still learning by doing are continually improving the implementation of the CSM, based on the gained experience :

- (i) Although the state of play is still reactive/lagging monitoring, mainly due to a short experience (CSM is applicable since 7 June 2013) the NSAs perceive some signs of establishment of proactive/leading monitoring activities/approaches;
- (ii) Although proactive monitoring might be in place in all companies, there is a difference between companies :

- ↳ Bigger companies have a proactive monitoring approach based on risk evaluation and assessments, whereas;
- ↳ Smaller companies use rather reactive strategies and rely on finding out the root causes via accident/incident investigation to develop their monitoring strategy and move towards a preventive approach;

- (3) Stakeholders having not (yet) well understood or not understood at all the CSM :

- (i) A few countries or stakeholders only have in place reactive monitoring;
- (ii) In some countries more familiar with the application of rules, the RUs have difficulties in separating the two concepts. There is not clear information available;
- (iii) Small RUs do not have enough resources for implementing the CSM, including proactive monitoring activities;
- (iv) Others have not implemented the CSM at all;

(e) Criteria used for the prioritisation of monitoring activities :

- (1) The stakeholders in point (c) above who do not prioritise but, regardless of whether the activity is of high or low risk, monitor equally all operational processes, procedures and risk control measures of the management system, do not have and do not use specific criteria. The criterion seems to be the impact of the activity on the safety;

- (2) The stakeholders in point (c) above who prioritise the monitoring activities determine the areas on which to focus based on :
 - (i) Results from risk assessments with regard to people;
 - (ii) The safety relevance of the activities of the company and the estimation of the severity of the consequence (e.g. high operational speed);
 - (iii) The analysis of statistics and risk registers;
 - (iv) Indicators the company management considers as valuable knowledge for the company operations;
 - (v) The experience gained during previous monitoring activities;
 - (3) One country reported the use of following criteria for prioritising the monitoring activities :
 - (i) the main safety objectives set out in the management system, focused on reduction of occurrences, skill improvement and increase of the employees' awareness;
 - (ii) operational areas where lack of effective monitoring leads to negative consequences;
 - (iii) monitoring of safety objectives not completed during the previous years;
 - (iv) threats with uncontrolled or poorly controlled risks;
 - (v) threats with slightly reduced risks;
 - (vi) results and non-conformities identified during previous monitoring cycles (e.g. results from internal and external audits);
 - (4) Stakeholders having not (yet) well understood or not understood at all the CSM : refer to point (c)(3) above;
- (f) Sufficiency of resources for monitoring – Understanding of the roles and responsibilities :**
- (1) Stakeholders (RUs, IMs, ECMs) having well understood and correctly implemented the CSM :
 - (i) Although in some cases human, physical means and financial resources for monitoring are kept confidential, the companies seem to allocate enough resources to monitoring activities, including the IMs and ECMs of the countries more familiar with the application of rules;
 - (ii) In some (smaller) companies, resources for monitoring are tight but not to the extent of not being able to comply with the monitoring requirements and objectives;
 - (iii) The roles and responsibilities of the staff taking part to monitoring seem also to be clearly defined and understood;
 - (2) Stakeholders still learning by doing and improving the implementation of the CSM :
 - (i) Some companies are not able to carry out their internal audits according to their plans;
 - (ii) The understanding is constantly developing and the CSM implementation is improving;
 - (iii) Small companies report not having enough resources for implementing a continuous monitoring;
 - (3) Stakeholders having not (yet) well understood or not understood at all the CSM, have not yet correctly implemented the CSM :
 - (i) In countries more familiar with application of rules rather than with risk management, contrary to the IMs, RUs estimate that Regulation 1078/2012 is

written in a very abstract way. This leads to difficulties in understanding and, put together with lack of resources, to incorrect or incomplete implementation of the CSM. There is thus neither assurance that sufficient resources are allocated to monitoring activities nor that the roles and responsibilities are clearly defined and understood;

- (ii) Small RUs do not have enough resources for implementing the CSM;
- (iii) Others have not implemented the CSM at all;

