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# Roles, use of data, governance and confidentiality for COR Safety Management Data

COMMON OCCURRENCE REPORTING PROGRAMME

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### 2. References, definitions and abbreviations

### **2.1.** Reference Documents

#### Table 1 Table of Reference Documents

[Ref. N°] Title	Reference	Version
<ol> <li>Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety (recast)</li> </ol>	f 2016/798	OJ: L138/102 of 26/05/2016
<ul> <li>[2] Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (recast)</li> </ul>	f 2016/797	OJ: L138/44 of 26/05/2016
[3] Regulation (EU) 2016/796 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Railways and repealing Regulation (EC) N° 881/2004		OJ: L138 of 26/05/2016
[4] Commission Regulation (EU) No 1077/2012 of 16 November 2012 on a common safety method for supervision by national safety authorities after issuing a safety certificate or safety authorisation	er 1077/2012	OJ: L320/3 of 17/11/2012
[5] Commission Regulation (EU) No 1078/2012 of 16 November 2012 on the common safety method for monitoring to be applied by railway undertakings, infrastructure managers after receiving a safety certificate or safety authorisation and entities in charge of maintenance	1078/2012	OJ: L320/8 of 17/11/2012
[6] Commission Regulation (EU) No 1169/2010 of 10 December 2010 on a common safety method for assessing conformity with the requirements for obtaining a railway safety authorisation	1169/2010	OJ: L327/13 of 11/12/2010
<ul> <li>[7] Commission Regulation (EU) No 1158/2010 of 9 December 2010 on a common safety method for assessing conformity with the requirements for obtaining a railway safety certificate</li> </ul>	1158/2010	OJ: L326/11 of 10/12/2010
[8] Commission Directive 2014/88/EU of 9 July 2014 amending Directive 2004/49/EC of the European Parliament and of the Council as regards common safety indicators and common methods of calculating accident costs Text with EEA relevance	2014/88/EU	OJ:L201/9 of 10/7/2014
[9] Commission Regulation (EU) No 445/2011 of 10 May 2011 on a system of certification of entities in charge of maintenance for freight wagons and amending Regulation (EC) No 653/2007 (Text with EEA relevance)	445/2011/EU	OJ: L122/22 of 11/5/2011
[10] Commission Implementing Regulation (EU) No 402/2013 of 30 April 2013 on the common safety method for risk evaluation and assessment	402/2013	OJ: L 121/8 of 3/5/2013
[11] Directive 2008/68/EC of the European Parliament and of the council of 24 September 2008 on the inland transport of dangerous goods	4 2008/68	OJ : L260/13 of 30/9/2008
<ul> <li>[12] Regulation concerning the International Carriage of Dangerous Goods by Rail (<u>RID</u>) (Appendix C to the Convention concerning International Carriag by Rail and its annex)</li> </ul>		2015
[13] DNV-GL Study – Review of Data quality and approach of the Agency annual report on safety		2015-12-09
[14] <u>COR project plan</u>	Project Plan ERA-PRG004	V1.0

### 2.2. Definitions and Abbreviations

#### 2.2.1. Standard Terms and Abbreviations

The general terms and abbreviations used in the present document can be found in a standard dictionary. Furthermore, a glossary of railway terms that focuses primarily on safety and interoperability terminology, but also on other areas that the Agency can use in its day-to-day activities as well as in its Workgroups for the development of future publications, is available on the Agency <u>website</u>.

### 2.2.2. Specific Terms and Abbreviations

#### Table 2 Table of Terms

Term	Definition
Agency	The European Union Agency for Railways such as established by the Regulation (EC) No 2016/796 of the European Parliament and of the Council of 11 May 2016
Hazard	A condition that could lead to an accident (Art.3.(13) of Regulation (EU) $402/2013 - CSM$ for Risk Assessment).
Monitoring	The arrangements put in place by railway undertakings, infrastructure managers or entities in charge of maintenance to check their management system is correctly applied and effective. (Art. 2.(b) of Regulation (EU) 1078/2012 [5] - CSM on monitoring)
TDG Competent Authority	Competent authority as defined in the RID [12]
Risk	The frequency of occurrence of accidents and incidents resulting in harm (caused by a hazard) and the degree of severity of that harm. (Art.3.(1) of Regulation (EU) $402/2013 - CSM$ for risk assessment)
Raw data	Data as input in a database (in a company, national or COR system), whether or not they have been checked regarding their completeness and quality
Analysed data	Data that been analysed following an analysis process (a company, national or EU level) for findings and outcomes definition purposes, and considered in a wider context as regards their implication for the railway system
Operator	Railway undertakings and infrastructure managers as defined in the Safety Directive

### Table 3 Table of Abbreviations

Abbreviation	Meaning	
COR	Common Occurrence Reporting	
CSI	Common safety indicators	
ECM	Entity in charge of maintenance	
IM	Infrastructure Manager	
NIB	National Investigation Body	
NOR	National Occurrence Reporting	
NSA	National Safety Authority	
RU	Railway Undertaking	
SMS	Safety Management System	
TDG	Transport of Dangerous Goods	
TDG CA	Competent Authority for Transport of Dangerous Goods	
TSI	Technical Specification for Interoperability	

### 3. Purpose of the document

This paper forms part of the Agency's <u>Common Occurrence Reporting project</u> and builds on previous consultation papers on Designing the common occurrences and taxonomy<sup>1</sup>, Legislation<sup>2</sup> and Phasing<sup>3</sup>. The purpose of this paper is to present an updated version of the aspects related to the roles of each actor in European railways, how each actor can contribute to the achievement of the stated objectives for safety management data sharing in particular, and the associated use of collected data. It aims also to introduce the aspects related to the governance of the system and the importance and resourcing of analysis of the data that would be needed to support an efficient and effective system capable of supporting the stated objectives.

This second version of paper has been established following the written consultation carried out between the 8<sup>th</sup> of February 2017 and the 4<sup>th</sup> of April 2017 and incorporates consultations responses and proposals received from the stakeholders (NSAs, NIBs, Ministry, OTIF, and Railway sector organisations (CER, UNIFE, RSSB, EIM)).

### 4. Scope and objectives

This deliverable analyses the requirements and the future needs as regards to roles, governance and access to the data issues for the future COR system.

The scope of this paper is focused on railway players as defined in the EU legal framework, both at operational and regulatory level, which are involved in the collection, reporting and use of safety data. This paper includes views about the potential use of a future COR system, and general aspects regarding roles related to the future use of a COR system shared at EU level, but does not propose neither any solution about a future architecture of the IT system nor detailed description about the future management of the system itself.

The scope of this paper focuses on the railway players having a direct or indirect role on the operation of the rail system. Some other actors are mentioned in the European legislation (e.g. keepers, loaders, etc.) but are not covered in this paper, mainly because their safety responsibilities are less well defined in the current legislative framework. Nevertheless, in the future, the COR system could be developed to support reporting and use of data by other actors and we welcome your views on this.

The objective of this paper is to explore and agree a common view on how each actor could use collected safety data to improve safety performance and to achieve the stated specific objectives for collection of safety management data in particular. This common view should support decisions about how much data is needed in order to achieve these objectives and the related uses of the future system. The paper intends also to provide an introduction to the aspects that relate to the governance of the future system, and potential issues regarding access and confidentiality of the data. Evidence gathered during consultation of the paper will feed into the planned impact assessment on these points. The final paper should support criteria or high level data use cases to allow evaluation of a number of different possible system proposals.

### 5. Better data collection and sharing are essential for better safety management

### 5.1. Problem statement

As established by the COR project plan, the specific objectives of COR Safety Management Data are the following:

<sup>&</sup>lt;sup>1</sup> <u>Paper on designing the common occurrences and taxonomy - ERA-PRG-004-TD-002</u>

<sup>&</sup>lt;sup>2</sup> Paper on phasing the COR safety management data collection - ERA-PRG-004-TD-004

<sup>&</sup>lt;sup>3</sup> <u>Paper on legislation – ERA-PRG-004-TD-001</u>

- Supporting convergence, through improvement, of Member State safety performance across all significant and non-significant accident categories, to achieve the current EU average;
- Improved understanding and management of the risks of significant and multi-fatality accidents in all Member States.

It is worth noting that all actors, through their related roles mentioned in the safety legal framework, take part, either directly or indirectly and in different ways, to the achievement of these objectives.

Regarding the objective described in the first bullet point, the need is not only to improve the safety levels of the Member States exceeding the EU average, but to support all Member States in achieving a better and more efficient safety, which requires a better targeting and better cost-efficiency.

The objective described in the second bullet point is of particular importance since risks of multi-fatality accidents influence the competitiveness of the railways compare to other transport modes. Indeed, each significant or multi-fatality accident impacts very negatively on the image of railway vis-à-vis the public and tends to reduce confidence in railways for government, passengers and commercial investors, even if rail safety performance is generally good compared to other modes.

In particular, this objective is designed to address the observable trend in recent years that, despite a general improvement of safety performance within EU over the past decade, multi-fatality accidents<sup>4</sup> still occur on the EU network, and in Member States with otherwise strong safety performance. The Agency believes that understanding and management of the risks of multi-fatality accidents could and should be improved. Rail operators are responsible for managing safety risks and making their own decisions about how best to do that. Furthermore, rail operators are commercial entities that are driven to improve their competitiveness. In such context, improving the general efficiency of safety management takes a crucial part in making the railways more competitive.

Several levers to improve the management of risks are suggested:

- Improvement of the analysis and understanding of underlying causes: Causes are always numerous and complex, and often linked to several contributory factors (human behaviour, organisational factors, etc.). Better collection and analysis of causes will help to better understand causal relationships and risk priorities, which finally supports better definition of measures to implement to avoid or mitigate accidents. Today, NIB's reports provide understanding of causes of accidents, but the number of investigated occurrences remains reduced and there is a need to extend understanding of causes to a larger number of occurrences.
- Better focus on proactive and predictive precursors, and enhancement of visibility of safety performance in Member States: Safety outcome indicators, such as the CSIs, describe what has happened, typically an accident or an incident, and are therefore purely reactive. They provide a limited ability to understand how safe or not an activity is in the present or near future. Implementation of a more pro-active approach will rely on the collection of more precursors in order to identify 'weak signals' before significant events occur. These weak signals can be seen as a kind of early signs, that first appears to be "background noise" but can be recognized as part of significant pattern by viewing it through a different frame or connecting it with other pieces of information<sup>5</sup>. In moving towards these goals we need to ensure that we obtain as much signal with the least amount

<sup>&</sup>lt;sup>4</sup> Six multi-fatality accidents occurred in 2016 in EU (Bad Aibling – Kolbermoor (DE), Serres (EL), Hermallesous-Huy (BE), on the Bari – Barletta line (IT), O Porrino (ES) and Hitrino BG). Please also refer to the last 2016 <u>biennial report on railway safety performance in the European Union</u> for more information about current safety trends

<sup>&</sup>lt;sup>5</sup> Reference : <u>Weak signals approach to Safety Performance (Eurocontrol project)</u>

of noise. To do this would require larger quantities of better quality data. Current CSIs were not designed for such purpose as they only consist of aggregated safety statistics and provide only a basic level of information about safety performance.

- Better risk-based decision making: The achievement of better risk management requires analysed and useful information to support safety decision-making. Analysis of data could, for example, support impact assessments for new initiatives, equipment or rules. Through the collection of more causes and precursors, as well as data about the consequences of each occurrence, it may in the future be possible to apply simple risk modelling techniques. Besides, as required by the CSM RA [10], the ability to monitor<sup>6</sup> the impact of changes is part of the criteria for assessing the significance of a change. This is because the full impact of making changes in the railway system, particularly system or organisational changes, generally take a long period of time to understand. Having a COR safety management data system will allow a better monitoring of safety-related events and ultimately will allow early warning and preventative measures, that should provide more confidence for those making changes.
- Improvement of sharing at EU level: The scope of existing National Occurrence Reporting systems (NOR) is limited to one Member State and does not allow observers to get the "full picture" of the risks, in particular because of the small number of multi-fatality accidents or the low frequency of certain occurrences. In addition, today the sharing is undermined also because, at national level, some Member States do not have an established national occurrence reporting system outside of the collection of CSIs, or, at company level, some smaller operators do not generate very much data by themselves. Sharing of data internationally would allow to create a wider pool of data, helping to identify trends or weak signals that cannot be detected at national level only with a smaller set of data.

