

Annex III: Matrix Guide NSA Monitoring GUI_WKG_v1.0

Making the railway system work better for society.

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NSA Monitoring



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Guide

NSA Monitoring Matrix

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Process Deployment	Core process > Monitoring > Monitoring Railway Activities	
Process Owner	Head of the Safety Unit	
Process Customers	National Safety Authority of concerned Member states. RUs and IMs are marginal involved in the process during the interview activity.	
purpose	To lay down the criteria of NSA Monitoring Matrix evaluations in order to ensure its harmonisation and consistency.	
Scope	This document is the methodology for the NSA Monitoring activity. Depending on the NSA decision, RUs and IMs can be interviewed during the process in order to get a picture of the performance of the NSA.	
Legal Basis	Regulation (EU) 2016/796	
	Art.13: Technical support – recommendations on railway safety	
	Art.33: Monitoring of the performance and decision-making of national safety authorities	

1 DEFINITIONS AND ABBREVIATIONS

IM	Infrastructure Manager
RU	Railway Undertaking
RSD	Railway Safety Directive
NIB	National Investigation Body
NSA	National Safety Authority
Standard	Used in its broadest term, meaning that a specific behaviour is described in written form. Depending on the type of risk regulation regime the "standard" can be a rule, norm, guidance or a standard issued by a standardisation body such as ISO, CEN, CENELEC etc.

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2 EXECUTIVE SUMMARY

The NSA Monitoring Matrix is a maturity model designed by the Agency to monitor:

- 1. the capacity of national safety authorities to execute tasks relating to railway safety and interoperability; and
- 2. the effectiveness of the monitoring by national safety authorities of safety management systems of actors as referred to in Article 17 of Directive (EU) 2016/798.

The NSA Monitoring Matrix is structured to analyse:

- the internal processes of the National Safety Authorities;
- the interfaces established between them; and
- the coordination of NSAs at European level.

All these 3 elements are crucial for the capacity to execute their core tasks and to monitor effectively the safety management systems of relevant players.

The NSA Monitoring Matrix also looks at how their tasks are carried out as foreseen in the Railway Safety Directive and to which extent they strive for continual improvement.

The NSA Monitoring Matrix is based on the latest research within the area of risk regulation regimes, basic system management models and ISO standards. Its effectiveness has been proven during the implementation of the Regulatory Monitoring Matrix, which is based on the principles but structured to evaluate Member States in their entireness.

The data used during the evaluation process is evidence-based and traceable. The NSA Monitoring Matrix can collect information from sources such as interviews, the national safety reports, Agency questionnaires, and previous NSA cross-audit reports.

Finally, through the NSA Monitoring Matrix, strengths and weaknesses can be identified in a systematic way and the reasons behind these can be described. This will help the Agency in prioritising its work and the NSAs in understanding their potential for improvement.

3 INTRODUCTION

The technical pillar of the 4th Railway Package has changed the role of the European Union Agency for Railways, which moved from having the sole role of promoting the establishment of a European railway area, to a being a railway authority. In fact, the Agency keeps its 'advisory role' towards the European Commission but also assumes, among others, the responsibility of monitoring National Safety Authorities.

To fulfil the last obligation, the Agency is oriented to use a capability and maturity model: the NSA Monitoring Matrix. The aim of this model is to evaluate whether the NSAs have the necessary processes and management system in place to execute their tasks properly but also the maturity level of the NSAs, i.e. measuring their attitude to prevent and react, in other words to prevent issues when possible and to learn from the experience.

4 THE STRUCTURE OF THE MATURITY MODEL

The NSA Monitoring Matrix is structured considering:

- The Plan-Do-Check-Act¹ cycle (P-D-C-A cycle);
- The applicable legal framework, to contextualise the evaluation in the EU railway system.

The first idea of the P-D-C-A cycle is that any organisation, which wants to control its outputs, firstly needs to identify its goals and organise itself in a way that will allow it to reach those goals (Plan). It then needs to carry out the activities that will lead to the fulfilment of the goals (Do), followed by measuring how effective

¹ Stewhart's cycle of plan-do-check-act.

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it is in reaching the goals (Check) and then, decide whether or not it needs to implement any changes in order to become better at reaching its goals (Act).

The Plan-Do-Check-Act concept may be divided into five basic elements that form the backbone of the NSA Monitoring Matrix. These five elements are in their turn divided into sub-elements in order to better define the individual building blocks of the EU railway risk regulation regime.

All in all, 17 sub-elements (see table below) have been identified. These are essential for NSAs to achieve their main tasks.

Elements of a management system	Basic elements	Sub-elements
	1. Steering	1.1 Goal setting 1.2 Leadership & Management
Plan	2. Organising	2.1 Establishment2.2 Accountability2.3 Safety culture management2.4 Interface management2.5 Risk-based approach2.6 Change management2.7 Record keeping
	3. Resourcing	3.1 Resource management
Do	4. Performing	 4.1 Supervision and Enforcement 4.2 Certification and Authorization 4.3 Promoting the safety regulatory framework 4.4 Authorisation of technical sub-systems 4.5 Monitoring the Sector
Check		5.1 Monitoring the Risk Regulation Regime
Act	5. Evaluating	5.2 Review

Table 1 – Main Matrix structure: PDCA cycle, basic elements and sub-elements

5 THE LEVELS

As described in the previous chapter, the Matrix structure is based on 5 elements created from the P-D-C-A cycle. Each sub-element is evaluated taking into account documents, reports and interviews. The evaluation is properly described in the NSA Monitoring Matrix Report, which will include also a level assigned to each sub-element (Table 2).

The levels are defined with the only purpose of providing a quick overview on the state of the NSA in relation to the specific sub-element, therefore they are not defined with the idea to set thresholds and passmarks.

Decis classes to		Cub alamanta	Measuring scale				
ва	sic elements	Sub-elements	1 Ad hoc	2 Initialising	3 Implementing	4 Managing	5 Improving
		1.1 Goal setting)		0 0	
1.	Steering	1.2 Leadership &					
		Management					
		2.1 Establishment					
		2.2 Accountability					
		2.3 Safety culture					
		management					
2.	Organising	2.4 Interface					
۷.	Organising	management					
		2.5 Risk-based approach					
		2.6 Change management					
		2.7 Record keeping					
3.	Resourcing	3.1 Resource					
5.	Resourcing	management					
		4.1 Supervision and					
		Enforcement					
		4.2 Certification and					
		Authorization					
4.	Performing	4.3 Promoting the safety					
		regulatory framework					
		4.4 Authorisation of					
		technical sub-systems					
		4.5 Monitoring the Sector					
		5.1 Monitoring the Risk					
5.	Evaluating	Regulation Regime					
		5.2 Review					

Table 2 – Elements, sub elements and levels

Effectiveness within each sub-element is measured against a five-step scale, ranging from *ad hoc* performance in the lower end to excellent performance at the top:

Level	Performance	Description
1	Ad hoc	Tasks are not delivered or delivered in a random and unstructured way.
2	Initialising	The creation of a structured way of delivering tasks has started, but structures and processes are not yet fully implemented.
3	Implementing	The processes that were created in order to deliver tasks in a structured way have been implemented.
4	Managing	As for Level 3, plus: The NSA controls the outputs by following-up and reviewing how well the processes help to deliver the tasks as required, including carrying out corrective actions when necessary. (reactive approach, correcting)

5	Improved	As for Level 4, plus: The NSA continuously strives to go beyond merely fulfilling the basic legal requirements and deliver its tasks in a better, more effective and efficient way (improving). (pro-active approach, preventing)
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Table 3 – The measuring scale: levels and descriptions

Being the NSA Monitoring Matrix a maturity model, the measuring scale does not express any approval or acceptance by the Agency. The measuring scale is designed to highlight strengths and weaknesses and to allow the National Safety Authorities to compare themselves against each other and against themselves as they evolve over the years.

During the Monitoring of NSAs, the evaluation team is guided by the general description of the five levels, as explained here, and applies these to the more detailed criteria related to each sub-element, which are described in Annex I.

In order to have a common understanding of the particular performance levels and to ensure consistent, objective evaluations of performance by each National Safety Authority, the Agency has detailed some typical criteria that would be expected to be present on each maturity level for each of the sub-elements. They should not be seen as exhaustive or exclusive. They are merely examples of what one could expect to find in an NSA.