(g) Organisation of monitoring across the company – Dedicated staff for monitoring or on the contrary, monitoring is shared among the staff :

- (1) Although other resources might be involved in collecting monitoring data, monitoring seems not to involve the whole staff of the company;
- (2) Two main trends can be found :
 - (i) either, the middle management and the top management are responsible for defining the monitoring policy and the monitoring strategy. They also review the results from monitoring (management reviews) and adopt the necessary action plans and priorities in case of detection of non-compliances. But they might be supported by some specialised individuals for managing the monitoring process, deploying the monitoring strategy, collecting monitoring data and analysing the results;
 - (ii) or, the complete implementation of the monitoring strategy and process is under the responsibility of (a few) specialised individuals of the company, usually within the departments/units dealing with safety-relevant tasks/activities;
- (3) Depending on the size of the company :
 - (i) For many big companies, the monitoring activities are anchored and organised through the safety department of the company;
 - (ii) For many small companies, the monitoring is under the single responsibility of a Safety Manager (i.e. one person);
- (4) When integrated management systems are in place (e.g. ISO 9001 QMS), monitoring can be combined with other types of surveillance (protection of workers, environmental protection, fire protection, etc.);
- (5) For less mature companies, monitoring seems to consist only of an internal and an external audit once a year;
- (6) The stakeholders who have not (yet) well understood or have not understood at all the CSM, do neither comply with the CSM nor have a clear definition of roles and responsibilities for monitoring. In some countries more familiar with the application of rules, the RUs have difficulties in putting in place the CSM for monitoring and allocating the roles and responsibilities throughout the organisational structure of the company;

(h) Approval by the NSA (or ECM certification body for ECMs) of the action plan before its implementation :

- (1) In general, the action plans resulting from monitoring activities are never submitted to the NSA (or ECM certification body for ECMs) for approval, unless it is requested by the NSA;
- (2) Usually, the stakeholders (RUs, IMs, ECMs) submit to the certification body (NSA or ECM Certification Body) only the action plans that are related to non-conformities identified

during supervision/surveillance of the management system by the NSA/ECM Certification Body;

- (3) In general, the NSAs/ECM Certification Bodies build the overall picture on the effectiveness of action plans during the supervision/surveillance activities of the RU/IM/ECM management system (where those action plans can also be discussed) and through the annual reports;
- (4) In some countries, the IM transmits an action plan to the NSA exceptionally (e.g. consecutively to major accidents) in case important measures need to be taken;

(i) Reporting to the NSA/ECM certification body for ECMs about CSM for monitoring :

- (1) The RUs/IMs/ECMs provide an Annual Report to the NSA/ECM certification body according to the EU legislation. But the quality of the report varies a lot in function of the company; it contains general information. It is thus difficult to get a good picture of the company compliance with the CSM for monitoring based just on the Annual Report;
- (2) Usually, the information gathered during regular supervision/surveillance activities of the RU/IM/ECM management system is the main basis for the NSA/ECM Certification Body understanding of the RU/IM/ECM monitoring activities. The NSA/ECM Certification Body can then cross-check on the ground the information contained in the report. Annual Reports may just form an additional source of information;

A.7. ^(Q3) Overall effectiveness of the CSM, measurement of the maturity of companies and improvement of use of the CSM :

In some countries more familiar with application of rules rather than with risk management, it is difficult to build an overall picture for all RUs on the overall effectiveness, the measurement of the maturity with the use of the CSM and the improvement of its use. The experience varies from case to case.

(a) Where indicators are used, level at which they are set and indicator use for cost/effort optimisation :

- (1) Many NSAs and ECM Certification Bodies who replied do neither have information on whether the indicators are set at the right level nor whether they are used to optimise the costs/efforts of the monitoring activities;
- (2) The other replies, report that in general the indicators seem to be set at the right level. But they do not aim at optimising the monitoring costs/efforts. The indicators seem also to be used for the continual improvement of the management system;
- (3) Although the indicators are setup and primarily focussed on :
 - (i) monitoring the safety performance achievement, the infrastructure conditions and the status of the rolling stock;
 - (ii) monitoring the avoidance of accidents, incidents and some precursor events;

the NSAs/ECM Certification Bodies do not have clear and sufficient information to confirm whether this is sufficient. They would require more detailed knowledge and analysis before replying accurately to the question;