Each of these levers of improvement needs safety occurrence data collection and sharing in order to be properly implemented. It is clear that, given the potential for use of safety data as described, the current level of data collection and sharing across the European Union means that risk management is not optimized for some, if not the majority, of European rail actors.

Therefore, it is proposed that the establishment of a European COR safety management data system would help to:

- Collect more precursors and identify causes , with a detailed taxonomy supporting better understanding and analysis of each event.
- Improve consistent occurrence reporting and sharing useful data at EU level, amongst all operational players, authorities, Member States, Agency, etc. Such sets of data collected at EU level can illustrate different conclusions than those from analyses at national or company level only. Such results can lead to the consideration of alternative priorities that would not have been seen as critical when considered only at national or company level.

Then, the analysis of this larger amount of data, shared between all actors across EU, would allow the:

Identification and monitoring of low frequency high consequences accidents and related risks. By providing access to a wider set of data, not limited to one company or one Member State, COR will enhance the possibility to identify and monitor low frequency events.

<sup>&</sup>lt;sup>6</sup> CSM on Risk Assessment [10], article 4.2 (d)

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- Ensure full visibility of safety performance in Member States, by providing, for all EU Member States, a more complete safety reporting requirement than CSIs.
- Identification of trends and / or weak signals, on the basis of monitoring indicators and statistical analysis, highlighting potential deterioration of safe management of risks before any serious and costly safety failures occur. On the basis that prevention of accidents is usually more cost efficient than clear-up and compensation following an accident, this will allow rail companies and authorities to focus resource where it is most needed at an early stage, supporting minor but effective adjustments to safety management measures. Collection of precursors will help to better understand underlying and latent risks, allowing a more predictive approach to safety risk management.
- Use of risk modelling techniques leading to the determination of the levels of risk affecting railway operation. Such risk estimation, whether it is qualitative or quantitative, needs data to build the model and support the risk estimation. The use of risk models would aim to construct a representation of some or all aspects of railway operations. The model is usually characterized by performing calculations and makes recommendations based on that information, which then will support decision making (cost effectiveness, proper safety management of a risk, etc.) about measures or changes to be implemented.

The use of COR will also enhance the sharing of good practices across Member States. A wider dataset could also provide evidences necessary to design and set the best cost effective measures.

Detailed description of the current limitations and future benefits COR Safety Management Data will bring to the different actors is provided in the sections below.

### 5.2. Role of RUs/IMs: SMS development and monitoring

5.2.1. Summary of the role and how it contributes to achievement of the objective of a COR safety management data system

According to the Safety Directive [1], the system responsibility for the safe operation of the Union rail system and the control of risks associated with it is laid upon the infrastructure managers and railway undertakings, each for their part of the system<sup>7</sup>. RUs and IMs therefore have a key role in the management of the risks of significant and multi-fatality accidents. To this aim and as required by the legislation, RUs and IMs have to design and implement a safety management system (SMS).

The SMS can be considered as a global risk control measure. The operator has to **identify hazards**, to **assess the risks** and then **design all the risk control measures** needed to deploy safe operations.

Additionally, according to the Safety Directive [1], after being certified to perform their activities, RUs/IMs have to continuously monitor the implementation and the effectiveness of their SMS. To ensure the implementation of a common process in Europe, a CSM on Monitoring [5] has been produced.

The CSM states that RUs, IMs (and ECMs) have to:

- a) 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) check the correct application of the management system as a whole, and if the management system achieves the expected outcomes, and;

<sup>&</sup>lt;sup>7</sup> Directive 2016/798 [1], article 4.1 (d)

c) 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.

As the implementation of SMS and its monitoring ensure that operations are managed safely and risks associated are controlled properly, RUs and IMs' SMS influences directly the management of the risks of significant and multi-fatality accidents.

For this purpose, RUs/IMs define the data collected for SMS monitoring purposes according to their own practices, technical and organisational constraints, to design and maintain their SMS. The definition of the internal monitoring process has to follow the framework setup in the relevant common safety method.

The legislation provides that data collected for this purpose relates to "accidents, incidents, near misses and other dangerous occurrences". Typically, this contains a very large amount of different types of occurrences, very likely to be wider than what is needed at a shared level. It is also important to remember that, as stated by the relevant legislation, RUs and IMs are the parties primarily responsible for the safety management of railway operations and therefore require a level of flexibility and discretion in order to fulfil that responsibility. In this regard, RUs and IMs have the responsibility, not only to determine by themselves which occurrences to collect and monitor but also to analyse these occurrences, draw conclusions, define and implement the necessary mitigation/resolution measures.

Attempting to harmonise and impose this wider data collection carries the risks of losing the detail needed to monitor specific local risks, and of confusing the responsibilities of RUs/IMs and authorities, by determining the risk monitoring priorities at a central, not local, level. These risks are effectively a constraint on the amount of data the COR safety management data can collect, even if this larger data set could be supportive of the objectives as stated. In other words, the ideal data set collected at a European level should be seen as a subset of data collected internally by RUs/IMs for SMS monitoring purpose. Consequently, each RU and IM will have to continue to define the data and the related taxonomy they need to collect for their own purposes. Therefore, their internal CSM monitoring systems which includes internal occurrences reporting should not be withdrawn and stay operational.

### 5.2.2. Why the current situation is not satisfactory/effective enough? And how COR will improve the issue?

Today, two different situations can be described:

- 1. Either no NOR exists beyond CSIs collection. In this case, RU or IM only get data from their own activity. Here the benefit of COR would be to provide access to a bigger amount of data coming from other operators.
- 2. Or a NOR system exists. Nevertheless, in this case and as described in the study conducted by DNV on the assessment of existing NOR systems<sup>8</sup>, sharing of safety data with other actors at national level is still very limited and actors do not generally have access to data/occurrences reported by other actors.

The establishment of a COR Safety Management Data system, allowing sharing of safety data between operators will therefore bring benefits in several ways:

### For the hazard identification:

The hazard identification can be done:

- using the professional judgment of the personnel working for the operator, supported by evidences;
- analysing past events data to understand the hazards and the risk behind them.

<sup>&</sup>lt;sup>8</sup> Assessment of Existing National Occurrence Reporting Regimes and Systems – Study by DNV

In both cases a comprehensive shared data set, designed as a global hazard log, might help operators in sharing information on hazards and risks. A better identification of poorly understood or known causes of accident would support also a better hazard identification. To date, a lot of hazards are already known in the railway industry but very rarely those that are shared among the operators. Moreover, new hazards, less known and more difficult to capture, can arise with the evolution of rail technology towards digitalization and new technology. A bigger dataset, allowing access to information coming from other actors having already experienced such similar new technology can support an operator in its identification of hazards not already capture when designing its SMS.

#### For the risk assessment:

When risks are evaluated, an historical database might help in evaluating frequency and severity, potentially including availability of exposure data relevant for quantitative risk assessment. This is necessary for risk ranking and for prioritising the allocation of resources on the appropriate risk control measures. The absence of this data may undermine seriously the reliability of the analysis, which might otherwise be based only on expert judgement and beliefs. Access to a bigger set of data is particularly important for instance, for low frequency occurrences (typical to multi-fatality accident for example). Wider amount of data can help and improve understanding and highlight trends or weak signals which cannot be highlighted at company and/or national level due to the lower amount of data, and eventually positively influence the definition of strategic priorities of the company. Besides, having access to data shared with the future COR Safety Management System could support decision-making of operators regarding significance or not of a change. Indeed, the implementation of the future COR system would enhance the ability to monitor the system when implementing a change, which is one the criteria to take into account to decide about significance of a change when applying the CSM on Risk Assessment [10]<sup>9</sup>. This improved monitoring would therefore potentially reduce the scope of significant changes and ultimately reduce the additional administrative tasks and costs required by the implementation of the full process of risk assessment and the need to get it assessed by an accredited/recognized assessment body.

### For the design of risk control measures:

This step poses often a question: "Is this solution safe enough?" or "is the solution unnecessarily costly / resource intensive?" or "should this risk have higher more priority than another one?". The answer cannot be given by a reporting system but data will support cost/benefit analysis, necessary to prioritise risks and allocate resources accordingly. To this purpose the COR Safety Management Data system might help if it supports benchmarking of risks between similar types of operators or other sharing of safety measures and outcomes. Although there are dangers in the inappropriate comparison between actors or regions, even simple or generic comparisons can provide the basis for further safety analysis and discussion, to support understanding and improvement.

### For the monitoring:

Monitoring the implementation and the effectiveness of risk control measures is a legal requirement defined in the CSM for Monitoring. The definition of a strategy, priorities and plan(s) for monitoring is heavily depending on the risk assessment process (if it is dangerous and likely to occur then it has to be monitored) so all the benefits for the risk management process can influence also the monitoring process.

Another important constraint of the current situation comes from the fact that, due to the absence of a COR today, international RUs operating in several Member States have to comply with different reporting requirement from one Member State to another. This creates additional burden and costs (without any benefits).

The establishment of a COR Safety Management Data system could help to resolve this issue, by providing a harmonised reporting regime, a harmonised/compatible structure of occurrences and taxonomy to be

<sup>&</sup>lt;sup>9</sup> Regulation 402/2013 [10], article 4.2 (d)

reported, and a common vision on the use of data. However, this will depend a lot on the final structure and architecture of the COR. For example, if it is decided to keep existing NOR systems (without amending/harmonising the taxonomies), it is likely that all of these constraints of non-harmonised reporting will not be removed.

The Agency might also consider supporting RUs and IMs by providing various additional tools such as reporting interfaces, analysis tools or business intelligence tools to help operators struggling to establish their own monitoring systems.

Similarly, the establishment of a COR Safety Management Data could reduce the burden of operators reporting to NIBs, as required by article 22.3 of the Safety Directive [1]. Please also refer to the <u>section related</u> to the role of NIBs for further details. Here again, this will depend on the final structure and scope of the COR system, which still have to be decided. However, the Agency view is that other arrangements than an IT tool are likely to be more suitable and efficient (such as for example, a phone call) to achieve the need of urgent notifications of NIBs by operators (which would imply availability and resources constraints regarding the use of an IT tool). This view has been confirmed by most of the stakeholders consulted. Therefore, such option to use the future COR for the purpose of urgent notification to NIBs will not be further explored.

### 5.3. Role of ECMs: Development and monitoring of system of maintenance

### 5.3.1. Summary of the role and how it contributes to achievement of the objective of a COR safety management data system

The Safety Directive [1]<sup>10</sup> states also that ECMs' activities have a potential impact on the safe operation of the Union rail system. ECMs contribute therefore to the achievement of the objectives set for the COR project, in particular regarding the improvement of the management of the risks of significant and multi-fatality accidents related to vehicles failures.

Similarly to the SMS development and monitoring performed by RUs/IMs (see section5.2), ECMs are required by the Safety Directive [1]<sup>11</sup> and the ECM Regulation [9] to implement and monitor their own system of maintenance in order to ensure a safe state of running of vehicles. Therefore, as part of this role, ECMs should define which occurrences are to be monitored according to their own needs, following their own risk assessment. Eventually, this monitoring aims to drive improvements of the system of maintenance, for instance through optimisation of maintenance processes, or better targeting and prioritisation of risks.

To do so, ECMs have to identify hazards, to assess the risks and then design all the risk control measures related to maintenance necessary to ensure that vehicles are in a safe state of running, and to monitor continuously their activities according to the CSM on Monitoring [5].

As for RUs/IMs, occurrences collected by ECMs for their monitoring purposes in application of the CSM on Monitoring are potentially more numerous and much more detailed than those needed at EU level through COR and the risks of imposing this level of harmonisation are similar.