The NSA Monitoring will however still look at how the NSA have structured and implemented their processes in conformity with the applicable legislation, which is one of the basis used to define the criteria detailed in Annex I.

When reading the performance levels it is possible to follow how a certain criterion develops from level 1 to level 5, for example in the sub-element of "Interface management" (2.4) it is possible to follow criterion B from level 1 to 5 accordingly:

Level 1	INTERNAL INTERACTION AND SHARING OF INFORMATION: The NSA is aware of its internal interfaces but
	manages them on an informal, ad hoc basis. There are no processes or structures in place to
	support an active and timely sharing of information within the organisation. The right
	information is not available for making decisions.
Level 2	INTERNAL INTERACTION AND SHARING OF INFORMATION: The NSA has started to put a process in place
	to identify the communication needs between units and sectors.
Level 3	INTERNAL INTERACTION AND SHARING OF INFORMATION: All internal interfaces are systematically
	identified and managed. There are processes and structures in place to support an active and
	timely sharing of information within the NSA.
Level 4	INTERNAL INTERACTION AND SHARING OF INFORMATION: As for level 3, plus: All processes related to
	internal interfaces and the internal sharing of information are managed and measured to assess
	their effectiveness.
Level 5	INTERNAL INTERACTION AND SHARING OF INFORMATION: As for Level 4, plus: Relationships are
	proactively built between departments and units to avoid working in silos. Working practices
	ensure that the organisation works as a coherent system and not as a group of individual or
	fragmented units. All processes related to internal interfaces and the internal sharing of
	information are regularly reviewed with the aim to continuously improve them.

Table 4 - Example of evaluation of the sub-element - Setting the legal framework

The structure of the NSA Monitoring Matrix detailed in Table 2 is designed to be flexible. Depending on the monitoring policy of the Agency, the configuration (e.g. type and number of sub/elements and questions asked for each of them) may vary. For instance, if the Agency believes that its priority for the monitoring cycle is the supervision process of the NSAs then the relevant sub-elements related to the safety certification process might be evaluated more superficially, while the one related to supervision might be evaluated with more attention.

Annex I: EXPLANATION OF THE MATRIX ELEMENTS

1 Steering

The basis for any well-functioning risk regulation regime is a common goal which all actors in the regime are trying to achieve. A common goal requires all actors to behave according to the same principles and/or similar rules. Poor performance in this area leads to a scattered system where measures taken by the individual organisations risk to be counterproductive. A sound Steering within a risk regulation regime includes clear goals and solid leadership. The National Safety Authorities are not an exception, "Goal settings" and "Leadership & Management" are part of a steering process which is essential to define goals and objectives of the organisation.

1.1 Goal setting

This sub-element looks at:

- > internal policies, objectives and targets (or similar) of the NSA; and
- consistency of policies objectives and target with the EU policy on railway safety and interoperability

There is no single method to work with goals that is acknowledged worldwide as being the best method in the field. There is even no single definition of normal terms such as *policy, strategy, goal, objective, priority, milestone, target* etc. The NSA Monitoring Matrix therefore does not set out to describe one ultimate way of working with goals that would automatically result in getting a Level 5.

The applicable legal framework requires the NSAs to set up policies, strategies and plans. Furthermore long-term and short-term goals are required to establish structured and auditable processes.

The National Safety Authorities should set out their objectives in collaboration with the competent ministry and a national transport policy, if this exists. This is because high level national goals concerning railway safety and interoperability would normally be found in the national transport policy and the NSA, as player in the system, should contribute to their achievement. However considering that the NSA Monitoring Matrix is not designed to assess the member state but only the NSA, the absence of a national policy will not influence the evaluation of the NSA.

From an EU perspective, a single European railway area can only be achieved if all National Safety Authorities move in the same direction. In practice NSA's internal policies are subordinate to the EU transport policy and the goals set in the EU legal framework and must be in line with them.

Level 5 in the Matrix is attributed when the NSA has an internal policy in place where strategies, goals, objectives, priorities, milestones, targets or other elements are defined. This policy is in line with European one and regularly reviewed with a risk based approach.

Interfaces with other National Safety Authorities are also taken into account when relevant.

The Matrix looks at the following criteria in relation to **Goal setting**.

Element 1: Steering				
Sub-element 1.1: Goal setting				
1 Ad hoc	A. INTERNAL GOALS: The NSA has no systematic way of establishing policies, objectives and targets (or similar). If there are some internal goals in place, these are often out of date or in conflict with each other and not in line with the EU policy.			
B. <u>IMPLEMENTING THE LEGAL FRAMEWORK:</u> the NSA's application of the rules is no always consistent, leading to unequal treatment of RUs and IMs.				

	С. <u>Соммол EU APPROACH</u> : There is hardly any recognition within the NSA of the need for a common EU approach therefore collaborating with the other NSAs
2	A. <u>INTERNAL GOALS</u> : The NSA is recognising the importance of working with policies, objectives and targets (or similar), and has started to form a system for establishing those on a regular basis. The need of consistency with between policy, targets and objectives and the EU policy is identified.
2 Initialising	B. <u>IMPLEMENTING THE LEGAL FRAMEWORK</u> : The NSA has started to create a process that ensures consistent application of the rules from one case to another.
	C. <u>COMMON EU APPROACH</u> : The NSA has started to investigate in which areas a common EU approach therefore a collaboration with other NSAs is needed.
3 Implementing	A. <u>INTERNAL GOALS</u> : The NSA has relevant policies, objectives and targets (or similar) for its organisation. There is a system in place to establish and implement these.
	B. <u>IMPLEMENTING THE LEGAL FRAMEWORK:</u> There is a process in place to ensure consistent application of the rules. The result of supervision activities undertaken by the NSA are addressed to the rule-maker as a proposed input to the process for drafting and updating the national legal framework.
	C. <u>COMMON EU APPROACH</u> : The NSA has a process in place which ensures that common templates and procedures (CSMs among other things) are used in order to be compliant with the EU regulatory framework. The NSA has an effective process to establish collaboration with other NSAs
	A. INTERNAL GOALS: As for Level 3, plus: The policies, objectives and targets (or similar) of the NSA are regularly updated based on feedback from monitoring of the railway system using a risk-based approach. Regular reviews ensure that policies, objectives and targets (or similar) are in line with each other and with the national/EU policy. The system to establish policies, objectives and targets is regularly reviewed in order to ensure that the system is still fit for purpose.
4 Managing	B. IMPLEMENTING THE LEGAL FRAMEWORK: As for Level 3, plus: The process is regularly reviewed in order to ensure that it is still fit for purpose, i.e. that it ensures that the legal framework is applied in a consistent way.
	C. <u>COMMON EU APPROACH</u> : As for level 3, plus: The process is regularly reviewed in order to ensure that it is still fit for purpose, The NSA actively seeks to harmonise their application of the rules with the application in other Member States. Common templates and procedures (CSMs among other things) are used with the aim to facilitate a harmonized treatment of RUs within the European railway system (including facilitating new and external RUs' entry into the market of the Member State). The process of collaboration with the other NSAs is regularly reviewed in order to ensure that it is still fit for purpose

	A. INTERNAL GOALS: As for Level 4, plus: The system for establishing and implementing policies, objectives and targets of the NSA is continuously improved. The policy includes a commitment to continually improve the efficiency and effectiveness of the core tasks of the NSA, with the aim to proactively improve safety in the railway system.
5 Improving	B. <u>IMPLEMENTING THE LEGAL FRAMEWORK:</u> As for level 4, plus: The process is continuously improved. Best practice in making and applying law is actively sought and implemented.
	C. <u>COMMON EU APPROACH</u> : As for level 4, plus: The NSA ensure consistency with EU approaches in all aspects of the NSA activities, including the collaboration with the other NSAs.

1.2 Leadership & Management

In order for a National Safety Authority to reach its high level railway safety goals (see Chapter 1.1), it is important that these are clearly communicated to and accepted by the relevant players in the system. It is also important that there is clear guidance on how the players should behave in order to meet the goals. Without knowledge of policy, objectives, targets and rules – and what good compliance to them looks like – it is difficult for the players in the system to live up to them. This sub-element is therefore studying different aspects of communication, leadership and management.