- (4) Usually the NSA/ECM Certification Body does not have information regarding the optimisation of the monitoring costs/efforts. It is not the focus of the NSA/ECM Certification Body supervision/surveillance activities. Some inputs seem nevertheless to

show that ECMs are using the monitoring indicators also to optimise the monitoring costs/efforts;

(b) Implementation of necessary action plans and verification of their effectiveness :

Of course, there is no common answer to this question which would be applicable either for every country or for every stakeholder in a country.

- (1) In general, the (risk control) measures defined in the action plans are implemented to correct the instances of non-compliance identified by the monitoring activities. However, although in some countries, or in some companies, the effectiveness of the measures proposed in the action plans is actually verified, usually there is no check of effectiveness of the action plans. These two variations can be observed during supervision/surveillance of the RU/IM/ECM management system. When the NSA/ECM Certification Body finds a non-compliance, the NSA request the company to set up an action plan;
- (2) Sometimes, although corrective and preventive measures are actually taken, formal and documented action plans are not systematically produced and thus, their effectiveness is not always verified;
- (3) Some stakeholders more mature with risk management consider the monitoring of the management system not separable from the risk assessment and risk management process. They have a strong link between the monitoring activities, the action plans resulting from monitoring and the risk management to manage effectively the identified instances of non-compliance.

The corrective and/or preventive measures of the action plans are based on risk assessments related to the identified non-compliances. Those companies regularly assess their respective action plans and apply the risk management processes to ensure that the action plans are up to date and reflect the actual situation within the management system of the company;

- (4) For the stakeholders having not (yet) well understood or not understood at all the CSM, action plans and checks of its effectiveness cannot be found;

(c) Improvement of the experience with the CSM between 2013 (year of application) and 2016 :

- (1) There is a slight increase of the understanding and a progressive improvement with the implementation of the CSM;
- (2) In the countries, and for the stakeholders, not yet fully familiar with risk management, a three year period is too short to be able to measure a visible improvement. Although some companies needed more time to implement the CSM, the regulation is gradually getting understood and correctly implemented;
- (3) Some stakeholders/countries more mature with risk management have gained a good overview regarding the indicators to be used, and thus the information that needs to be collected and analysed. Those stakeholders became well prepared for an improved compliance with the CSM. The NSA opinion is that those companies with greater expertise have implemented, and improved, a more mature management system. The most mature companies have even progressed towards integrated monitoring and management systems (e.g. combining monitoring of safety and quality) with more prioritised monitoring activities;
- (4) For the stakeholders having not (yet) well understood or not understood at all the CSM, there is even no sign of a qualitative improvement of the understanding and implementation of the CSM;

(d) Use of the experience with the monitoring to review and adjust the monitoring strategy, priorities and plans for the following year :

- (1) In general, the results from the monitoring activities are reused by the companies to review and adjust the strategy, priorities and plans for the monitoring of the year after. Although some companies are better than others (e.g. management reviews are systematic and priorities and decisions are taken on a yearly basis), there is still room for improvement;
- (2) Some companies acknowledge that the risk management and risk monitoring concepts are new. They need time to improve the analysis of the information collected through the monitoring and to find the areas for improvement or readjustment of the priorities and monitoring strategy;
- (3) For similar reasons, even some companies/countries more mature with risk management do not undertake large-scale changes of monitoring priorities and strategy, unless it is necessary to correct serious weaknesses in the monitoring activities. They want to avoid increasing existing risks or giving rise to new risks;
- (4) For the stakeholders having not (yet) well understood or not understood at all the CSM, and thus having not implemented it yet or correctly, it is premature to speak about review and adjustment of the monitoring strategy, priorities and plans for the next year. The CSM needs to be implemented;

(e) Perception of the monitoring : “an active tool to optimise the company business costs” or “just an obligation for complying with the legislation” :