### 5.3.2. Why the current situation is not satisfactory/effective enough? And how COR will improve the issue?

The use of safety data by ECMs is similar to that of RUs/IMs, namely, to support the identification of hazards, perform risk assessments, design risk control measures and continuous monitoring. By having access to data reported by other railway actors, ECMs could improve their risk assessment of maintenance activities, in particular their maintenance procedures or maintenance steps. Access to occurrences reported concerning vehicles (or even other similar vehicles) they have to maintain is essential for ECM to carry out their

<sup>&</sup>lt;sup>10</sup> Directive 2016/798, article 4.4

<sup>&</sup>lt;sup>11</sup> Directive 2016/798, article 14

maintenance activities. Having access to the whole data concerning a particular vehicle could help ECMs to improve their maintenance requirements. However, such use would require that data shared at EU level through COR Safety Management Data system includes information regarding the identification of vehicles. Further details about confidentiality and access issues are described in the <u>dedicated section of this paper</u>.

Moreover, as many vehicles, especially freight wagons are mainly used in international traffic, ECMs, have to comply with reporting requirements and NORs different from one Member State to another, creating additional burden and cost. The establishment of a COR Safety Management Data system used by ECMs could also help to solve this issue, by providing a harmonised reporting regime, as well as a harmonised structure of occurrences and taxonomy to be reported.

Such access to a wider pool of data could also support ECMs to improve approaches about predictive maintenance. A bigger amount of data could provide more accurate evidences regarding the frequency and gravity of failures of an equipment, and then improve predictive model that are under development across the industry. This use of data could benefit from a 'big data' approach as explored within the related Agency paper<sup>12</sup>.

Another potential use of safety occurrences relates to the management of safety critical components. The Safety Directive [1]<sup>13</sup> requires that one of the requirement applicable to ECMs is that "all maintenance activities affecting safety and safety-critical components are identified and correctly managed and that all the necessary changes to those maintenance activities affecting safety are identified, properly managed based upon the return of experience and the application of Common Safety Methods for risk assessment". Safety data collected and shared through COR Safety Management Data system could potentially support these tasks as it could provide return of experience about in service behavior of safety-critical components. Again, this will only possible if data related to such components will be finally required to be reported through the future COR Safety Management Data system.

Besides, ECMs, being one of the crucial actors of the safety chain of railway operation, are required to share information related to safety through the contractual arrangements chain between them, keepers and RUs. To this aim, it could be envisaged to consider the design of the COR system to support this need of information exchanges from ECMs towards RUs. Nonetheless, whatever will be the choice of the architecture for the final COR proposal, the integration of such use of COR is likely to require additional features to the system (such as consideration of full time availability tool with immediate operational procedures for reporting, etc.), which can potentially lead to a more costly and less simple system. For that reason, the Agency is not currently including this use case in the development of system options.

Most of the stakeholders who provided comments during the consultation considered that including ECMs and occurrences detected during maintenance in the scope of COR would need further work, both in term of taxonomy and roles description. As a first step, the Agency proposes to focus firstly on reporting by RUs and IMs as they are the closest to operation and so most of the occurrences. This aims to facilitate the implantation of a COR regime at the level of the organisations primarily concerned by them. However, if in time the need to include ECMs in the scope of COR is confirmed, this possibility and the related needs will be further considered at a later stage.

<sup>&</sup>lt;sup>12</sup> See <u>here</u> for Agency paper on Big Data for Safety Management

<sup>&</sup>lt;sup>13</sup> Directive 2016/798, Annex III

### 5.4. Role of TDG competent authorities

### 5.4.1. Summary of the role and how it contributes to achievement of the objective of a COR safety management data system

In the framework of the transport of dangerous goods, the RID [12] provides, in its chapter 1.9 in particular, that a RID Contracting State may apply certain additional provisions or restrictions to the international carriage of dangerous goods by rail on its territory. Such restrictions shall be developed and made applicable by the competent authority (TDG CA) of the Contracting State and aim to be additional safety requirements. The RID states also that the TDG CA shall provide evidence of the need for measures, meaning that such decisions may be based on an estimation of the risk (risk-based approach).

The RID [12] requires also in its section 1.8.5 that "If a serious accident or incident takes place during loading, filling, carriage or unloading of dangerous goods on the territory of a RID Contracting State, the loader, filler, carrier, consignee or if the case may be the railway infrastructure manager, respectively, shall ascertain that a report conforming to the model prescribed in 1.8.5.4 is made to the competent authority of the RID Contracting State concerned at the latest one month after the occurrence.". In turn, the competent authority may share, if necessary, the information with the other RID contracting states, by making a report to the Secretariat of OTIF.

#### 5.4.2. Why the current situation is not satisfactory/effective enough? And how COR will improve the issue?

Today, despite the existing requirement in the section 1.8.5 of the RID to collect safety occurrences data, this collection and the related sharing between competent authorities is limited. Additionally, these reporting is not design to provide the data with the necessary transparency and robustness, and therefore does not allowing to develop appropriate and recognized risk models actually supporting risk estimation, ultimately undermining mutual acceptance of safety measures between States.

The Agency has a working group set up to create a roadmap for a common methodology across different transport modes for risk evaluation and management in the context of the transport of dangerous goods. This roadmap covers both data management, risk estimations and decision-making, in order to provide an integrated solution to the identified issues related to the use of a risk-based approach.

To support such risk estimation, it has already been recognised that data, in particular consistent safety occurrences, will need to be used. One of the work streams of the Agency's TDG roadmap is to define which data is necessary to consider for the risk evaluation method developed. As today there is no unique and consistent regime of reporting allowing access to the relevant data, the COR safety management data could be the way to collect the necessary data, in a harmonised and comprehensive way, as regard safety occurrences. Other data, not related to safety, such as data related to volume of transport that would be necessary for the risk evaluation method, will have to be collected through other means - for instance through TAF TSI requirements. Interfaces between TDG roadmap and COR project have already been identified and we are working to achieve a consistent approach between both. In particular, it is important to keep in mind that the TDG roadmap work stream could consider the need to legislate in order to fulfil the needs identified for the risk estimation methodology, especially in term of data collection. Considering use of COR safety management data for this purpose is one possible option and both projects would benefit from each other in this case. Performing more robust risk estimations require more data (in particular not limited to accidents in the field of TDG) than what is collected today, and the COR Safety Management Data would allow a more systematic reporting of safety occurrences than the current requirements. However, this means that it could require a mandatory collection of certain data through the COR system, and this is likely to be achievable only through a mandatory system. For instance, reporting of accidents and primary causes are likely to be essential for the risk estimation method developed through the TDG roadmap, and will influence the scope and the extent of the future COR system if it is finally decided to use it for this purpose. Considering the wider geographical scope of the COTIF's contracting states, the use of COR system for this purpose would also require to consider access to the system to rail actors from States outside of the scope of the EU. For the purpose of this use, access to data by competent authorities will be needed.

Finally, the added value of including this data collection purpose within COR is to reduce the reporting burden for actors involved in the transport of dangerous goods, and to harmonise the collection of the data needed for the risk estimation method currently developed.

# 5.5. Roles of NSAs: Ensuring maintenance or improvement of safety level at national level, supervision, certification, vehicle authorisation and enforcement

- 5.5.1. Ensuring maintenance or improvement of safety level at national level
- 5.5.1.1. Summary of the role and how it contributes to achievement of the objective of a COR safety management data system

As further explained in the <u>section related to the role of Member States</u>, this task is primary allocated to Member States. But it impacts obviously NSAs as they are widely involved in the fulfilment of this task by their intrinsic duties, in particular when supervising RUs and IMs.

# 5.5.1.2. Why the current situation is not satisfactory/effective enough? And how COR will improve the issue?

As already explained in the paper related to legislation<sup>14</sup>, actions on maintenance or improvement of safety level should be done on the basis of sufficient access to safety data and indirectly calls for occurrence reporting, collecting and sharing in order to allow proper analysis to facilitate the necessary proactive approach.

One way to achieve this role is for the NSA to analyse safety occurrences (and a range of other information) in order to better understand the risk profile of the network and rail actors, through identifying relevant safety trends and weaknesses, doing appropriate benchmarking, understanding the complex causes of accidents and using the data to model risks (e.g. related to a type of activity, between operators, between Member States, etc.). These could then allow NSAs to define key risks areas and strategic priorities on safety issues to take into account, whether by NSAs themselves to target and prioritise their supervision activities (please refer to section 5.1.4.1 above), or by the RUs/IMs to consider in their SMS development and monitoring. This analysis performed by NSAs could also support Member States for the setting up of national safety plans as required by the Safety Directive (please refer to section 5.1.3.1 above).

Additionally, as required by the Safety Directive [1]<sup>15</sup>, education and learning is already organised in some Member States (e.g. through regular meetings at national level) based on occurrences reported. This aims to collaborate on identifying and managing shared risks, share experience and good practices between the railway actors and so actively contribute to the achievement of the two objectives set for COR Safety Management Data. This collaborative approach requires that sufficient data are collected by the NSA in order to target and provide evidence for these initiatives.

Safety occurrences analysis will also provide appropriate evidences necessary to build commitment for collaboration across the sector. Authorities (NSAs and even NIBs when relevant) and industry actors would then focus for a period of time on targeted safety issues to achieve the biggest impact. However, this will require careful balancing of the responsibilities of RUs and IMs to prioritise and manage their own risks.

NSAs are potentially the best placed to organise such feedback at national level as they are deemed to have the best comprehensive overview of the system. Nevertheless, it has to be recognised that in some Member States, such collaborative use of evidence is led by the industry itself, with similar results and efficiency.

<sup>&</sup>lt;sup>14</sup> Paper on legislation – ERA-PRG-004-TD-001

<sup>&</sup>lt;sup>15</sup> Directive 2016/798, article 16.2 (i)

However, this is only an example and for the time being, it seems that this approach is not commonly used across all EU Member States.

More generally, the development of a COR Safety Management Data could provide the following benefits to support the achievement of this role:

- A harmonised set of occurrences and taxonomy, that would allow NSAs having less robust NOR system to collect more data than currently, strengthening their analysis and eventually allowing better targeting and prioritisation of their supervision activities.
- The possibility to share data collected all over EU, and therefore reciprocally to have access to data collected and reported not only at national level but also at EU level. This would provide benefits for all NSAs, including those already having a robust national system. Having access to such pool of data can improve understanding of rare occurrences on their territory and therefore highlight trends or weak signals which would not have been highlighted at national level due to the lower amount of data.

Please also refer to the section related to analysis of the data for further details.

### 5.5.2. Supervision of RUs/IMs

# 5.5.2.1. Summary of the role and how it contributes to achievement of the objective of a COR safety management data system

The Safety Directive [1] requires<sup>16</sup> explicitly that NSAs have to perform supervision of RUs/IMs in order to oversee compliance with the legal obligation on a railway undertaking or infrastructure manager to apply a safety management system to ensure the control of all risks associated with their activities.

The CSM on Supervision [4] further details how supervision shall be performed and provides also that NSAs shall target and prioritise their supervision activities according to a supervision strategy and plan(s)<sup>17</sup>.

This NSAs' supervision contributes therefore to the achievement of the objectives set for COR system since they support performance and improvement of the SMSs of RUs/IMs (by ensuring a consistent maintenance of SMS application over time or even by requiring improvement of the SMS through enforcement actions by a NSA).

# 5.5.2.2. Why the current situation is not satisfactory/effective enough? And how COR will improve the issue?

The CSM on Supervision [4] requires that NSA's supervision strategy and plan(s) shall be set using data "from a variety of sources" including "accident/incident reports or data"<sup>18</sup>. The application of this use of data can be done in two different ways:

- To define the supervision strategy of the NSA: following analysis performed as explained in the previous section related to the task of maintenance or improvement of safety level), the outcomes are usually used by NSAs to review or adjust annually their supervision plan according to new trends and priorities defined at national level.
- To guide and support NSA's supervision activities on a day-to-day basis. To do so, NSA's inspectors (supported or not by dedicated data analyst experts, and/or according to inspectors' competences) could consult the safety occurrences data more regularly, even daily, in order to support the ongoing supervisory relationship between RUs/IMs and the NSA. It should be clear that it is not to create a

<sup>&</sup>lt;sup>16</sup> Directive 2016/798 [1], article 16

<sup>&</sup>lt;sup>17</sup> Regulation 1077/2012 [4], article 3

<sup>&</sup>lt;sup>18</sup> Regulation 1077/2012 [4], annex

purely reactive or punitive approach to NSA regulation, which would deter full reporting. This information should inform the ongoing implementation of the NSA supervision strategies and plans and their revision.