Communication is an important instrument in the NSA work to get both the staff's and the sector's trust and co-operation. It is equally important that the NSA co-ordinates its activities with the Ministry, the NIB and the industry so that all aspects of railway safety work are covered. It is therefore necessary that the NSA has an open and regular dialogue with all the other players of the railway system.

This sub-element also addresses leadership in its widest sense. It includes the leadership that the NSA and the industry in terms of a continuous dialogue about their tasks: monitoring how their activities are impacting on railway safety. In addition to this, the NSA require leadership from their Directors and Senior Managers so that the employees understand their roles within the risk regulation regime and how their actions affect the sector. In its turn, the railway sector requires a clear message from the NSA concerning the responsibility for the RUs, IMs and, when relevant, ECMs to manage the risks of their operations.

Any organisation that wants to function efficiently should consider implementing some kind of management system. By applying a systematic approach on the organisation's tasks it is possible to ensure consistent results and qualitative results. The Matrix does not prescribe any specific type of management system but it states that the NSA should have management systems in place ensuring that tasks are delivered in a consistent, effective and efficient way.

The Sub Element 1.2 point D – Support for the work of the NSA – can be evaluated only if the industry is involved in the NSA Monitoring Matrix.

	Element 1: Steering
	Sub-element 1.2: Leadership & Management
	 A. <u>COMMUNICATION OF INTERNAL GOALS</u>: There is no or little communication to staff about the policies, objectives, targets and procedures of the National Safety Authority. Leadership does not support deliverance of tasks in line with the overall goals and internal procedures of the organisation. B. <u>HIGH LEVEL COORDINATION OF THE MANAGEMENT OF RAILWAY SAFETY</u>: There is no or little dialogue between the different departments of the NSA on how to deliver their tasks. The dialogue that does take place is irregular and does not follow any particular structure.
	C. <u>ENSURING THAT THE SECTOR TAKES ITS RESPONSIBILITY FOR RAILWAY SAFETY:</u> There is little or no recognition within the NSA of its possibility and capability to push the sector towards managing safety performance through the adoption of an SMS.
1 Ad hoc	D. <u>SUPPORT FOR THE WORK OF THE NSA</u> : The NSA is not recognized by the industry as an important player in the realization of railway safety. RU/IMs are not aware of what the NSA does.
	E. <u>GUIDANCE ON NATIONAL LEGAL FRAMEWORK:</u> There is little or no guidance on national rules in force. Changes in the legal framework are not being consulted or are not consulted with all relevant stakeholders.
	F. ENSURING A STRUCTURED AND CONSISTENT DELIVERY OF THE NSA TASKS: There is no system within the NSA managing the activities with an aim to ensure efficient, effective and consistent delivery of the tasks (hereafter "management system").
	G. <u>LEADERSHIP MANAGEMENT WITHIN THE NSA:</u> There is no process in place within the NSA to select, create, support, maintain and measure leadership. There is no evidence of leadership. Incidents such as certificates being issued to clearly incapable RUs are seen as unavoidable.
	A. <u>COMMUNICATION OF INTERNAL GOALS</u> : Most of the policies, objectives, targets and procedures of the NSA are communicated to staff. However, due to the lack of a structured way of doing this, the information might be overlapping, out of date or not reaching all of its destined audience. Some of the managers communicate the importance of working in line with the organisation's policies, objectives, targets and procedures, but not all.
2 Initialising	B. <u>HIGH LEVEL COORDINATION OF THE MANAGEMENT OF RAILWAY SAFETY:</u> A process for regular dialogues, between the different departments of the NSA, on how to deliver their tasks together is being developed and put in place.
	C. <u>ENSURING THAT THE SECTOR TAKES ITS RESPONSIBILITY FOR RAILWAY SAFETY:</u> The NSA recognizes its role in pushing the sector but the attempts to ensure that RUs and IMs take their responsibility for railway safety are still not structured. This lack of structure might result in confusion within the sector about how they are expected to perform.

	D. <u>SUPPORT FOR THE WORK OF THE NSA</u> : The sector accepts the NSA as an important players in the realization of railway safety but since there is little communication between the different departments of the NSA on what messages to convey to the sector, this might lead to mixed messages. There is some knowledge by the RU/IMs of what the NSA does but they do not always know why.
	E. <u>GUIDANCE ON NATIONAL LEGAL FRAMEWORK:</u> The NSA is starting to put a process in place which ensures that information, including guidelines, about the applicable railway safety rules is communicated to the sector. The law-making entity (or entities) is starting to put a process in place for consulting the stakeholders on new rules.
	F. ENSURING A STRUCTURED AND CONSISTENT DELIVERY OF THE NSA TASKS: There are some procedures in place but there is no identification of links between the different procedures and they are not organised into an overall management system. However, a formal plan exists for further alignment of procedures, which has been initiated. Processes and procedures across the organisation are being mapped and potential synergies identified.
	G. <u>LEADERSHIP MANAGEMENT WITHIN THE NSA:</u> The NSA understands the need to have a process in place to select, create, support, maintain and measure leadership. Such a process is being drafted. For example, managers demonstrate leadership skills but these are not recognised or used consistently within the organisation. There is some awareness among individual staff about what impact their performance might have on the overall possibilities for the RUs and IMs to deliver safe railway transports, but there is yet no structured way for managers to support staff in doing a good job in this respect.
	A. <u>COMMUNICATION OF INTERNAL GOALS:</u> Policies, objectives, targets and procedures of the NSA are clearly communicated to all staff. Managers communicate the importance of working in line with these. These activities are following an established process.
3	B. <u>HIGH LEVEL COORDINATION OF THE MANAGEMENT OF RAILWAY SAFETY:</u> A process is in place which allows the NSA to ensure a regular dialogue with the Ministry and the NIB on how to manage railway safety on a national level, but focus is on specific issues rather than on how to improve the system as a whole.
Implementing	C. <u>ENSURING THAT THE SECTOR TAKES ITS RESPONSIBILITY FOR RAILWAY SAFETY:</u> The NSA recognises its role in leading the sector. The NSA actively pushes/inspires the sector to implement and maintain solid safety management systems. (However: If there is a voluntary association lead by the different railway companies in cooperation, supporting the management of railway safety issues for the whole system, it is appropriate that the NSA takes a step back and just monitor and support the activities of this organisation.)
	D. <u>SUPPORT FOR THE WORK OF THE NSA:</u> The industry generally accepts the NSA as important players in the realization of railway safety. The NSA and NIB cooperate regarding their respective communication with the sector in