- (1) In general, the stakeholders perceive the monitoring only as a legal obligation. This shows an insufficient stakeholder awareness of the importance of an effective monitoring system;
- (2) In general, as reported in point (a) above, the NSA and ECM Certification Bodies do not have information concerning the costs of monitoring;
- (3) Although there are exceptions, the stakeholder maturity with risk management and management systems is not yet at a level where monitoring would be used as an active tool for optimising the company costs. Therefore, the majority of stakeholders does not yet see that the combination of monitoring and risk assessment constitutes a powerful tool for both optimising the business costs and stimulating the railway competition;
- (4) Although monitoring is not yet considered as an opportunity for business improvement, some progress is being observed towards business optimisation. For example, some big companies with sufficient staff power are trying to fit the safety performance monitoring within their overall strategic planning and decision making process;
- (5) Specifically, concerning the perception of ECMs :
 - (i) initially most of ECMs perceived the CSM just as a legal obligation;
 - (ii) now the understanding is slowly rising that an effective monitoring can also bring economic advantages;
 - (iii) the “abstract monitoring process” described in the CSM is not a European invention. Comparable methods can be found in other management system requirements;

A.8. (Q 4) Sharing of information identified during the monitoring :

(a) Contractual arrangements for monitoring the safety performance of subcontractors : directly by the stakeholders or contractors reporting on the application of the CSM :

- (1) Although the contractors might be requested to communicate various safety documents or information (e.g. safety policy, training records for staff, etc.), the stakeholders do not request their contractors to implement the CSM within their organisations. So, the contractors do not need to report on the implementation of the CSM;
 - (2) In general, the RUs/IMs/ECMs monitor the safety performance of their contractors, and the correct execution of the contracted tasks. This is usually achieved by dedicated processes imbedded in the RU/IM/ECM management system. When the RU/IM/ECM identifies non-conformities it tracks their correct implementation by the contractor/supplier;
 - (3) Usually, all contractors/suppliers are not systematically inspected/audited. It is more on a sampling basis, but all contractors/suppliers would be checked from time to time;
 - (4) The inspections/audits are simplified when the contractors are certified according to EU legislation or ISO/IEC standards (e.g. maintenance workshops of freight wagons which are certified vs. the ECM Regulation 445/2011);
 - (5) One country reported the use of following methods for the contractors/suppliers monitoring :
 - (i) evaluation of suppliers;
 - (ii) a list of qualified suppliers (contractor ranking);
 - (iii) audit of suppliers and contractors;
 - (iv) formal acceptance of work/service performed by contractors;
 - (v) legal provisions in the agreements regarding the exchange of information related to safety (in particular dealing with risk) and current supervision over the outsourced services;
- (b) Actions undertaken when identifying non-compliances within the area of responsibility of another actor - Inform directly the right stakeholder or just report to the NSA :**
- (1) The non-conformities are almost never reported to the NSA/ECM Certification Body;
 - (2) The non-conformities are communicated directly to the right stakeholder who is requested to take the necessary corrective/preventive actions. If the contractor does not implement them, the RU/IM/ECM might break the business relationship;
 - (3) If the RU/IM/ECM considers the non-conformities serious, the contractor may be removed from an approved list of contractors;
 - (4) In exceptional cases, the non-conformities are communicated to the NSA. If there are serious disagreements between the RU/IM and the contractor/supplier, the RU/IM might involve/contact the NSA who in this case would help to find a consensus (arbitration);
 - (5) In general, there is a lack of sharing of knowledge and experience among the stakeholders because they compete with each other;
- (c) Specific actions taken concerning defects and construction non-conformities or malfunctions of technical equipment :**
- (1) The question has not fully been understood. The survey seek whether the manufacturer of the technical equipment is informed about its defects and construction non-conformities or malfunctions;
 - (2) With the exception of one reply, there is no explicit indication that the manufacturer of the technical system is informed about the defects unless specific contractual arrangements are in place between the RU/IM/ECM and the manufacturer;

- (3) If the manufacturer is considered as a contractor, then the information in point (b) above is applicable;
- (4) Regardless whether the manufacturer is involved or not, the RU/IM/ECM manages the non-conformities of the technical equipment until the necessary corrective-preventive actions are implemented to keep the railway system safe;
- (5) Depending on the organisation of the company (e.g. a central company with regional units), the defects and construction non-conformities or malfunctions of technical equipment are also shared through the organisational structure of the company;
- (6) In some countries, it is mandatory that all companies report to the NSA the defects and non-conformities of technical equipment which are critical for the railway safety. The NSA spreads then those non-conformities through the Safety Information System (SIS). Problems are also discussed during Safety Monitoring Group Meetings with RUs, IMs, ECMs, suppliers, etc.