If NOR can generally support this role, their differences in term of level of details and absence of sharing across NSAs remains an issue, as explained in the <u>previous section related to the task of maintenance or</u> <u>improvement of safety level</u> and in the <u>section related to the problem statement</u>.

Another way the COR Safety Management Data could support NSA's supervision concerns supervision of international operators. Indeed, a NSA might want to get access to safety performance of this operator outside its territory in order to get a comprehensive view about accidents and incidents reported overall by this operator, and then eventually better target the supervision activities. Sharing and access to such data in a harmonised and commonly understood format could also support better coordinated supervision between NSAs.

The supervision activities carried out by NSAs is also one of the main way used to monitor, promote, and, where appropriate, enforce the safety regulatory framework<sup>19</sup>. Here the use of safety data would help to understand the risk level and decide about which enforcement actions would be reasonably practicable when it is observed that the safety performance of an operator is below the acceptable level.

### 5.5.3. RUs/IMs certification

5.5.3.1. Summary of the role and how it contributes to achievement of the objective of a COR safety management data system

Please refer to the section related to the <u>role of the Agency regarding RUs/IMs certification</u> which covers also this role of NSAs.

### 5.6. Role of NIBs: Investigations of accidents/incidents

### 5.6.1. Summary of the role and how it contributes to achievement of the objective of a COR safety management data system

NIBs are required by the Safety Directive [1] to carry out investigation after any serious accident, with the objective to maintain and, where possible, improve railway safety and the prevention of accidents<sup>20</sup>. In particular, this is done through the investigation report and safety recommendations issued by a NIB after each investigated accident. These safety recommendations should be addressed to the NSA which shall then ensure through their activities that these recommendations are properly implemented by the relevant players. Moreover, as identification of causes and contributory factors forms a crucial part of the analysis of accidents made by NIBs, outcomes from investigation and implementation of safety recommendations impacts therefore directly the objectives of the COR project to improve safety performances and management of risks of multi-fatality accidents.

Besides, article 20.2 of the Safety Directive [1] states also that, beyond serious accidents, NIBs have the discretion to decide whether to investigate or not "accidents and incidents which could have led to serious accident, including technical failures". The decision to investigate other accidents/incidents relies on NIB's expertise and also resources. This means that these sort of "non-mandatory" investigation are usually done on a targeted basis and intends to be more pro-active by identifying areas which can potentially help to better understand and improve management of risks of potentially multi-fatality accidents.

<sup>&</sup>lt;sup>19</sup> Direction 2016/798 [1], article 16.2 (i)

<sup>&</sup>lt;sup>20</sup> Directive 2016/798 [1], article 20.1

### 5.6.2. Why the current situation is not satisfactory/effective enough? And how COR will improve the issue?

Today, the access of NIBs to NOR when they exist, and so the use of safety occurrence data, is not shared or common across the EU. Here again limitations of the current situations are similar : the lack of sharing at EU level is likely to hinder NIBs to get the full "picture" of actual risks, in particular regarding low-frequencies occurrences, typical serious accidents NIBs investigate. Further, understanding the main causes of accident types may help NIBs to focus or direct their investigations, particularly regarding organisational or human contributions to accidents. The future COR system will intend to answer these issues by providing a harmonised framework and better sharing for all NIBs within EU.

It is also important to recognise that NIB's investigations could lead to identify causes which are not included in the taxonomy used for COR. In this case, the common taxonomy used for COR could be improved and updated on the basis of NIB's findings.

Use of safety data could also support decision by NIBs to conduct non-mandatory investigations of non-"serious" occurrences, according to article 20.2 of Safety Directive. Indeed, through identification of safety trends and issues, NIBs could decide more easily about investigation or not of certain types of accident and incident in order to prioritise their action on the most relevant area of risks.

Different ways of achieving these objectives exist and typically, NIBs could either use directly COR Safety Management Data to perform their own analysis, or rely on analysis made by other authorities such as NSAs or the Agency.

Besides, the future COR Safety Management Data could also cover the need for NIBs to share their investigation reports and related safety recommendations, through for instance, additional functionalities to the future system. Today, this need is covered by the ERAIL database, but, if in time it is decided to have only one common system to cover both the occurrences reporting need and the sharing of investigation reports, it could be considered to phase out ERAIL and develop the future COR system also for this purpose. This will be considered as an option for the future impact assessment that will support the system proposal the Agency will provide in 2017. If this use is finally retained for the future system, it could also influence the design of the IT tool in order to keep traceability in the system (through several versions of an occurrence reported, as it is likely to be the case if the system would manage both report from an RU and from the IM when relevant – please refer to the <u>section of this paper related to data preparation</u>) both the reported causes identified through the investigation conducted internally by the operator and the causes finally identified by the NIB through its investigation.

### 5.7. Role of ECM Certification bodies: Certification and surveillance of system of maintenance

### 5.7.1. Summary of the role and how it contributes to achievement of the objective of a COR safety management data system

The ECM Regulation [9] states that certification of ECM is based on the assessment of the system of maintenance according to requirement provided in Annex III of the same Regulation, and includes also "*a system of surveillance to ensure continuous compliance*" with those requirements. Here, ECM certification bodies follow the approach of certification/supervision comparable to safety certification or authorisation of RUs and IMs.

Therefore, surveillance activities of ECM by ECM certification bodies is intended to identify potential weaknesses in their system of maintenance and call for their further improvements when needed. And as explained in the <u>section related to the ECMs</u>, ECMs' activities directly influence safety levels of the railways as it relates to safe state of vehicles and to a key role in the management of potential precursors or railway

vehicles failures. Thus, surveillance of ECMs takes an essential part of the achievement of COR project objectives.

### 5.7.2. Why the current situation is not satisfactory/effective enough? And how COR will improve the issue?

Today, ECM certification bodies do not have always access to national occurrence reporting systems. Moreover, taking into account the scope of these non-harmonised NOR systems, access to them might not be relevant for ECM certification bodies, in particular if NOR does not intend to collect relevant data (when limited to CSIs for example), such as occurrences and causes related to technical failure of vehicles.

The setting up of a COR system accessible to ECM certification bodies could allow them to have an easier access than today to wider data, including in particular precursors and causes related to vehicles failures, that can be analysed and used to define more accurately surveillance activities.

In this regard, ECM certification bodies could use data collected through the COR safety management data to set priorities for the surveillance of ECMs, similarly as NSAs use data to target their supervision activities of RUs/IMs' SMS. Access to shared data at EU level could support ECM certification bodies by giving them access to weak signals that can be only identified at a wider level than a company or a national level. For instance, identification of general trends about increase of a certain type of incidents, such as axle failures, could support ECM certification bodies in their decision to target more their surveillance on how procedures related to axle failure management by ECMs are implemented and followed and to identify potential relevant weaknesses in this area. Harmonisation of this use by ECM certification bodies would allow them to act according to same principles and eventually allow overall improvement of safety management by ECMs.

Nevertheless, if it is finally decided that ECM certification bodies can access the future COR Safety Management Data system for the purpose of better targeting their surveillance activities, it will be likely to require that additional data (probably not often collected nowadays through NOR systems) related to this need has to be collected, such as data related to rolling stock identification or occurrences specifically related to maintenance activities.

# 5.8. Role of Member States: Maintaining or improving the safety level and setting up of safety plans, developing the national legal framework and making decisions about investments

### 5.8.1. Summary of the role and how it contributes to achievement of the objective of a COR safety management data system

The Safety Directive [1] provides that Member States shall ensure the maintenance and, when reasonably practicable, the improvement of railway safety<sup>21</sup>. The way this role is performed is defined by each Member State, mainly when assigning the appropriate roles to the actors when transposing the Directives, and we know through our audits and assessments that, beyond the tasks allocated by the European legislation, the role of NSAs and NIBs in particular are different in each Member State. Member State governments further fulfil this responsibility by ensuring adequate resources, overseeing key executive appointments, and developing and communicating appropriate national transport policies<sup>22</sup>.

Maintaining or improving the national safety level is carried out at Member State's level, for instance, through the definition of national strategic priorities to be taken into account by the different actors when fulfilling their roles.

<sup>&</sup>lt;sup>21</sup> Directive 2016/798 [1], article 4.1 (a)

<sup>&</sup>lt;sup>22</sup> Please refer to the <u>guidance the Regulatory Monitoring Matrix</u> developed by the Agency to measure the maturity levels of railway safety within Member States for further details.

Additionally, the Safety Directive [1] provides also that Member States shall "develop and publish annual safety plans setting out the measures envisaged to achieve the CSTs"<sup>23</sup>. This contributes also to the management of the risks of significant and multi-fatality accidents, since the national plan should direct resources and activities toward the areas of key risk.

Besides, Member States develop their own national legal framework, including national rules, where allowed by the European legislation. National legislation also support the achievement of the two objectives set for the COR project, as it contains both provisions aiming at achieving safety performances (e.g. national safety targets) and provisions for management of strategic or priority risks at national level (e.g. national technical or operational rules).

### 5.8.2. Why the current situation is not satisfactory/effective enough? And how COR will improve the issue?

Today, NOR, when they exist, can support the performance of this role by providing relevant evidence to support risk based decision making. However, analysis made from data collected at national level only may be less accurate or informative than from an EU-wide pool of data shared between all Member States. Additionally, strategic priorities defined at EU level (please also refer to the <u>section of this paper related to</u> the role of the Agency regarding improvement of safety level) would also complement and/or support the national priorities, allowing more accurate targeting of key risks areas.

COR Safety Management Data can also be used at Member State's level for benchmarking between Member States, in particular in order to identify areas where others Member States have managed to achieve better safety performance and improve their knowledge about measures to be taken that have proved their effectiveness. COR Safety Management Data could also provide evidences for impact assessments carried out to support prioritisation of investments decided by a Member States or for setting up of national rules.

### 5.9. Roles of the Agency

5.9.1. Ensure safety level at EU level and prevention of serious accident

# 5.9.1.1. Summary of the role and how it contributes to achievement of the objective of a COR safety management data system

This role<sup>24</sup> is comparable to the similar role allocated to Member States (please refer to <u>the related section</u> <u>above</u>), but at EU level, and with a focus on the prevention of "serious accidents". This is a new provision of the recast Safety Directive and this is complemented by the objective fixed by the Agency Regulation [3] to the Agency to guarantee a high level of railway safety<sup>25</sup>. Achievement of the objective set up for the COR safety management data will contribute to the achievement of this new role.

There are potentially a lot of different ways the Agency can achieve this role and a part of it is already fulfilled by the other roles allocated to the Agency and mentioned later in this section. However, as also explained in the Legislation paper, the full achievement of this role requires improvement on the current safety performance, which, in turn, will require new tools and measures in order to effectively influence the reasonably practicable improvement of safety levels. This will, necessarily, include the greater collection, sharing and use of occurrence reporting data.

<sup>&</sup>lt;sup>23</sup> Directive 2016/798 [1], article 4.1 (f)

<sup>&</sup>lt;sup>24</sup> Directive 2016/798 [1], article 4.2

<sup>&</sup>lt;sup>25</sup> Regulation 2016/796 [3], article 2

### 5.9.1.2. Why the current situation is not satisfactory/effective enough? And how COR will improve the issue?

For the time being, the Agency collects only the CSIs, as required by the Safety Directive. Nevertheless, as already explained in the previous papers, the CSIs are not sufficient as the collection of precursors is limited and data are reported only at an aggregate level, and with no information about the context or the causes. The CSIs only allow the Agency to monitor high-level trends, and the analyses which can be done from them are limited.

Having access to safety occurrences and precursors in particular will allow better monitoring of trends, to identify the areas where risks are higher and target appropriate proactive interventions and measures. The final outcomes of these could be to identify areas for improvements and / or strategic priorities relevant at the EU level, carry out dissemination to raise awareness of these strategic priorities and risks and lead or facilitate collaborative efforts to better manage risks.