 order to ensure that there are no mixed messages. The NSA ensures that RU/IM is aware of their activities and how they affect them. E. <u>GUIDANCE ON NATIONAL LEGAL FRAMEWORK:</u> The NSA clearly communicates applicable railway safety rules (EU and national) to the sector, incluwhat good compliance with them looks like. The NSA explicitly declare the sector that guidelines are not mandatory and ensures that they are contradicting the EU regulatory framework and related guidelines. F. <u>ENSURING A STRUCTURED AND CONSISTENT DELIVERY OF THE NSA TASKS</u>: The NSA a management system in place which are being used properly in n circumstances. The management systems present a systematic approad control the business risks of the organisations and to deliver their tasks consistent, effective and efficient way. Procedures are kept up-to-date. G. <u>LEADERSHIP MANAGEMENT WITHIN THE NSA</u>: There is a process in place with the NSA to select, create, support, maintain and measure leadership. A managers make sure that the members of staff understand their part o the system and how their actions influence the conditions of the RUs ar IMs. 	the ding s to not has nost h to in a
 applicable railway safety rules (EU and national) to the sector, incluwing what good compliance with them looks like. The NSA explicitly declares the sector that guidelines are not mandatory and ensures that they are contradicting the EU regulatory framework and related guidelines. F. ENSURING A STRUCTURED AND CONSISTENT DELIVERY OF THE NSA TASKS: The NSA a management system in place which are being used properly in micricumstances. The management systems present a systematic approace control the business risks of the organisations and to deliver their tasks consistent, effective and efficient way. Procedures are kept up-to-date. G. LEADERSHIP MANAGEMENT WITHIN THE NSA: There is a process in place with the NSA to select, create, support, maintain and measure leadership. Al managers make sure that the members of staff understand their part of the system and how their actions influence the conditions of the RUs are support. 	ding s to not has nost h to in a
the NSA to select, create, support, maintain and measure leadership. A managers make sure that the members of staff understand their part o the system and how their actions influence the conditions of the RUs ar	
	F
A. <u>COMMUNICATION OF INTERNAL GOALS</u> : As for level 3, plus: The proces communicate policies, objectives, targets and procedures to stat	
continuously reviewed to ensure that it stays fit for purpose.	
B. HIGH LEVEL COORDINATION OF THE MANAGEMENT OF RAILWAY SAFETY: As for L	
3, plus: The NSA has a systematic dialogue with the Ministry and the	
which is focuses on how to improve the railway system as a whole ar based on monitoring data from the NSA, accident investigation experies	
from the NIB, and other informed sources. The structure of the dialogu	
regularly reviewed in order to ensure that it is still fit for purpose.	
C. ENSURING THAT THE SECTOR TAKES ITS RESPONSIBILITY FOR RAILWAY SAFETY: AS	
Level 3, plus: The NSA influences the RUs and IMs to continuously rev their Safety Management Systems to ensure that they are still fit	
purpose.	101
4 D. <u>SUPPORT FOR THE WORK OF THE NSA:</u> As for Level 3, plus: The NSA is bro	adly
Managing recognised by the industry for providing added value for safety.	
E. <u>GUIDANCE ON NATIONAL LEGAL FRAMEWORK</u> : As for Level 3, plus: Effect procedures for gathering feedback on the industry's perception of	
legislation and rules (EU and national) make sure that it understands t	
purpose. The consultation process concerning changes in the I	
framework is continuously reviewed to ensure that it stays fit for purp	ose
and covers all interested parties.	evel
F. Ensuring a structured and consistent delivery of the NSA tasks: As for I	
F. ENSURING A STRUCTURED AND CONSISTENT DELIVERY OF THE NSA TASKS: As for I 3 plus: The management system effectively ensures that the NSA acts in	line
F. Ensuring a structured and consistent delivery of the NSA tasks: As for I	line
 F. ENSURING A STRUCTURED AND CONSISTENT DELIVERY OF THE NSA TASKS: As for I 3 plus: The management system effectively ensures that the NSA acts in with the policy, business objectives and targets of the organisation. system is continuously reviewed to ensure that it stays fit for purpose. G. LEADERSHIP WITHIN THE NSA: As for Level 3, plus: The process is continuously 	line The
F. ENSURING A STRUCTURED AND CONSISTENT DELIVERY OF THE NSA TASKS: As for I 3 plus: The management system effectively ensures that the NSA acts in with the policy, business objectives and targets of the organisation. system is continuously reviewed to ensure that it stays fit for purpose.	line The

	A. <u>COMMUNICATION OF INTERNAL GOALS:</u> As for level 4, plus: The process to communicate internal policies, objectives, targets and procedures staff is continuously improved. Staff's views are collected and taken into account when establishing internal policies, objectives, targets and procedures.
	B. <u>HIGH LEVEL COORDINATION OF THE MANAGEMENT OF RAILWAY SAFETY:</u> As for Level 4, plus: The structure of the dialogue is regularly reviewed with the aim to continuously improve it. New ways to improve the railway system as a whole are continuously sought out and implemented.
	C. <u>ENSURING THAT THE SECTOR TAKES ITS RESPONSIBILITY FOR RAILWAY SAFETY:</u> As for Level 4, plus: All activities of the NSA aim to have the maximum effect on the businesses that are regulated. The industry is lead towards business excellence. The NSA is continuously restating the expected benefits from the regulatory regime. RUs and IMs are influenced to continuously improve their Safety Management Systems.
5	D. <u>SUPPORT FOR THE WORK OF THE NSA</u> : As for Level 4, plus: There is structured and trust-based cooperation between the NSA and the industry on improving the safety levels and general performance of the whole railway system.
Improving	E. <u>GUIDANCE ON NATIONAL LEGAL FRAMEWORK:</u> As for Level 4, plus: The NSA continuously improves its support to the sector on how to correctly and efficiently apply the legal framework. The consultation process concerning changes in the legal framework is continuously reviewed with the aim to improve it. There is early stakeholder involvement in drafting, public consultation takes place for all changes in the legal framework, and other good practices are being explored and applied.
	F. ENSURING A STRUCTURED AND CONSISTENT DELIVERY OF THE NSA TASKS: The management system of the NSA is continuously improved on the basis of experience and risk management. Good practice of other competent bodies in managing their activities is sought out and implemented. Processes and procedures are consistently reviewed and improved. Senior management is involved and contributes. Staff is actively involved in their improvements.
	G. <u>LEADERSHIP WITHIN THE NSA:</u> As for level 4, plus: The process is continuously reviewed to ensure that it is improved. Managers at all levels inspire confidence and commitment in staff. Leadership is measured and controlled on all levels of the organisation with the aim to continuously improve how leadership contribute to the organisation's reaching of its overall policy and objectives.

2 Organising

The second basic element of the railway risk regulation regime concerns the set-up of bodies that are responsible for overseeing the regime and making sure that it fulfils its purpose. The NSA Monitoring process is not looking at the functioning of Ministries and NIBs, so this section will deal only with the organisation the NSA. In particular, the basic element 2 – Organising – looks at:

- working conditions;
- clarity of roles, so that everyone in the railway system know who does what;
- *independency from the industry;*
- proper setup of the legal framework, with clear definition of mandates and enforcement power.

In this basic element it is also relevant to look at the capability of these organisations to analyse their environment, adapt to changes and focus on the areas where their efforts are most needed.

The sub-elements related to Organising are "Establishment", "Accountability", "Safety culture management", "Interface arrangements", "Risk-based approach", "Change management" and "Record keeping"; all presented more in detail in the following sections.

2.1 Establishment

This sub-element addresses how clearly the roles and responsibilities of the NSA are described in the legislation and communicated to the sector. It also looks at how individual roles and responsibilities are distributed within these organisations. The clearer the roles, responsibilities and mandates are within the risk regulation regime, the better.

Responsibilities must also correspond with the mandates; for example someone who is responsible for monitoring railway safety performance must have the corresponding power to request representatives of the railway sector to send information on their performance.

This sub-element also addresses the independence of the NSA from the industry. It is crucial that the NSA is independent in relation to the sector so that it can challenge the choices of RUs and IMs when it supervises them or refuse to approve the start-up of operations to organisations with no potential for an effective management of safety.

Independence can also be affected by the funding and resourcing of the NSA, which mechanism shall be clear, transparent and avoid any conflict of interest.

Some NSAs are governed by a board. In the cases, it is important that this does not influence the independence of the NSA. The independence could for example be compromised if the board included representatives from the industry.

Element 2: Organising	
	Sub-element 2.1: Establishment
	A. <u>ROLES:</u> Within the NSA the roles, tasks and responsibilities are unclear among units and teams, leading to overlapping work and inconsistencies.
1 Ad hoc	The roles, tasks and responsibilities of the NSA are not clear. As a result the sector is not aware of exactly what the NSA does. For example, there could be overlaps or gaps in the tasks of the different actors, e.g. NIB and NSA both engaged in supervising the sector or investigating accidents. The NSA might lack some of the necessary legal powers to carry out its tasks in accordance with the RSD.
	B. <u>INDEPENDENCE OF THE NSA FROM THE INDUSTRY:</u>