A.9. ^(Q5) Observed differences between companies :

(a) Differences between big and small railway companies in understanding the CSM and in correctly implementing it :

Although big companies can afford allocating more resources to monitoring activities than the small companies, the size of the company is not always the (only) determining parameter. Usually big companies have quite high ambitions concerning the monitoring system whereas small companies have both quite modest ambitions but also smaller needs :

- (1) Some replies report there is not any observed difference in function of the company size;
- (2) Frequently, small RUs face more problems regarding the resources they are capable to allocate to the monitoring activities :
 - (i) They face a workload which is difficult to deal with because usually the same staff is responsible also for other activities within the company;
 - (ii) For some small companies, monitoring activities are limited to periodic risk assessments, inspections, audits and management reviews. They do not use monitoring indicators at a large scale whereas this is usually the case within big companies;
 - (iii) As reported in previous points, some smaller companies have rather reactive strategies : they are learning from the results of monitoring. They rely on finding out the root causes via accident/incident investigation to develop their monitoring strategy and move towards a preventive approach;
 - (iv) Nevertheless, other replies report that small companies with limited operational scopes have simpler management systems and monitoring processes. The monitoring processes are well-established and made proportionate to the limited scope of their operations;
- (3) Big companies usually have better and proactive monitoring systems, with defined objectives. However, being dispersed (e.g. a central company with regional units), they are facing different challenges due to the complexity of their organisations and more complex management systems. So, they are still at a very early stage of implementation of the CSM and need still to improve;
- (4) For the IMs, there is no fundamental difference between big and small companies;

- (5) For the ECMs, usually the size of the company is of minor relevance. The most important parameter is the management commitment in allocating the necessary staff and financial resources for the establishment of an effective monitoring system;
- (6) Finally, companies where risks are high (e.g. transport of dangerous goods) pay more attention to monitoring. Their monitoring process is relatively more extensive.

(b) Differences between former incumbent and newcomer railway companies in understanding the CSM and in correctly implementing it :

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

- (1) Some replies report having not found any difference with newcomer railway companies;
- (2) In countries more familiar with the application of rules rather than with risk management :
 - (i) contrary to the IMs, newcomer RUs seem to have even more difficulties than the former incumbent railways in understanding and implementing abstract and theoretical requirements of the CSM into a practical safety organisation;
 - (ii) although the new comer 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;
- (3) In some countries more mature with risk management, big differences in knowledge, understanding and implementation of the CSM have not been observed.
An example is given of an ambitious newcomer (a light rail-metro operator) which implemented the CSM at a quite high level. The monitoring activities are well prioritised proportionately to the company scope of operation and management system. The results from monitoring are then fed back into the decision-making processes of the company management system;
- (4) The same general differences as in point (a) above are reported again. Big companies can afford allocating more resources to monitoring activities whereas small companies have less resources for monitoring. Usually, small companies have less complex organisations and management systems which require simpler monitoring processes due to a limited scope of operation.

ANNEX B : Questionnaire

Gathering of Return of Experience (REX) with the use of the CSM for monitoring (Regulation 1078/2012)

LEGAL BASIS - OBJECTIVES

This questionnaire is the first step to address the requirements that are set out in Article 5 of Regulation 1078/2012 on the CSM for monitoring 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 implementation and effectiveness of Regulation 1078/2012. The NSA and ECM certification body replies to the questionnaire should help building a representative picture of the return of experience and identifying, where necessary, areas for improvement of the legal text or of the associated application guideline.