For instance, such sharing could be organised through some sort of collaborative exchange with European safety analysts coordinated by the Agency. The aim would be to exchange knowledge and decide priorities and perhaps measures, amongst EU railway actors (authorities as well as operational actors) on the basis of the collection of occurrences. The Agency could also communicate these aspects through publishing of safety analysis on a regular basis (e.g. through newsletter, videos, etc.) in order to improve knowledge and sharing of good practices within Europe. Eventually, such sharing with railway stakeholders and other authorities could positively influence the different actors to take into account these EU strategic priorities in their different respective roles.

Elaborating such EU strategic priorities will require that the Agency ensures that safety performance statistics and information based on collaborative analysis are correct and agreed with the railway players concerned. This will require the putting in place of a clear, transparent and shared process (e.g. regarding terms of reference for a safety analysts platform), to agree on the methods to be used and/or on the results of the analyses. This will be necessary to ensure that results of these collaborative analysis are acknowledged by the relevant actors and will support their final consideration.

The different way of carrying out this role by the Agency will need to be further explored and will depend on the definitive scope of the COR system as well as available resources at a European and national level. Please also refer to the section of this paper related to the use and analysis of data.

### 5.9.2. Draft technical specifications, opinions, recommendations and briefing after an accident to the Commission

# 5.9.2.1. Summary of the role and how it contributes to achievement of the objective of a COR safety management data system

According to the Directive on safety [1], interoperability [2] and the Agency Regulation [3], the Agency is responsible for drafting TSIs, CSMs, and other implementing or delegated acts and providing the related recommendations to the Commission for their adoption. The Agency also provides opinions to the Commission regarding deficiencies in TSIs, or requests by Member States for non–application of TSIs. The Agency Regulation<sup>26</sup> [3] also provides for the Agency to address recommendations to the Commission in the field of safety. Here the goal is to improve the safety level and it is therefore closely linked with the objectives stated for COR. For these purposes, the Agency Regulation [3] requires that "the Agency shall conduct an impact assessment of its recommendations and opinions"<sup>27</sup>.

<sup>&</sup>lt;sup>26</sup> Regulation 2016/796 [3], article 13

<sup>&</sup>lt;sup>27</sup> Regulation 2016/796 [3], article 8

The Agency can also "issue detailed guidance concerning standards for the relevant European standardisation bodies to complement the mandate given to them by the Commission", as required by the Agency Regulation<sup>28</sup> [3]. In particular, this intends to support CEN-CENELEC in the drafting of standards according to the appropriate needs identified for the EU railway system.

The Agency provides also support to the European Commission when a major accident occurs on the European rail network. In such case, the Agency is asked by the Commission to provide a briefing about the accident, in order for the Commission to communicate properly vis-à-vis the whole Europe. Such briefing details what occurred and the general context regarding railway safety in the concerned Member States and/or regarding the type of service.

### 5.9.2.2. Why the current situation is not satisfactory/effective enough? And how COR will improve the issue?

As for its previous role, today, the Agency is limited in the way safety data can support decision making in the area of drafting technical specifications, opinions about TSIs deficiencies, and safety recommendations, as the CSIs provide only aggregated data, and with a relatively limited amount of precursors, and no information about specific technical systems or equipment involved.

For instance, having access to a wider pool of data, with details about their causes and consequences could support decision making when drafting TSIs. Indeed, as safety is one of the essential requirement applicable to the subsystems in the scope of the Interoperability Directive [2]<sup>29</sup>, analysis of safety occurrences could lead to identify safety risks areas that would need a better consideration in the relevant TSI, or require an improvement of their specifications. Moreover, the technical specifications have an important impact on the cost of railway equipment or vehicles. The development of technical specifications requires that an impact assessment have to be performed in order to take the most efficient decisions considering the cost, the interoperability and safety impacts. Here again, access to wider pool of data would provide robust evidences for measuring cost and safety-related impacts of technical specifications.

Safety data from the future COR Safety Management Data system could also support the drafting of the impact assessments the Agency shall conduct for each of its recommendation and opinion. For instance, the system could provide data that can be used for a better identification of assumptions for an impact assessment.

Similarly, the safety data could also support the drafting of technical opinions<sup>30</sup> and/or guidance concerning standards for the European standardisation bodies<sup>31</sup>. The use of safety occurrences could support these tasks through monitoring of safety trends and risks identification which can lead to prescribe more details about the design of a type of equipment: for instance, trends at EU level showing an increase of door failures of passengers vehicles could suggest that more requirements are needed in the related EU standard to better manage these risks. On the basis of such outcome, the Agency could therefore better support its recommendations concerning standards for CEN-CENELEC to complement the mandate given to them by the Commission on the basis of evidences collected through the COR Safety Management Data system.

The outcomes of analysis of safety occurrences collected through COR can also obviously support the Agency when drafting recommendations in the field of safety. For instance, the Agency can be required by the Commission to provide a technical opinion about the relevance of a safety plan issued by a Member State as answer to a CST<sup>32</sup> assessment showing a probable decrease of safety performance. In this example, the Agency could use the safety occurrences reported through COR to deliver a more robust and evidence-based

<sup>&</sup>lt;sup>28</sup> Regulation 2016/796 [3], article 19.1 (i)

<sup>&</sup>lt;sup>29</sup> Directive 2016/797 [2], annex III

<sup>&</sup>lt;sup>30</sup> Regulation 2016/796 [3], article 19.1 (d)

<sup>&</sup>lt;sup>31</sup> Regulation 2016/796 [3], article 19.1 (i)

<sup>&</sup>lt;sup>32</sup> Decision 2009/460, article 5

analysis, about the relevance of the safety enhancement plan of a Member State, including careful and appropriate benchmarking. In the same spirit, data and information from COR safety management data would support more detailed conclusions and analysis about safety performance of the Union rail system, in particular through the Agency's safety reports.

Similarly, the safety occurrences and related outcomes from their analysis could also support the Agency when providing briefings to the Commission in case of major accident. A wider pool of data than today would give the Agency more accurate and relevant information regarding the accident and its context and eventually improve the relevance of the briefing notes provided to the Commission.

### 5.9.3. NSA monitoring

### 5.9.3.1. Summary of the role and how it contributes to achievement of the objective of a COR safety management data system

The new Agency Regulation [3] provides<sup>33</sup> that the Agency "shall monitor the performance and decision making of national safety authorities through audits and inspections". The aim of this is to ensure that NSAs carry out their actions efficiently and in a consistent way.

Similarly to NSAs' supervision of railway operators, the Agency could perform targeted and prioritised monitoring by using, in particular, safety occurrences reported for the definition of their strategy and plans.

### 5.9.3.2. Why the current situation is not satisfactory/effective enough? And how COR will improve the issue?

As explained for its previous role, CSIs have not been designed for this purpose.

Therefore, this new activity for the Agency could benefit from safety related data collected through COR Safety Management Data by giving to the Agency robust and consistent outcome information about the efficiency of the NSA's strategy regarding safety performance maintenance and enhancement. For instance, analysis of safety occurrences by the Agency could highlight weaknesses related to the NSA's supervision strategy and/or plans not allowing proper implementation of national and/or European top priorities (please refer to the section related to role of the Agency regarding ensuring the safety level).

### 5.9.4. Issuing of single safety certificates to RUs

For the first award of a safety certificate or authorisation, clearly neither safety data nor outputs from supervision activities exist regarding the concerned RU/IM, so that the first assessment is limited to assessment of the SMS itself. All subsequent renewals or amendments of the safety certificate or authorisation rely on the results and outputs from supervision.

The current CSMs on Conformity Assessment [6] and [7] (as well as their on-going revision) do not explicitly require that the safety certification body (i.e. the Agency or possibly a NSA for RUs with an area of operation limited to one Member State) uses safety occurrences relating to the applicant to support the assessment of safety certificates/authorisation. The certification process defined by the CSMs on Conformity Assessment requires that the past supervision activities carried out by the NSAs concerned shall be considered by the safety certification body for the renewal of a safety certificate/authorisation. As explained below in this paper in the <u>section related to supervision by NSAs</u>, the use of safety occurrence data collected from any occurrences reporting system is already required to be done by NSAs to support, among other source of information, the definition of their supervision strategy and plan. Then, this means that there should be no direct use by the safety certification body of neither safety occurrences raw data, nor outcomes of analysis of the data (such as identified strategic priorities), as a direct use of safety occurrences for certification purpose would be likely to undermine the building of a better reporting culture amongst railway operators.

<sup>&</sup>lt;sup>33</sup> Regulation 2016/796, article 33

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Nevertheless, outcomes from analysis of the data (such as strategic priorities) could be used by the safety certification body when it coordinates with NSAs regarding their supervision role, in order to ensure that these outcomes have been taken into account when the supervision activities were carried out. Results of these exchanges between the safety certification body and the NSAs could then influence the other roles of the Agency, in particular the <u>development of the regulatory framework</u>, the improvement of its internal procedures regarding safety certification, or the <u>monitoring of NSAs</u>.

### 5.9.5. Issuing vehicles authorisation

Safety occurrences collected and analysed through the future COR Safety Management Data system could highlight underlying risks areas related to the design of railway vehicles.

Therefore, it is important that outcomes and conclusions drawn from the analysis of safety occurrences data (whatever entity performs this analysis) relevant for vehicles are brought to the attention of:

- The manufacturers and suppliers, in order for them to take such outcomes into account in their risks assessment and general design of vehicles;
- The conformity assessment bodies, in particular the Assessment Bodies (AsBos) in charge of checking the application of the CSM on Risk Assessment [10], in order for AsBos to take these outcomes into account in their assessments (e.g. a type of design of the braking system has shown weaknesses in operation as several incidents (SPADs for instance) occurred due to inadequate braking performance under certain conditions; in such case the AsBo needs to be aware of this outcomes when checking future application of CSM on RA on braking system); for this purpose, it is not necessary that AsBos get a full access to COR data, but it would require that outcomes from analysis done at national and EU level are communicated and shared with them.
- The assessors of the authorising entity (i.e. the Agency or possibly a NSA for vehicle with an area of use limited to only one Member State), in order for them to build their knowledge regarding risks related to railway vehicles.

As described in the section 5.9.2 of this paper, outcomes from analysis of COR data regarding the design of technical equipment should primarily lead to their taking into account at the level of regulations or standards. However, considering the timescale of this process, and as analysis of COR data can also lead to new or unknown risks to be considered by proposer/applicant/manufacturers/suppliers when performing risks assessment. In the latter case, access to evidences provided by analysed safety occurrences data, would support the authorising entity in its discussions with the applicant, in particular at the pre-engagement stage. Such discussion at pre-engagement would allow the applicant to consider such outcomes (when those have been agreed following the analysis process described in the section 6.1 of the paper. This may concern for instance, underlying risks that have not been yet managed or which have not been documented yet. Besides, and when such risks would not have been demonstrated to be managed by the applicant in its application file, the safety occurrences data would provide to the authorising entity the necessary evidences for raising a justified doubt and require the applicant to provide supplementary information or to carry out additional verifications.

However, it is important to state that raw data about occurrences should not be used directly to not issue a vehicle authorisation or to suspend an authorisation already issued. Only analysed data from safety occurrences should be used to draw useful conclusions, and eventually provide robust evidences for decision-making regarding authorisation of vehicles.

### 5.10. Role of the European Commission: proposal of legislation and EU funding

#### 5.10.1. Summary of the role and how it contributes to the achievement of the objective of the COR project

According to the Treaty of Lisbon, the European Commission is empowered to propose the introduction of legislation (into the legislative process). In the field of railway safety, any new proposal from the Commission is therefore likely to have potential impact on the objectives of the COR project.

Besides the above, the Commission makes direct financial contributions in the form of grants in support of projects or organisations which further the interests of the EU or contribute to the implementation of an EU programme or policy. Such grants are allocated following calls for proposals to which interested parties can apply. Then the Commission decides whether to allocate grants to projects or not. Such decision needs data and information to be supported and justified.

### 5.10.2. Why the current situation is not satisfactory/effective enough? And how COR will improve the issue?

An impact assessment is required for Commission initiatives that are likely to have significant economic, environmental or social impacts<sup>34</sup>. This is part of the "Better Regulation"<sup>35</sup> principles which intends to ensure that its proposals meet policy goals at minimum cost and deliver maximum benefits. Impact assessment promotes more informed decision-making and contributes to Better Regulation. Today, safety data available at EU level to support these are limited to CSIs, which, as already explained before, cannot provide more information than aggregated statistics. This is likely to limit the robustness and adequacy of evidence being able to support future legislative proposals. As further explained in the guidelines of European Commission on Impact Assessment<sup>36</sup>, data are needed as part of the evidences collected to support assessment of impacts. The lack of data is recognized as a potential challenge that can create limitations or uncertainties when assessing impacts of a new proposal.