	The NSA is not independent in relation to the sector. For example:NSA staff are also employed by an RU/IM;
	 members of the NSA Board are also owners of an RU/IM;
	 one of the main RUs/IMs funds the NSA for a large part of its budget.
	There is no or little separation of the state functions concerning regulation
	and those providing railway transport services (e.g. RUs/IMs). There is no
	internal policy to ensure the independence of staff in relation to the sector.
	A. <u>Roles:</u>
	As part of setting up its management system, the NSA is creating a process
2 Initialising	that will ensure a systematic identification and implementation of roles, tasks and responsibilities within the organisation.
	An analysis of the roles, tasks and responsibilities has started with the aim
	to clarify the purpose of each type of actor in the railway system and to establish the necessary legal powers of the NSA.
	B. INDEPENDENCE OF THE NSA FROM THE INDUSTRY: The NSA, supported by the
	competent ministry, has started a process to ensure its independency from
	the sector. Dealing with the topic has been defined and communicated.
	A. <u>Roles:</u>
	Roles, tasks and responsibilities are clearly allocated between units and
	individuals. The process that will ensure a systematic identification and
	implementation of roles, tasks and responsibilities within the organisation is
	implemented. Thanks to this process the right task will be allocated on the
3	competent person and it is clear to everyone in the organisation what their responsibilities are.
Implementing	Roles, tasks and responsibilities of the NSA and sector are clear. The NSA is
Implementing	essentially free to decide its own organisation and manage its day-to-day activities.
	B. INDEPENDENCE OF THE NSA FROM THE INDUSTRY: The NSA has an internal process
	in place to ensure its independence from the industry. In alternative, there
	is legislation in place to ensure this. Internal procedures are in place to prevent bribery.
	A. <u>Roles:</u>
	As for Level 3, plus: The internal process to allocate roles, tasks and
	responsibilities ensures that these are a clearly linked with and support the
	overall policy and objectives of the organisation. The process is regularly reviewed.
4	There is a process in place to ensure that overlaps and gaps in the
Managing	responsibilities of the NSA with other national bodies are continuously
	identified and sorted out.
	B. INDEPENDENCE OF THE NSA FROM THE INDUSTRY: As for level 3, plus: The NSA
	staff is fully aware of the importance of being independent, a declaration
	of absence of any conflict of interest is signed and independence is a natural

	aspect of day-to-day activities. Bribery is actively sought out and enforced against.
	A. <u>Roles:</u>
	As for Level 4, plus: The roles, tasks and responsibilities within NSA, are clearly allocated and formally accepted by the individuals. The process that will ensure a systematic identification and implementation of roles, tasks and responsibilities is continually improved.
5 Improving	Roles and functions of the NSA are periodically reviewed and adapted when necessary, trying to forecast changes in the legislation, etc.
	B. INDEPENDENCE OF THE NSA FROM THE INDUSTRY: As for level 4, plus: The output of the NSA can be analysed, when necessary, and assessed by a third party against any possible conflict of interest (e.g. complaints made by applicants or external audits specifically focusing on independence issues). All players in the system see bribery and other signs of partiality as an important safety risk and therefore something that has to be avoided.

2.2 Accountability

For responsibilities to be effective it is necessary to hold the persons and organisations that have been appointed with these responsibilities accountable for their actions.

This sub-element therefore addresses the accountability of the NSA in the risk regulation regime. Basically, what needs to be in place in an effective risk regulation regime are both external and internal systems that allow a control of the activities of the different players in the regime (governmental bodies and staff within these bodies). For the control to be effective it is also necessary that the actions of the NSA are transparent, otherwise it is difficult to discover malpractice. Internal controls can be carried out through regular performance reviews of staff and by giving the board a mandate to question decisions that are in conflict with the organisation's goals. The ultimate purpose of holding the persons and organisations that are set to guard the risk regulation regime accountable for their actions is to facilitate the fulfilment of the safety aspects of the EU policy.

The NSA Monitoring Matrix looks at the following criteria in relation to **Accountability**:

	Element 2: Organising	
	Sub-element 2.2: Accountability	
	A. <u>TRANSPARENCY</u> : The decisions/actions of the NSA are non-transparent. Interviews to journalists or answer questions/requests from the public/stakeholders. The activities are considered as classified.	
	B. EXPECTATIONS ON THE QUALITY OF WORK:	
	Employees of the NSA are rarely held to account for their actions. There is no performance review system in place.	
1 Ad hoc	The NSA is not required to report on its accomplishments to external entities.	
	C. <u>Respecting the goal and mandate:</u>	
	In case where there is a board: The board has no power to hold the executive management responsible for decisions that are in conflict with the organisation's goals. There is no or little separation of tasks between executive management and the board (the governance task might for example be carried out by the senior management of the NSA).	
	There is no mechanism in place that allows the state to hold the NSA to account for actions that are contrary to its mandate.	
	 A. <u>TRANSPARENCY:</u> The problem of non-transparency is recognised by NSA and a process has started with the aim to improve this aspect. B. <u>EXPECTATIONS ON THE QUALITY OF WORK:</u> 	
2 Initialising	The NSA has started to put a performance review system in place, which includes also an improvement framework.	
	The need for the NSA to report on their accomplishments to external entities (through annual safety reports to the Ministry and ERA, budgetary reports etc.) has been identified and processes for establishing these obligations has started.	
	C. <u>Respecting the goal and mandate:</u>	

	In case where there is a board: The NSA is starting to put a system in place
	to ensure internal checks and balances, mandating the board to hold the executive management responsible for decisions that are in conflict with the organisation's goals.
	The state has started to put a process in place that allows it to hold the NSA accountable for actions that are contrary to their mandate.
	A. <u>TRANSPARENCY:</u> Decisions/actions of the NSA are transparent. There are laws in place that ensure a judicial review of the decisions of the NSA.
	B. EXPECTATIONS ON THE QUALITY OF WORK:
3	There is a system in place to regularly review performance of staff with the aim to tackle problems. Performance in regulating railway risks/investigating railway accidents gets reasonable attention in relation to other business targets. There is internal guidance available to staff on how to take decisions.
Implementing	The NSA has a structured way to report on its activities to external entities (by for example analysing and reporting trends in safety).
	C. <u>Respecting the goal and mandate:</u>
	In case where there is a board: The board has a mandate to hold the executive management responsible for decisions that are in conflict with the organisation's goals.
	There is a control mechanism in place to ensure that the NSA does not overstep its mandate.
	 TRANSPARENCY: As for Level 3, plus: The NSA has a process in place to ensure that decisions/actions are being continuously reviewed with the aim to stay transparent. EXPECTATIONS ON THE QUALITY OF WORK:
	As for Level 3, plus: The internal performance review process is regularly reviewed in order to ensure that it stays fit for purpose.
4	The (external) reporting process is regularly reviewed to ensure that it stays fit for purpose.
Managing	C. <u>Respecting the goal and mandate:</u>
	As for Level 3, plus: The board has a strong, independent role in challenging executive management on regulatory issues and policies in a proportionate way. The board regularly reviews its role and activities.
	As for Level 3, plus: The control mechanism is regularly reviewed to ensure that it stays fit for purpose.

	A. <u>TRANSPARENCY:</u> As for Level 4, plus: Best practice in working in a transparent and including manner is actively sought out and implemented by the NSA.
	B. EXPECTATIONS ON THE QUALITY OF WORK:
	NSA: As for Level 4, plus: The internal performance review system first and foremost aims at helping staff improve their performance. There is evidence that staff at all levels proactively take responsibility for their actions within a strong management framework.
5	The NSA links its report on achievements with the overall goals of the risk regulation regime.
Improving	C. <u>Respecting the goal and mandate:</u>
	As for Level 4, plus: The board (if any) challenges the executive management to deliver improvement. There is a fruitful, open and respectful dialogue between the board and the executive management on how to best fulfil the organisation's overall goals. The board regularly measures its own activities against recognised good practice with the aim to continuously improve its work.
	There is a system in place to perform external audits of the NSA in order to hold it responsible for misuse of resources or a wrong implementation of its tasks.

2.3 Safety culture management

This sub-element examines the culture or the underlying values and behaviours within the NSA in general, and how these relate to the performance of the risk regulation regime.

In particular, it addresses how the behaviour of the NSA triggers a safety response in the sector.

In a standards-based system, a sound safety culture helps to ensure compliance with the standards. But in a risk-based system, such as the EU railway risk regulation regime, a safety culture is even more important since safety has to be driven and ensured by the operators themselves.

A success factor in safety culture management is to strive for a just culture as opposed to a blame culture.

A just culture focuses on learning from experience incidents, while a blame culture is focussed more on finding the person guilty for a specific behaviour. It is clear how a blame culture can impact on safety, for instance if someone is punished for reporting a mistake, they are less likely to report other incidents in the future. This consequence can limit drastically the opportunities to learn and improve the system. However a just culture does not mean that anything is passively accepted. Significant or deliberate non-compliances should be enforced.