At a second step, the Agency will organise a workshop with all involved NSAs and ECM certification bodies to share their opinions, identify recommendations (e.g. if applicable, necessary action plans) and build a report on the CSM for monitoring. The workshop should be held in autumn 2016 following the analysis of all received inputs.

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

*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 and ECM certification body may provide a representative picture of the overall sector experience with the use and implementation of that Regulation. **If the NSA or ECM certification 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 Regulation 1078/2012.*

Replies to this questionnaire are to be returned to the Agency by at latest 31 October 2016.

There is no imposed form or template for replying the questions. The NSAs and ECM certification 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.

QUESTIONNAIRE

Remark : only for countries where the NSA acts as ECM certification body, the NSA should also provide the experience of entities in charge of maintenance of freight wagons with Regulation 1078/2012.

Q 1. What is the general understanding of railway undertakings (RUs), infrastructure managers (IMs) and entities in charge of maintenance of freight wagons (ECMs) concerning the Regulation 1078/2012 on the CSM for monitoring?

- (a) Is it well understood and correctly implemented? Please describe.
- (b) Does monitoring actually check the correct application and the effectiveness of the operational processes, procedures and risk control measures of the management system?
- (c) Are qualitative and quantitative indicators used for monitoring?
- (d) What is the balance between the use of qualitative and quantitative indicators?
- (e) How are indicators defined (based on technical expertise or on outcomes of risk assessments)?
- (f) How are monitoring activities documented (level of detail and traceability with respect to the management system of the documentary evidence)?

Q 2. Describe the variations of strategies used by companies for monitoring their safety performance :

- (a) Is implementation of Regulation 1078/2012 separate from the management system or on the contrary monitoring is an integrated part of the management system used to check the effectiveness of the company processes and procedures in achieving the planned safety performance?
- (b) What is the basis for the development of the monitoring strategy : company documentation, statistic data, analysis of accident or incident trends, internal audits of entire management system, all processes and procedures of the management system, management reviews, others?
- (c) Is monitoring focussed on the areas of greatest risk (i.e. prioritised) or on the contrary are all operational processes, procedures and risk control measures of the management system monitored with the same effort?
- (d) Is monitoring done proactively to prevent dangerous situations to occur, or on the contrary, is it reactive where investigations are done to identify the reasons for the dangerous situations and action plans are defined to prevent them to happen again in future?
- (e) When prioritised, what criteria are used for the prioritisation?
- (f) Are enough resources allocated to monitoring activities? Are the roles and responsibilities clearly defined and understood?
- (g) How is monitoring organised across the company? Is it a duty of everyone or just the task of a few specialised individuals?
- (h) Are the action plans systematically submitted to NSA (to the ECM certification body for ECMs) agreement before their implementation?

- (i) 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?

Q 3. Indication of the overall effectiveness, measurement of the maturity and improvement of use of Regulation 1078/2012 :

- (a) Where indicators are used, are they set at the right level (i.e. well targeted) and are they used to optimise the monitoring costs/efforts?
- (b) Are action plans implemented to manage the identified non-compliances and is the effectiveness of those plans verified by the companies?
- (c) Is there a measurable difference between 2013 (when the method became mandatory) and 2016, i.e. three years after its date of application?
- (d) Are results from monitoring reused to review and adjust the strategy, priorities and plans for monitoring of the year after?
- (e) Is monitoring used as an active tool to optimise the company business costs, or on the contrary is it seen as an obligation which is applied only for fulfilling the legal obligations?

Q 4. Sharing of information identified during the monitoring :

- (a) How do companies monitor the safety performance of their contractors? What are the contractual arrangements? Do they monitor themselves the contractors or are they asking the contractors to report on the application of Reg. 1078/2012?
- (b) What actions are undertaken when identifying non-compliances within the area of responsibility of another actor? Do they inform the right stakeholder directly or do they just report to the NSA?
- (c) Are specific actions taken concerning defects and construction non-conformities or malfunctions of technical equipment? Who is informed about it?

Q 5. What differences between companies do you observe?

- (a) Between big and small railway companies?
- (b) Between former incumbent and newcomer railway companies?