The future COR Safety Management Data would allow the European Commission to have access to robust safety management data providing shared and agreed evidence able to support impact assessments and decision making regarding proposals for new legislation and project funding.

### 6. Use of data and information

### 6.1. Data analysis, turning data into information

The benefits of a system for Common Occurrence Reporting of Safety Management Data have already been discussed in this paper. They do not come only from the collection itself, but mostly from their sharing and analysis, and ultimately the implementation of actions, measures or changes aiming at solving the issues identified.

The main point is to have consistent data and information on the railway system in order to trigger coordinated actions to improve the overall safety of the system. To do that, common data have to be analysed at all actors level (company/operator level, national level and European level) according to a common risk management process, in order to identify what are the safety issues to be solved. The results of this analysis has to be agreed at this different levels and then be accessible, maybe at different levels of details, by all the actors responsible for preserving and improving the safety level within EU. Using this analysis, actors could work to define and agree on actions to be implemented to answer the safety issues and finally to implement and monitor the effect of these actions. Therefore, it is crucial to recognise that the analysis of data require a high level of knowledge and operational expertise and that data itself should be

<sup>&</sup>lt;sup>34</sup> Communication from the Commission on impact assessment:

http://trade.ec.europa.eu/doclib/docs/2005/february/tradoc 121479.pdf

<sup>&</sup>lt;sup>35</sup> <u>Better Regulation Guidelines</u>

<sup>&</sup>lt;sup>36</sup> Link to EC Guidelines on Impact Assessment

seen as supportive material to take decisions that can be implemented at different levels (operational, or



regulatory). As referred in the project plan [14], a stage of the project called "building capability" will be dedicated to these aspects.

As a first attempt to describe the overall process, the structure of the process dealing with data reporting and data analysis can be summarised as followed:

#### Figure 1: Safety occurrences from reporting to outcomes

The requirement for analysis is already regulated at the level of railway undertakings, infrastructure managers and entities in charge of maintenance by the CSM on Monitoring [5]. The proposed approach illustrated in the figure above, aims to extend consistently and to promote an harmonised approach at all

different levels (company, national and EU level), and to keep consistency with existing practice, in particular following the CSM on Monitoring. Such a harmonised approach will ensure a proper implementation of the future COR regime and that the expected benefits from the COR are delivered.

However, the fact that a harmonised process is used by the different actors at the different levels does not mean that the analysis performed deliver the same outcomes. Each actor and each level has to perform its own analysis, according to its own needs, context and responsibilities.

### 6.1.1. Data preparation

Firstly, data preparation step consists in collecting the data from the organisations which generate them. The obligation to report or not will depend mainly on the mandatory character or not of the future COR system. Whatever choice will be made, the duty to report will rely on the railway operators, namely RUs, IMs, ECMs, and maybe manufacturers, keepers and other rail actors. The final scope of which actors will have to report has still to be defined, and will be further explored for the development of the system's specification (please also refer to the phasing paper regarding the possible phasing options already identified). If the decision to implement a new legislation for COR is finally the solution chosen, this legislation will have to precise who shall report, what are the obligations to report (especially regarding potential non mandatory fields for instance, but also the timeframe) and who has to ensure that the reporting is properly done by the operators and what are the possible enforcement actions that can be taken when an operator does not report as required (please refer to the next section of this paper about supervision role).

Finally, because IMs are in a position to be able to report almost all occurrences on its network, there will likely be considerable double recording of many occurrences (e.g. reporting by the IM and by an RU of the same occurrence, each from their perspective). There may be interesting conclusions to be drawn from the analysis of both perspectives, potentially allowing for instance the highlighting of a problem of communication between parties, with further details only possible from one perspective. We are working with the other EU transport agencies<sup>37</sup> to understand what automatic or manual options there are to limit the rate of double recording while keeping the benefit of having reporting by different entities involved in an occurrence, and would welcome experience from NSAs on how this is currently managed.

Besides, there could be efficiencies in recognising the particular role and opportunities of IMs by designating them a system oversight role for the COR system. However, following the consultation of stakeholders, giving such a role to IMs is not widely supported as there are some limitations and drawback if such a choice was made (not suitable for all networks and issue of roles and responsibilities vis-à-vis of NSAs). However, if the choice is made to establish a COR system relying on NORs, there might be a need to potentially accommodate with different existing national systems, managed and governed in different ways.

This step of reporting and collection will require that data reported to the future COR system will need to be in a suitable format (occurrences to be reported and related taxonomy) and IT technology, whatever will be the architecture (e.g. allowing connection with national occurrence reporting systems or not) and scope of COR.

The second step related to data preparation consists in the validation of the data. Data quality is discussed in the <u>related section of this paper</u>.

Finally, at this stage, sharing of data is expected with the relevant actors. Nevertheless, the extent of this sharing (who can access what), as well as the state of data shared (raw data or information from already analysed data) will be determined following the consultation of the stakeholders about the needs identified above for each actors. Further details about access and confidentiality are provided in <u>the related section of this paper</u>.

<sup>&</sup>lt;sup>37</sup> EASA, Eurocontrol and EMSA

### 6.1.2. Analysis and definition of actions

As detailed in the section 5 of this paper, all actors mentioned shall use safety occurrences to perform their roles and the way and extent of their use depends on their needs and their expected outcomes from the data.

According to the CSM on Monitoring [5], occurrences have to be investigated firstly by those who reports, namely RUs, IMs and ECMs, for their own purpose of safety monitoring and continuous improvement. The extent of the investigation carried out depends obviously on the level of risks and the characteristics of each occurrences.

Therefore, analysis is a matter of all actors, and each actor have to establish their own methodology according to their own approach and needs. Nevertheless, some limitations due to non-harmonised way of doing it are already identified. Where comparable, transferable risk assessments are required, it might be worth developing harmonised methods of risks modelling. A risk model is already being developed in the context of the Agency's TDG roadmap workgroup and will already provide a harmonised methodology for risk estimation regarding TDG. A similar approach for the other domain of rail operation (e.g. development of a risk model methodology regarding risk of freight train derailment) could be followed thanks to the data collected through a future COR system. However, development of such harmonised methods are not in the scope of the COR project itself and will subject to future discussions. Please refer to the related section of this paper for further information. Different ways of achieving the objective for other areas than TDG can be considered and will need to be further discussed as regards how the analysis is organised at national and EU level, the involvement of the Agency, the NSAs, etc. This should be seen as a longer term perspective than the COR project itself, and it is not foreseen to deal with the particular aspect of risk modelling harmonisation in the current project plan. It has also to be reminded that a risk model is already being developed for the TDG in the context of the Agency's TDG roadmap workgroup. Please refer to the related section of this paper for further information.

Additionally, analysis of safety occurrences is likely to require also to have access and consider additional information regarding the context of the occurrences (e.g. information related to the traffic, transport volumes, operational rules used, technical systems in place) that would not be collected through the COR system. This information will be essential to draw accurate conclusions and to avoid potential misinterpretation. It is also important to acknowledge that data used for analysis (from COR and from other potential sources as described just before) needs to be with sufficient details in order to be able to compare comparable situation.

The Agency might also consider supporting authorities and stakeholders in decision-making and prioritisation by developing (IT) tools for analytic hierarchy processes (e.g. visual risk modelling techniques – as an example) and risk classification methods. However, it is important to recognise that developing data set, analysis and model can only support railway actors making their own assessments of their own risks, and should not consist in developing a risk model that would assume or replace the responsibility of railway operators to perform their risks assessment of their own risks.

On the basis of the aviation model, implementation of common analysis group under the form of a European platform of safety analysts coordinated by the Agency to exchange experience and knowledge amongst EU railway actors can also be envisaged. Such platform would allow to carry out analysis at EU level, by gathering expertise from the Agency, NSAs, NIBs, RUs, IMs and ECMs on the analysis of the most relevant occurrences. Outcomes from such platform could be, for instance, to agree among all actors on prioritisation, recommendations or actions plans, on issues relevant at EU level or to improve coordination of safety initiatives between actors. The way decisions and agreements about measures that would be taken at EU level, as well as the monitoring of their implementation (please refer to the section 6.1.4 of this paper) will need to be further defined at a later stage, as it will depend also on the final governance and scope of the final proposal. However, it is recognised that it will require a strong involvement and commitment by all concerned parties.

This approach would participate also to the achievement of the role of the Agency to maintain or improve the railway safety in EU, as described in the related section of this paper. Such approach would generally also goes in the direction of better harmonised approach and understanding and would promote better analytical capacity all actors can rely on.

Similar platforms of exchange can also be envisaged at national level in order to define and agreed on priorities relevant at national level. This supports also better sharing of experience and knowledge at a local level that cannot reasonably reached through European groups. Some Member States have already set such cooperation/coordination groups in order to identify areas of improvement on safety issues, facilitating cooperation on safety matters across the industry and sharing of good practices, with positive results (e.g. System Safety Risk Group managed by RSSB in UK, feedback meetings at French level managed by EPSF). The implementation of COR will also support the setting up of such approaches in Member States where this is less developed.

As analysis of safety occurrences has to be undertaken at all levels (company level, national level, EU level), different conclusions about measures to be implemented might be different and not fully aligned, in particular because of the differences of context. For instance, a decision to prioritise the implementation (and so the investment) of technical measures at local/national level (e.g. installation of a new train detection system on single track lines because of several accidents) might be not aligned with a more global European strategy on the same topic but providing different conclusions (e.g. priority at EU level is put on level crossing whereas there is no need to take measures regarding train detection at EU level considering the data). In such case, there will be a need to ensure proportionality and proper cost-benefit analysis to take the best decision at each level.

### 6.1.3. Communication

After definition and agreement (at whatever level it is done) on what are the actions to be taken to improve to management of a safety issue, there is then the need to communicate these results to the right organisations and people. It is expected that each actor, each at their level, in particular the Agency, the NSAs and railway operators, will communicate the relevant outcomes from the analysis of the data collected.

The Agency, through a platform of safety analysts where all relevant actors would be represented as described in the previous section, could develop supportive materials (leaflets, guidance, presentations, etc.) in order to facilitate a more consistent communication across all European Union.

Besides, the implementation of a COR system is intended to support improvement of the reporting culture within the Union rail system, and therefore the safety culture within rail companies and authorities (please refer to <u>safety culture project</u> for further details). But to achieve this, the actions of reporting and analysis will need to be supported by communication, feedback and sharing to and among the relevant actors about the different outcomes and conclusions that can be drawn from the COR, in order to demonstrate the value and benefit of reporting.

### 6.1.4. Actions

Actions and measures, decided at all levels, have to be implemented by the concerned actors, each at their level and in the extent of their applicability and relevance. Actions could target potentially RUs, IMs, ECMs, NSAs, the Agency as well as others actors described in the section 5 of this paper, and could consist in a wide range of different types of safety actions or measures to be implemented (changes in operators' SMS to consider new risks, change of supervision plan to consider new priorities, change of a TSI, change of a national rule, etc.).

Then, the implementation of these actions has to be monitored, again at every level of the actors involved, in order to ensure their proper implementation and their efficiency in the improvement of safety

performances. This monitoring could often need to define which performance indicators to be followed. The monitoring is also important for instance, to check if a safety action does not decrease performance of another area of safety. Additionally, if the monitoring of the safety performances shows that the measures were not efficient enough, a new risk assessment process should be carried out, following the steps presented <u>above</u>.

# 6.2. Access and confidentiality: who can see what, across borders and between commercial competitors?

As detailed in the previous section 5, the achievement of the objectives of improving safety level within EU as well as better management of the risk of multi-fatality accidents is a matter relevant for all actors

The paper related to the set of occurrences and taxonomy<sup>38</sup> intends to provide the common structure that will support a sharing at EU level from the perspective of the content of the data. The sharing of data collected through the future COR system will also depend a lot on the system architecture of the future solution and the IT solutions (especially in term of data format). Different ways of sharing can be envisaged and several proposal options will be made later in the project when the Agency will provide a system proposal (see <u>project plan</u>), but not in this paper.