This sub-element also addresses the influence that staff within the NSA has on the possibility to achieve safety in the railway system. Employees in NSA have important roles to play in supporting the RUs and IMs to achieve their required performance. If the staff do not have a clear understanding of their position in the regime and how they may influence the sector, they will not be able to provide this support. The employees of the NSA could thereby be seen as ambassadors for the regulation and as such it is important that managers within the NSA consult with their employees so that they are clear about their role and that the messages they give the industry are consistent.

Equal importance has open sharing of feedback, experience and issues among railway players, other NSAs and the European Union Agency for Railways. The NSA should proactively encourage such processes with the view of safety improvements and in relation to their tasks of monitoring the safety regulatory framework.

The NSA Monitoring Matrix looks at the following criteria in relation to Safety culture management:

	Element 2: Organising	
	Sub-element 2.3: Safety culture management	
	A. <u>ATTITUDES OF THE NSA TOWARD THE SECTOR</u> : Railway accidents are seen as occurrences that often can be blamed on individual persons rather than systemic problems. The immediate effect of this attitude may result in over-regulating the sector. The need to manage safety culture within the railway system as such is not recognised within the NSA. The industry is not encouraged to share feedback, experience and issues.	
1 Ad hoc	B. INTERNAL ATTITUDES AND LEARNING CULTURE IN THE NSA: The need to manage safety culture within the NSA is not recognised. There is poor employee involvement and poor learning arrangements. Members of staff are not aware of or convinced about the impact on the system that their activities can have. They are only doing what they are told without reflecting. Policies, objectives, targets and processes are not seen by all staff as relevant guides for their daily work, nor as essential to securing a safe and efficient railway, and they are therefore seldom paid attention to. There are differences between what is done, what is said and what is understood (i.e. poor twoway communication). There is a blame culture where focus is placed on finding out who is to blame instead of focusing on how to avoid making the same mistake twice. Incidents such as unfortunate decisions such as a safety certificate being issued to a clearly incapable RU are seen as unavoidable.	

2 Initialising	 A. ATTITUDES OF THE NSA TOWARD THE SECTOR: There is an increasing tendency to see railway accidents as occurrences that may be caused by systemic problems but there is still some ground to cover before this viewpoint is an integrated part of how the NSA works. There is growing commitment within NSA towards supporting the sector in establishing a just safety culture across the railway system. The NSA has internal expertise on safety culture and internal documents (policies, procedures, etc.) acknowledge its importance. B. INTERNAL ATTITUDES AND LEARNING CULTURE IN THE NSA: Senior management within NSA is aware of the need to focus some resources on developing and measuring the internal safety culture among staff, but the issues of what will be measured and when are still being discussed. The employees understand how they contribute to a safe railway system and therefore reflect upon the way they should carry out their tasks. They are for example increasingly aware of mistakes that are made by their organisation and the necessity and possibility to improve its performance. But they are not consulted in a systematic way on how the work of the NSA, and thereby the railway system, can be improved. Senior managers only become involved if incidents increase and administrative enforcement action is likely to be taken against the NSA. Internal roles, tasks and responsibilities still form part of a command and control approach, but the need to improve the two-way communication is noted and improvement measures are sought. Internal discussions on the negative aspects of having a blame culture have started.
	A. <u>ATTITUDES OF THE NSA TOWARD THE SECTOR</u> : The viewpoint that railway accidents are occurrences that may be caused by systemic problems forms an integrated part of the daily work of the NSA. This means among other things that new national rules should not be in reaction to an accident. There is a process in place, at least within the NSA, to actively communicate the importance of having a just safety culture to the sector.
3 Implementing	B. INTERNAL ATTITUDES AND LEARNING CULTURE IN THE NSA: There is a process in place within NSA to manage safety culture among staff. The safety culture is regularly measured and the results are available within the organisation. There is evidence that the management realises that employee involvement is essential for improving performance of the organisation (thereby becoming better at supporting the improvement of safety performance in the railway system). For example, there is an on-going dialogue with staff to collect useful ideas on how to improve the work of the organisation and it is ensured that members of staff are aware of and accept their roles, tasks and responsibilities.
	A. <u>ATTITUDES OF THE NSA TOWARD THE SECTOR</u> : As for level 3, plus: The NSA inspires the sector to actively collaborate on improving the safety culture.
4 Managing	B. INTERNAL ATTITUDES AND LEARNING CULTURE IN THE NSA: As for level 3, plus: Members of staff show that they understand how their activities affect safety in the railway system. They take proactive action to improve railway safety when possible (for example suggests changes in legislation where safety benefits are identified). The process managing safety culture among staff is regularly reviewed. Employees who wish to improve safety-related

	performance (in the organisation as well as in the sector) are supported by the organisation. Safety culture enablers and disablers are identified and shared with other governmental bodies.
	A. <u>ATTITUDES OF THE NSA TOWARD THE SECTOR</u> : As for level 4, plus: Lessons learned in previous national railway accident investigations as well as investigations in other Member States and sectors (such as maritime and aviation accidents) are analysed on a regular basis with the aim to improve railway safety in general. Lessons learned are sought and implemented in joint efforts by the NSA together with other national bodies and the industry.
5 Improving	B. INTERNAL ATTITUDES AND LEARNING CULTURE IN THE NSA: As for level 4, plus: The NSA anticipates and responds to risks; develops a learning, adaptable, prepared and informed culture; i.e. aims to be resilient. There is excellent two-way communication between management and employees. Managers welcome "bad news" as an opportunity to learn and improve the organisation's performance. Senior management and employees are proactively and jointly participating in continuously improving the internal safety culture, supported by mutual trust. Improvement plans are set to ensure that employees are aware of and support the organisation's shared beliefs, assumptions and values regarding internal safety as well as safety in the railway system as such.

2.4 Interface management

This sub-element addresses the issue of stakeholders and the need to share information within the railway system. The sub-element - Interface management - identifies who the stakeholders are and the best ways to co-operate with them.

There is less emphasis on interfaces in a rules-based regime. There the interface arrangements are simple in that prescriptive standards are set and then complied with and this achieves the necessary cooperation at the interface. In the case of a risk-based regime such as the one chosen for the EU railways, a greater level of cooperation is required between the Ministry, NSA and NIB and the sector (the NSA is evaluated on how this is sought and achieved). There is also need for a greater cooperation between countries and with the ERA.

A common, therefore interoperable, risk-based approach across different countries is effective when there is consistency in the application of a common risk regulation framework across the member states. In the EU, each Member State has its own system of national rules and its own way to implement the EU safety regulatory framework into this system. In order for this implementation to be in line with the overall goal to harmonise the safety regulatory framework, there must be cross-border consultation on new rules (if applicable) and collaboration on the interpretation of existing rules.

Internally, within the NSA, the interfaces between the various departments should be managed so that all the policy objectives are achieved in a consistent manner. A well-functioning organisation is characterised by transparent, clear and purposeful communication on all levels.

Links with other sub-elements:

There is a link here with sub-element 2.6 on Change management. In their Interface management the organisations analyse – among other things – which information they and their stakeholders need in order to manage changes.

The NSA Monitoring Matrix looks at the following criteria in relation to Interface management:

Element 2: Organising	
	Sub-element 2.4: Interface management
1 Ad hoc	 A. EXTERNAL INTERACTION AND SHARING OF INFORMATION: The NSA's identification and interaction with external stakeholders is infrequent and unstructured. There is co-ordination of practical issues between employees of the NSA and individuals of other national and external organisations, but no organised procedures are in place. Societal concerns are rarely taken into account when establishing the national railway safety policies and rules. With regards to the interface with ERA, the NSA either does not participate in network meetings or continuously changes their representative or does not send participants that can take part in discussions (i.e. someone that has not the right mandate or competence or background information on the subjects). B. INTERNAL INTERACTION AND SHARING OF INFORMATION: The NSA is aware of its internal interfaces but manages them on an informal, ad hoc basis. There are no processes or structures in place to support an active and timely sharing of information within the organisation. The right information is not available for making decisions.