The other issue related to the sharing of data concerns the different levels of access and confidentiality requirements that come with sharing of safety data at EU level, within competitors and between certified/authorised entities and authorising/certifying entities.

It is assumed that IMs/RUs/ECMs will be contributors to the COR system and they will either make the relevant data accessible from their own systems, or submit first occurrence reports either through NOR or via European OR system (please refer to phasing paper for more details). Depending on the option, they will need to have access to an European IT tool to report directly or to transfer periodically a compatible file/information to COR or NSAs will transfer this information to COR from NOR system.

In any of above mentioned options, several sub-options regarding the access to COR given to the different actors can be considered:

- Either contributors (IMs/RUs/ECMs) will have access to the future COR system to use safety management data to fulfil their roles and responsibilities. NSAs/NIBs and the Agency are not direct contributors of the occurrences, but will also use safety data and information to fulfil their roles according to EU legislation (different needs and roles of the actors were already described in this paper).
- Or access to COR data is only provided to those (NSAs, NIBs, TDG CAs and the Agency mainly) responsible for analysing the data at a collective level. Then, outcomes from these collective analysis are provided to all relevant actors. This option would facilitate protection of individual data (please refer also to the section related to <u>data protection issue</u>)

General Principals which should be considered for the future COR system on access and confidentiality are presented in the following table:

RUs/IMs	Need to have access to their own submitted occurrences and to have general access/overview of the occurrences on national and EU level (e.g. safety performance). No need to have access to data related to confidentiality issues such as the name of companies involved in the occurrences (unless they are involved party). This will prevent harm to reputation of the companies or unfair competition
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### Table 4 General principals on access and confidentiality for different actors

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<sup>&</sup>lt;sup>38</sup> Paper on designing the common occurrences and taxonomy - ERA-PRG-004-TD-002

	e.g. using safety performance data in tendering procedures, attractiveness to passengers, etc.
ECMs	Need to have access to their submitted occurrences and to have general access/overview of the occurrences on national and EU level. No need to have access to data related to confidentiality issues such as the name of companies involved in the occurrences, unless they are ECMs of RUs rolling stock. Furthermore, no need to have access to occurrences related to infrastructure operations.
Other railway actors and researches and universities	Need to have access to general overview of the occurrences on national and EU level for research and other legitimate purposes. These purposes should be defined e.g. by legislation or there should be a process for access on a case by case basis with defined criteria. No direct access to the COR system should be necessary and rules on how to answer upon request from such actors will have to be defined.
NIBs	Need to have full access (including confidential data such as name of RUs/IMs/ECMs) to submitted occurrences on national level (taking into account cross-borders accidents and incidents) and general access/overview on EU level.
NSAs	Need to have full access (including confidential data as name of RUs/IMs/ECMs involved, excluding names of individuals) to submitted occurrences on national level in terms of supervision activities (taking into account foreign RUs/ECMs operating in national network) and general access/overview on EU level.
TDG CAs	Need to have full access (including confidential data as name of RUs/IMs/ECMs involved, excluding names of individuals) to submitted occurrences on national level and general access/overview on EU level.
ECM certification bodies	Need to have access to confidential data related to ECMs an ECM CB has certified. Need to have general overview of occurrences at EU level. No need to have access to confidential data of companies other than those it has certified.
The Agency	Need to have general access to national and EU level. No need to have access to confidential data (e.g. name of the company) unless only for governance purposes or issues with the occurrence report (e.g. quality check) depending on the design of future COR system and governance.

It is clear, that different actors will have different access rights to the COR system, taking into account confidential information such as the name of the reporting company and other companies involved in the occurrence in order to avoid unfair competition in the context of sharing occurrences and data. It will be also necessary to consider the confidentiality and access rules in relation with hazards linked to security matters which can lead to prevent access to some information and influence the rules regarding the policy on granting of access to the future COR. However, certain categories of the occurrence report should be treated as non-confidential (e.g. consequences/causes, etc.). Furthermore, some of the future information generated from the data will need to be publicly reported and available (e.g. the safety performance reporting done today) without information related to direct actors involved (RUs/IMs/ECMs) and specific and more detailed information on each occurrence.

In addition a future COR system can provide a valuable resource for research. Thus, restricted and limited access for researchers and universities (with confidential elements removed) in railway sector should be considered as well. Data could be used for international comparative research, while informing the public about emerging issues in rail safety. The same approach is used in other transport modes e.g. aviation and non EU countries e.g. USA and Australia. Thus, some part of COR data could be either public or provided with

limited access (e.g. the scheme could be confidential in terms of the identity of the reporter and any other individual named within it. On receipt the report could be first anonymized in that any identifying details are removed before the report is available to the appropriate body or group for action. Certain categories of report could be however not treated as confidential and provided for the user), if this is a direction in which the Agency and stakeholders and users wish to go.

It is worth noting that, today, there is a growing trend towards open data, including open source data consisting in safety occurrences reported and shared (e.g. <u>SNCF</u>, <u>DB</u> public databases). Third parties could provide real value by analysing open data for different purposes. It is not always the case that data generators that are the best providers of data analysis. Also, open data is already used by train companies and journey planning app developers etc. Thus, it could bring additional benefits if future COR data could be open as much as possible, subject to the need to keep some details or specific data as confidential. However, as the <u>DNV study</u> showed, the majority of the NOR systems (three quarters of them) are confidential and no access is provided for non-railway actors (e.g. journalists, members of public, etc.). Thus, the common position on the open data and access should be considered for future COR system by all relevant parties.

From this analysis and the needs highlighted in the previous section 5 of this paper on how the future COR system will answer current limitations in achieving the objectives set, it can be considered that three different "levels" of sharing will have to be defined:

- Sharing within each operational actor (RU, IM, and ECM): data collected by operational actor have
  first to be shared within the company. The goal is to use these data as required by the CSM
  monitoring. Data collected for this internal purpose has to be defined by each operator, according to
  their own needs, on the basis of their own risk assessment. The amount of data collected internally
  here is supposed to be wider than the collection and sharing at COR level.
- Sharing between authorities/certification bodies (NSAs, NIBs, TDG CAs and ECM CBs) and operational
  actors, for supervision purpose mainly. Here, the aim is to achieve sharing between the operator
  which reports occurrences and the authority which perform supervision/surveillance activities of this
  operator. The authority needs to have access to confidential data related to the companies within its
  scope of activity. Today, this level is done usually at national level through NOR system and any future
  COR system will need to take these national systems (and needs, for those without comprehensive
  NOR) into account as far as possible whilst still achieving the overall objectives of European sharing.
- Sharing at EU level, within all actors (RUs, IMs, ECMs), authorities, certification bodies, the Agency: This level of sharing aims to allow sharing of safety management data among all EU actors, as identified in the section 5 of this paper. At this level, sharing of data will have to be done according to the same structure, with the same level of detail, wherever data have been collected and reported first. This issue is treated already through the paper related to the structure of occurrences and related taxonomy<sup>39</sup> which provides what has to be collected and reported for the future COR system. At this level, confidentiality aspects and access rights will have to be considered as explained earlier in this section.

This can be represented by the following diagram:

<sup>&</sup>lt;sup>39</sup> Paper on designing the common occurrences and taxonomy - ERA-PRG-004-TD-002



Figure 23 Different levels of sharing

This diagram shows only the different level of sharing that has to be considered for the future COR system. It does not intend to represent exactly neither the future situation as we recognize its limitations, nor the future architecture of the system.

# 7. General overview of COR system future governance (Registration, administration of the system, responsibilities to be defined)

In order to achieve COR objectives, collaborative governance of the future COR system has to be established, ensuring stakeholder involvement and their contribution to the COR system is required. Moreover, in order to tackle different risks and barriers, shared governance between Agency and stakeholders has to be established by appropriate means (e.g. MoU, Terms of Use, legislation) clearly defining the governance roles and responsibilities of each of the actors, possible usages and rules of the future COR system.

The future COR system will require a management and administrative component. Occurrence reporting in other sectors is usually characterised by a governing or steering committee of users and reporters who could input to or direct these decisions and ideally provide an early indication of a need to change the occurrence reporting system. The purpose of the "user group" would be to provide governance of the future COR system and in particular to propose changes for the system and associated occurrences and taxonomy. The User group should monitor the COR system against the objectives it has set and propose amendments as

appropriate and ensure quality of the database. This links to the precondition on the validation and verification of the data.

It is likely that the Agency will be a data processing organisation and will be responsible for the overall COR management, including relations with the IT solution providers, who will supply the technical infrastructure to the system and ensure data protection, data integrity and the overall system security.

Furthermore, as it was mentioned before, clear rules defined by Terms of Use, Memorandum of Understanding (MoU), legislation or guidelines have to be elaborated for future COR system management as well to identify responsibilities and different roles of the users. Moreover, future COR IT system will be designed according to the specification. A user group could contribute to elaboration of the above mentioned documents.

### 8. Ownership, validation and quality of the data

Future COR system will define the reportable occurrence list and taxonomy associated with each occurrence, the definitions of the occurrences and taxonomy and provide an electronic IT system to accept the data and, possibly depending on the technical solution, store it. It is clear that the Agency will own the future COR IT system, whether national systems connect to this European platform or report directly into it. However, as it was mentioned before, it will be used by different stakeholders for different purposes.

Data validation is important in removing errors and providing common interpretation of occurrences. The use of an analyst is needed to validate the data and follow up with the reporter concerning any missing or ambiguous information. For a future COR system to have value it should be consistent and complete. Many organisations involved in occurrence reporting maintain dedicated personnel to do this. The same should apply for any future COR system, depending on the chosen option for final structure between NOR and COR systems. This means, that data validation needs to be ensured in the reporting organisations (RUs/IMs/ECMs), NOR system authorities (NSAs/NIBs) and COR system on EU level by the Agency (depending on the final option of future COR system). Thus, dedicated resources have to be ensured by all relevant parties.. This information will support impact analysis of the final COR system proposal next year.

The easier the future COR system will be to use, the greater will be the use of the system. This is why standard forms and templates based on a limited set of simple criteria encourage reporting. Taking into account the first proposal on occurrence categorisation and taxonomy, it is clear that any EU reporting tool will be based around tick boxes or drop down menus (although some free text fields will be provided) with each occurrence being associated with a limited and specific set of reporting requirements which would be easily validated. Furthermore, it may be possible to automate the system to validate much of information, and to consider connection to other databases to facilitate the reporting and limit inputting errors (e.g. connection with RINF, ECVVR, etc.).

It is important that data should be validated and verified as appropriate to the agreed objective. Safety critical decisions should only be made on comprehensive and accurate data and access to a wider dataset than today will only bring benefit if there is a good quality of data recorded in the future COR system. Both verification and validation are best and most easily undertaken as close to the source of the occurrence as possible, both in geographical and cultural terms i.e. Member state level. Moreover, the COR system should consider implementing measures for ensuring data quality by appropriate guidance, definitions and terms of the system and possible measures to avoid double reporting (reporting protocol/rules) and incorrectly identified occurrences or missing occurrences.

Finally, COR system should consider strict and transparent information sharing rules and possibilities for access to data. Data could remain in the ownership of data providers, it does not become public after being transmitted to the future COR system taking into account clear rules, which would allow publication of the

data and information gained from the data. Also, COR system should provide guidelines for appropriate interpretation and use of the COR system outputs as well as to provide guidance on how to use benchmarking as one tool amongst others. Regular trainings and supports from the Agency about the use of the COR system to the different users will have to be provided as well. This will ensure correct interpretation of data by different stakeholders.