2 Initialising	 A. EXTERNAL INTERACTION AND SHARING OF INFORMATION: The NSA has started to analyse the need for exchange of information and views with others and is creating structures for this regarding both national and international communication. A process is being set up to formally consult relevant stakeholders on new railway safety policies and rules. The NSA has started to structure its participation in network meetings in order to send the right person with the right mandate to take part in discussions. B. INTERNAL INTERACTION AND SHARING OF INFORMATION: The NSA has started to put a process in place to identify the communication needs between units and sectors.
3 Implementing	 A. EXTERNAL INTERACTION AND SHARING OF INFORMATION: The NSA actively analyses who its (national and international) stakeholders are and the related need for exchange of information and views. There are processes in place to ensure effective communication, consultation and cooperation with the public and other organisations, including MoUs. Sufficient information is available for the players in the railway system when they take decisions that affect safety. Interface arrangements ensure that anyone in the NSA, making a decision relating to railway safety, is in possession of the right information. This increase awareness on the effects that those decisions might have on the achievement of the high level national goals. The NSA takes due consideration to send the appropriate staff members to international network and working group meetings. B. INTERNAL INTERACTION AND SHARING OF INFORMATION: All internal interfaces are systematically identified and managed. There are processes and structures in place to support an active and timely sharing of information within the NSA.
4 Managing	 A. <u>EXTERNAL INTERACTION AND SHARING OF INFORMATION</u>: As for Level 3, plus: The processes for identification of and interaction with stakeholders are continuously reviewed to ensure that they stay fit for purpose. B. <u>INTERNAL INTERACTION AND SHARING OF INFORMATION</u>: As for level 3, plus: All processes related to internal interfaces and the internal sharing of information are managed and measured to assess their effectiveness.
5 Improving	 A. EXTERNAL INTERACTION AND SHARING OF INFORMATION: As for Level 4, plus: Information needs are analysed and acted upon in a proactive and long-term perspective. The processes ensure that all exchanges with stakeholders are consistent with the overall policies and objectives. Real-time sharing of safety-related data is in place with respect to the management of safety. Safety-related performance information is systematically analysed with the aim to present the public with a comprehensive view on achieved safety performance and trends. The NSA seeks to proactively drive discussions in networks and working groups with an aim to achieve the goals of the RSD. In general, experiences are shared with other organisations with similar tasks in order to learn and spread good practice. B. INTERNAL INTERACTION AND SHARING OF INFORMATION: As for Level 4, plus:
	B. <u>INTERNAL INTERACTION AND SHARING OF INFORMATION</u> : As for Level 4, plus: Relationships are proactively built between departments and units to avoid

	working in silos. Working practices ensure that the organisation works as a coherent system and not as a group of individual or fragmented units. All processes related to internal interfaces and the internal sharing of information are regularly reviewed with the aim to continuously improve them.
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2.5 Risk-based approach

The EU railway risk regulation regime is structured around a risk-based approach. In its centre is not a framework of highly descriptive safety rules. Instead RUs and IMs are requested to manage the risks of their activities through a safety management system. How they do this is more or less up to them. They should for example be free to adjust the safety management system after the nature of their operations. This needs to be reflected in the work of the NSA. In order to do this, the NSA need to have a full understanding of the current and future risk profile of the sector. Equally, the activities of the NSA should be based on an analysis of where their actions are mostly needed.

Links to other sub-elements:

This sub-element links with sub-element 2.6 on Change management. Since it is good practice to analyse the consequences of a change before it is implemented, the attributed levels in change management will necessarily reflect the lack of evidence of a risk-based approach.

Element 2: Organising		
	Sub-element 2.5: Risk-based approach	
1 Ad hoc	The everyday work of the NSA is based on the assumption that safety is managed by making sure that RUs and IMs follow detailed safety rules and technical barriers. Approval processes are imposed even when not foreseen by the EU legislation. Decisions to carry out activities are ad-hoc. The NSA does not support the application of the CSM for Risk Evaluation and Assessment. The management of NSA pays no or little attention to a risk-based approach. In general, the legal framework is not compatible with a risk-based approach, the sector is exclusively regulated by highly detailed railway safety rules. The acceptance of risks is implicitly or explicitly forbidden. Unrealistic safety targets are imposed by the law.	
2 Initialising	The everyday work of the NSA is still based on the assumption that safety is managed by making sure that the sector follows safety rules and technical barriers, but they are aware of the possibility for the sector to apply the CSM for Risk Evaluation and Assessment and CSM for Monitoring. Although, the concepts that these are based on have not been understood by neither the NSA nor the RUs/IMs. Some tasks are prioritised from a risk-based approach but far from all, and not in a systematic way. Management of NSA is starting to address the necessity to have policies on a risk-based approach. The need to make the legal framework compatible with a risk-based approach has been identified and reported to the competent body. A discussion, with the relevant national bodies, on the possibility to move to a risk-based from a rules-based system has started. There is cultural change in the NSA toward the acceptance of residual risks.	
3 Implementing	The legal framework is mainly compatible with a risk-based approach. The NSA has moved toward a more risk-based system.	

The NSA Monitoring Matrix looks at the following criteria in relation to **Risk-based approach**:

	The CSMs on Risk Assessment and Monitoring are fully implemented, actively applied by the sector and enforced by the NSA. The NSA is actively promoting the importance of having an SMS and how this is supposed to operate. Guidance on SMS and Risk Assessment is provided by the NSA. All activities of the NSA are based on the understanding that the responsibility to manage safety risks lies on the sector. The NSA is aware that if it finds out that the sector does not control the risks that it introduces into the system, then it is the task of the NSA to enforce that. The activity of NSA is normally risk-based.
4 Managing	The NSA has a continuous dialogue with the sector on how to best approach and manage operational risks. Best practice in risk assessment and monitoring is actively sought and implemented.
5 Improving	As for level 4, plus: All levels of the workforce in the NSA contribute to understanding the risk profile of the sector. The NSA is competent to challenge the risk assessments done by the sector and the risk profile described by them. The activities of NSA are completely risk-based. Information is automatically fed into the risk assessment procedure from all relevant sources (monitoring, supervision, certification, accident investigation etc.). The organization is capable of reprioritizing an activity ad-hoc, based on newly arising safety concerns. The risk assessment process is continually reviewed. The NSA cooperates with the NIB for a better understanding of the risk profile of the sector.

2.6 Change management

Change is an essential and necessary part of a risk regulation regime according to which the regime should constantly adapt to the risks in the sector, the introduction of new technologies and work practices, and the expectations of society.

This sub-element addresses the management of these changes by the NSA. Given that the regime is ultimately steered by the EU policies, there needs to be a readiness within the NSA for external incentives.

NSA representatives should come to discussions in EU/ERA working groups with an understanding of how changes might affect their home market but should also have a fair understanding of how certain changes might affect the whole single EU railway market.

Internally, in each NSA, the changes from a rules-based railway system to an EU risk based regime, should be planned and managed with a risk-based approach.

Change management principles are also applicable to the internal organisation of the NSA. Any changes should be evaluated and planned beforehand. Best practice in deciding on whether to make a change would be to assess the impact of that change in the beginning and not at the end of the process (when it is difficult to do any amendments) and then to monitor the impact after the change has been introduced in order to evaluate if amendments are necessary.

The NSA Monitoring Matrix looks at the following criteria in relation to **Change management**:

Element 2: Organising		
	Sub-element 2.6: Change management	
1 Ad hoc	A. The NSA has no process in place to manage changes that are considered by the own organisation or changes that are coming from external sources. The impact that planned changes might have on the own organisation or on the railway system as a whole are therefore not considered.	
2 Initialising	A. There is an awareness within the NSA of the need to manage changes that are considered by the own organisation as well as changes that are coming from external sources. Some impact assessments are done, some information is analysed and some action owners might be identified, but the activities related to changes are yet not fully structured. The work to create and implement a process for change management has started.	
3 Implementing	A. There is a process in place within the NSA to manage changes. The process ensures that there is an impact assessment and consultation with relevant stakeholders (employees, sector representatives, other national and international government agencies) prior to the final decision on the change is taken. The NSA ensures that it has access to relevant information so that it can anticipate and adapt to changes in relation to new or amended responsibilities and tasks (for example keeping up-to-date with EU legislative developments).	
4 Managing	A. As for level 3, plus: The change management process of NSA includes an element where, a while after a change has been implemented, its effects are reviewed (through stakeholder questionnaires or other means) in order to learn lessons for future change management. It is recognised that an organisational change might have a negative effect on the organisation's capability to carry out its tasks. Employees and the members of the sector	

	understand the need for change and confirm that they are consulted on how changes are introduced.
5 Improving	A. As for level 4, plus: All impact assessments include a risk-assessment. The change management process of the NSA ensures a consistent achievement of the EU legal framework goals, even following organisational changes. The Member State participates actively in change management within the EU risk regulation regime taking both national considerations and the overall goals of the EU legal framework into account.