### 9. Data protection issues

A strong level of data protection has to be guaranteed for future COR system: legally and technically. This will help to ensure, that risks related to the use of the safety management data for judicial or commercial purposes, as well as data leakage, is prevented and avoided. The following risks or barriers should be considered in the future COR system:

a) Personal data sensitivity of the reporter and users. COR system should consider compliance with applicable data protection legislation, technical data protection, identification of users and possibility not to collect personal data.

b) Safety management data use, access and confidentiality. COR system should consider technical data protection, identification and data usage rules allowing to differentiate access rights according to the type of user and type of data. This could be done by appropriate governance and rules defined by Terms of Use, MoU, legislation and guidelines, ensuring that safety enhancement is the sole purpose of the COR system. Different levels of access will be possible, thus users may be able to store and process data only for their own purposes and only accessible to them.

c) Use for enforcement or legal prosecution, data disclosure. COR system should consider defining clear collaborative governance that excludes use of data for any enforcement or prosecution actions. Nevertheless, impact of a future dedicated COR legislation is likely to have a very limited impact on the achievement of this, as such aspects remains at national legislations level and cannot been legislate at EU level. There should be also an appropriate legal framework, limiting the risk of having to disclose specific (e.g. names or staff involved, personal data, etc.) data or information upon judicial or other request taking into account possibility to disclose basic factual information. In addition, it might be relevant and justified to disclose reports showing a timeline or similar occurrences and etc.

d) Data leakage or cyber security breaches. COR IT solution providers should supply the technical infrastructure to the system and ensure data protection, data integrity and the overall system security from any forms of hacks and etc. Although, clear terms of use could be created, it would not be possible to prevent individuals to e.g. taking the photos or screenshots, copying and sharing the text/data from the system.

Any additional risks or barriers with mitigating actions which should be considered in the future COR system for data protection are welcomed by the Agency during stakeholders consultation.

### 10. Outcomes from the consultation

The first version of the paper on roles, use of data and governance was elaborated by the Agency and provided for comments to railway stakeholders (including railway operational actors and authorities) from 08/02/2017 and 04/04/2017. A dedicated workshop was organized by the Agency on 22nd and 23rd February 2017 in Lille to support the consultation.

This second version includes the comments received as a result of the consultation, and also those provided during the above mentioned workshop.

The Agency appreciates all received comments and proposal from the various railway organisations and authorities. This consultation provided a general view to the Agency of stakeholders expectations and raised questions and issues which should be tackled for the future development and implementation of the COR project. These questions, comments and proposal have been taken into in this revised version of the paper to the extent possible, or will be considered for the next step of the project, in particular the impact assessment and the system proposal as expected by the project plan.

To support the consultation, the Agency raised a number of questions regarding the first version of the proposed paper related to the legislation. The following table provides the most common views and outcomes provided in the course of the written consultation or during the supporting workshop:

Question raised in the paper	Stakeholders' views	Agency's views
Question raised in the paper Should some other actors listed in article 4 of the Safety Directive and not mentioned in this paper be covered ? If any, for what purpose these other actors should have access to the future system and how would they use data ?	The stakeholders views The stakeholders generally supported the scope of the paper and consider that all potentially relevant actors are targeted. There is also a general support by the stakeholders on the fact that the reporting bodies should be limited to operational actors (RUs, IMs and ECMs), as they are the ones the best placed to report occurrences. Some stakeholders also highlighted that integrating ECMs in the scope of reporting is clearly challenging as they are not covered in current NORs systems and might be difficult to capture.	Agency s views The Agency agrees on the need to clearly define the roles of the different actors, in particular regarding the access rights given those actors. This will be further detailed in the system proposal that will be released by the Agency by end of 2017. The Agency also agrees on the necessity to limit the occurrences reporting to RUs and IMs as they are the best placed to do that. that they are not covered today in NORs. Covering reporting by ECMs (and more generally reporting of occurrences from maintenance activity) will require to be considered in a longer term perspective and might not be feasible at the beginning of the implementation of a COR system. The role of ECMs certification bodies should also be considered in this regard.
For each of the roles described in section 5.1, the Agency would welcome contribution and evidence on the data needed to fulfil these data use, as well as other related constraints such as timescale necessary, with reference if possible to the earlier consultation paper on Designing the common occurrences. For each of the roles described in section 5.1, the Agency would welcome contribution and evidence on the data needed to fulfil these data use, as well as other related constraints such as timescale necessary, with reference if possible to the earlier consultation paper on Designing the common occurrences	The stakeholders generally considered that this paper and the paper on taxonomy sufficiently describe the data needed for each actor. Several stakeholders mentioned the need to define a risk classification scheme in order to classify each occurrence according to their related risks, allowing a proper risk-based approach and in order to proportionate investigations of occurrences to those that are really relevant.	The Agency shares the views of the stakeholders and will consider this in the future comprehensive system proposal that will be released by end 2017. Regarding risk classification, the Agency recognises its relevance, as explained in the taxonomy paper. However, some NORs already having developed different methodology for such risk classification, there will be a need to further consider and discuss the need or not for an harmonised approach within a future working party at a later stage of the project.

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What would be the actual benefits of the COR SMD system on the monitoring process of railway companies (RUs, IMs, ECMs)? o Is a harmonised data set would support their own SMS or system monitoring activities, particularly smaller, less well-resourced organisations? Either by establishing a common structure for data collection, even if not all of that data is shared, or by creating a wider shared data set to support internal monitoring? o Would the possibility for operational actors to add their own specific taxonomy to a future common reporting system for their own needs and purposes of managing their own data collection, support RUs/IMs/ECMs monitoring activities? Are there are any other ways the data could be used to support SMS development by operational actors?	Stakeholders stressed the need to let operators define their own need in term of collection for their own purpose, which remains wider than COR. There is a support in developing a common basis in order that COR data can provide more statically relevance than only company or national databases. However, for this, setting up of common definitions will be crucial. Respondents also broadly supported that COR focuses on serious accidents as they are the most relevant for all actors, whereas a large number of occurrences might not be of relevance for every actor as they might be too specific. Some stakeholders mentioned also that the added value in having COR system is seen limited for biggest companies. The need for smaller companies to be resourced enough to provide the right analysis has also been reported has a potential issue. Respondents considered that the use by operators of COR data would consist mainly in: benchmarking, using of a wider set of occurrences for monitoring of low frequency/high consequence accident, and getting feedback for their SMS design.	As mentioned in the paper, the need for RUs, IMs and ECMs to assess their own risks to design their monitoring needs will remain and the future COR system does not intend to take over that responsibility which is defined in the CSM on Monitoring. Nevertheless, one of the benefit of COR will be to establish a common basis (notably a common set of occurrences and a common reporting and sharing regime of those occurrences) recognised and usable by all actors, in order to improve in turn, the knowledge and decision-making regarding safety issues. The benefits that can be expected from a COR system are explained in the paper for each of the actor concerned. These benefits will be further assessed in the impact assessment from a cost-benefit perspective.
What would be the actual benefits of the COR SMD on the risk assessment process of railway companies, in particular with regards to the CSM for Risk evaluation and assessment: o How data can support the system definition? o How important is a list of known hazard to support the "Hazard identification and classification"? o How the whole risk analysis activity can be improved by having more and better quality data?	Some stakeholders supported the establishment of a common hazard log, provided that this does not intend to replace own company risk analysis as such a list of hazard would be limited and might not covered each company specific case. Such list of known hazard should be seen only as a support to railway undertakings and infrastructure managers, when applying the CSM RA for example, and especially for company with none or less data. The improvement of quantitative risk analysis at EU level has been also mentioned by some respondents as a	As mentioned in the previous comment and in the different papers, the Agency's view is fully in line with these comments.

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<ul><li>o How the risk evaluation can be more accurate by using an historical safety database?</li><li>o How important could be a safety data to support the demonstration of compliance with safety</li></ul>	benefit expected from having access to COR data.	
compliance with safety requirements?		
Should COR cover also the purpose of article 22 of the Safety Directive (immediate notification to NIBs) and include an urgent reporting function of accident to answer NIBs' needs.	There is a global support to not intend to cover this aspect through the future COR system as urgent information to NIBs require a specific and more immediate process.	This view is also shared by the Agency.
Will it be a need for the Agency to develop tools usable by all different actors to support decision-making for targeting and risks classification methods?	Most of the respondents declared that no need are identified, in particular because actors are already deemed to have developed and implemented something. This topic is seen at the border of the scope of COR and of less priority for the time being. However, in term, some stakeholders recognised that there might be potential benefit in having a common and recognised risk classification.	The Agency , as it is foreseen in the project plan, will not develop such tools and methods in the context of the COR project. Such development should be considered for a longer term perspective and will depend on the final shape and capability of the COR system. However, developing a system such as COR should also enhance the need for such methods when enough data will be available. Further discussion in the future with the stakeholders will help to identify clearly what will be the needs.
Do you support a future setting up of collaborative groups at EU level, coordinated by the Agency, in order to identify actions to be implemented to improve safety at EU level, and helping the development of analytical capability of the railway actors ?	The setting up of collaborative groups at EU level is broadly supported by the respondents. The need to clarify what will be done at this level and how (decisions about measures to be implemented, support the development of analytical capability of actors, etc) has been also stressed.	The Agency welcomes the answers from the stakholders and the general support to this approach. Governance and roles' aspects of such collaborative groups will be further developed in the next stage of the developments of the COR project and will be subject to discussion with the relevant parties in order to define the best approach.
Do you agree/disagree on general principles which should be considered for the future COR system on access and confidentiality? Is something missing?	Respondents highlighted that the future confidentiality principles for COR will require to consider national regulations which already impose some requirements. Respondents also stressed the need to cover the confidentiality issues with more details.	The Agency agrees on the principle to consider some information confidential for the sharing among all actors. However, it is likely that confidentiality will have to be considered differently according to the different levels of visible information, as introduced in the section 6.2 of the paper.
What kind of information in the occurrence report should be considered as confidential and which information should be deemed as non-confidential? Please give specific justification and examples to support your views.	Broad support by the stakeholders to the basic principles described in the paper. However, the need to have further details and to take into consideration existing systems which might have stricter rules at national level.	The Agency recognises that confidentiality remain one of the most important topic and will continue the work with the stakeholders on this aspect in the next stages of the project.

Should other railway stakeholders (railway researchers, universities) have access for data analysis for research purposes? To which data they should have access? Should non-railway actors (e.g. journalists, members of public, etc.) have an access for COR system?	No support by respondents for granting access to COR to actors which are non-railway organisation. However, providing data from the COR could be considered upon reasoned request, following commonly agreed rules between all involved actors in the system.	The Agency supports also the view and the general principles broadly provided by the respondents and which are already partly covered in the section 6.2 of the paper. The process and rules related to answer to request from non-railway organisation such as researchers or public, will depend on the final shape and governance of the future COR system and will be worked out with the stakeholders in the dedicated working party, if a legislation if finally developed.
Should the "User group" be established for future COR governance? Who should lead and facilitate this group? What should the tasks and competences of this or these group(s) be?	The establishment of user group is seen as essential by the respondents, though the definition of the roles of such group will have to be further defined.	User representative. Agency might facilitate but open to see how it should regulated. It will depend on what the system is finally.
How much resources today are dedicated and spent per year by different stakeholders to the data validation and quality for their internal OR systems and NOR systems? Please specify in numbers and amounts if possible.	The Agency thanks the answers given by the respondents and will use this information to support the on-going impact assessment.	
Do you see any additional risks or barriers which should be considered in the future COR system for data protection? What should be mitigating actions to tackle this additional risks or barriers?	Some respondents have identified the risks related to security issues (cybersecurity/hacking) and mis-use of data as risks to be considered for a future COR system. Some respondents stressed that defining the right confidentiality rules will be crucial to build the necessary confidence and willingness to report.	The Agency recognises that the security aspects is also an issue that will need to be tackled and will be covered when technical specifications of the IT system (if any) will be developed.

### 11. Proposed next steps

This is the first proposal aiming to achieve a common understanding of the different aspects related to the roles of the actors and the governance of the future COR system. The final aim of this paper is to serve the definition of the comprehensive proposal for a European COR SMD that the Agency will define in 2017, supported by an impact assessment.

It should be noted that the interpretation given in this proposal that has been developed by the COR project team, to start the discussion with a wide range of stakeholders and experts in order to find common ground

between all parties. The objective of this document is to serve as a common basis for the other deliverables of the COR project.

In time, if a decision is taken by the Commission to issue a mandate for legislation, considerable work will be needed, working with stakeholders, to develop, and agree as far as possible, a recommendation, according to the Agency's normal working procedures.