2.7 Record keeping

This sub-element addresses the possibility to trace decisions taken by the NSA. Record keeping is an essential aspect of transparency in that decisions and the processes by which decisions are made should be clearly set out and made publically available. The possibility to trace decisions also facilitates the examination of NSA decisions in a judicial review, an important part of any risk regulation regime. Last but not least it is important to keep track of decisions and information in order to improve the quality of the organisation's performance.

The NSA Monitoring Matrix looks at the following criteria in relation to **Record keeping**:

	Element 2: Organising	
Sub-element 2.7: Record keeping		
1 Ad hoc	There are few or no written records. No corporate, only individuals memory.	
2 Initialising	There are some records of information, but the records are inconsistent and there is no systematic approach.	
3 Implementing	There are processes and standards (i.e. a document management system) in place for keeping record of important information and decisions.	
4 Managing	As for level 3, plus: Documented processes, standards, guidelines, information and decisions are available to users and decision-makers. All decisions are traceable and evidence based. The document management system is continuously reviewed. Records are used to inform the Monitoring (5.1) and Review (5.2) processes of the organisation.	
5 Improving	As for level 4, plus: The reviews of the document management system aims for continuous improvement with the ultimate goal of having an efficient and effective record keeping process that is not adding any burdens to staff but rather facilitates its everyday job.	

3 Resourcing

3.1 Resource management

The NSA need to be capable to carry out their work. An important aspect of capability is budgeting and planning the workload effectively. The organisation should be able to anticipate periods with larger quantities of work than normal and find ways in advance to cope with these. Budgeting, workload planning and competence management must be done in a systematic way and be linked with the business objectives of the organisation. One example of this is the NSA making sure, within its capabilities, that enough competent staff is available when a large number of safety certificates are up for renewal. In addition, the allocation of resources should be reviewed on a regular basis in order to ensure that they stay allocated in a way that is effective and in line with the regulatory framework. For the competent bodies within the EU it is particularly important that their competence management systems can handle the transition from the previous (mostly) standards-based national railway risk regulation regimes to the current (mostly) risk-based EU railway risk regulation regime.

Some NSAs are governed by a board. In the cases where there is a board, it is important that this does not have a negative effect on the possibilities for the NSA to carry out its work. This would for example be the case if the board did not understand and support the role of the NSA in the risk regulation regime. In cases where the NSA has a board it should have included in their competence management system some requirements on necessary competence of their board members.

Links with other sub-elements:

There is a link between sub-element 1.2 and criteria C regarding competence in this sub-element. If an evaluation concludes that the MS has a management system in place (at least level 3), this should include a competence management system and it is therefore not possible to give level 3 to sub-element 1.2 and then only give level 2 to sub-element 3.1 saying that there is no competence management system in place. However, the other way around is possible, you could have a fully developed CMS without having a full management system in place.

	Element 3: Resourcing	
	Sub-element 3.1: Resource management	
	A. <u>BUDGETING:</u> Budgeting of the NSA is not planned with the aim to support the fulfilment of more general objectives (e.g. internal policy). Budgeting is planned on an annual basis not taking future needs of the NSA into account.	
1	B. <u>STAFFING</u> : Staffing (i.e. number of people) of the NSA is not planned. There is little or no control of workload. Some people are overloaded while others are lightly loaded. The use of consultants is not managed.	
Ad hoc	C. <u>COMPETENCE:</u> There is no competence management system in place at the NSA. Some training is organised, but not in a systematic way. This has as a result that there is no assurance that all relevant staff is trained in the EU regulatory framework for railway safety. Members of the board or high level decision makers are not trained in (or there are no requirements for the board members to have a certain level of understanding of) the role of the NSA within the railway system. There is no performance review of staff.	

2 Initialising	 A. <u>BUDGETING:</u> The need to plan the budgeting of the NSA has been identified. A process that takes the overarching goals of the national transport policy (if any) and the long term objectives of the organisation into account is being developed. B. <u>STAFFING:</u> The need to plan staffing, control workloads and manage the use of consultants has been identified. Processes are being developed, when they are developed are not consistently implemented. C. <u>COMPETENCE:</u> The need to manage competence has been identified. A competence management system is being developed. Recruitment and training policies, if they exist, are not yet in line with the business objectives. Requirements about the competence of board members are being developed.
3 Implementing	 A. <u>BUDGETING:</u> The budget of the NSA is planned in accordance with the goals of the national transport policy (if any) and the objectives of the organisation. B. <u>STAFFING:</u> The NSA has processes in place to plan staffing, control workloads and manage the use of consultants. In relation to the use of consultants, this includes at least: Competence requirements; Identification of activities that can be delegated or outsourced; Performance evaluation; Clear allocation of tasks and responsibilities through contractual arrangements. C. <u>COMPETENCE:</u> There is a competence management system in place. This includes at least: The development of competence profiles for each job, position or role; The selection and/or recruitment of staff, assessing them against the established competence levels; The maintenance of competence by training, development and assessment of staff against the established competence; Communication between HR and operational departments; Specific procedures for ensuring board members' competence. The competence management system ensures that the following competencies are held by individuals or shared amongst team members: Knowledge of the relevant regulatory framework as it applies to supervision tasks; Experience of the supervision of a safety or similar management system in the railway sector or a safety management system in a sector with equivalent operational and technical challenges; Knowledge of and experience in interviewing skills.
	Relevant non-technical competencies, including, but not limited to, problem solving, communication and team working that enable them to carry out their tasks.

4 Managing	 annually on the base of results achieved by the NSA (reactive revision). B. <u>STAFFING:</u> As for level 3, plus: The processes to plan staffing, control workloads and manage the use of consultants are continuously reviewed to ensure they stay fit for purpose. C. <u>COMPETENCE:</u> As for level 3, plus: The process is continuously reviewed to ensure it stays fit for purpose. Performance review is part of the process.
5 Improving	 BUDGETING: As for level 4, plus: The review of the long term planning takes future needs (e.g. changes in the legal framework) and risks into account (proactive revision). Prioritisation of resources ensures that activities are carried out consistently and proportionately. B. <u>STAFFING:</u> As for level 4, plus: The review of the processes aims to continuously improve their efficiency and effectiveness (proactively). There is a staff policy regulating the use of consultants. There are processes managing the subcontracting of consultancies. Prioritisation of resources ensures that activities are carried out efficiently, consistently and proportionately. There is pro-active planning of workload at all management levels which takes feedback from the sector into account. Extra time is planned in for un-foreseen tasks and care is taken to make sure that nobody is overloaded with work. C. <u>COMPETENCE:</u> As for level 4, plus: Policies on recruitment, selection and training are in line with identified objectives. They are based on thorough risk assessment of tasks, to create a clear competence management system. The review of the processes aims to continuously improve their efficiency and effectiveness (proactively). Business continuity is part of the process and a link between Staffing and competence management is established (e.g. identifying when bad performance is a result of heavy workload). Best practises in managing competence from other sectors are considered and implemented. Training of staff includes exchange programs with other organisations that might have best practises on how to carry out the core tasks. The employees of the NSA are well aware of the EU regulatory framework for railway safety and how it relates to their individual work processes. Appropriate priority is given to managing competence

4 Performing

As mentioned in the introductory chapters, the NSA Monitoring Matrix reflects the three basic concepts of a risk regulation regime: standard setting, behavioural change and information gathering. Standard setting is covered by the sub-element of 'Goal setting' (SE 1.1).

The other two concepts are mainly covered in the basic element of Performing: Enforcement, Certification and Promoting relate to behavioural change while Supervision and Monitoring relate to information gathering.

4.1 Supervision & Enforcement

This sub-element relates to two of the three corner stones of a risk regulation regime; *information gathering* and *behavioural change*.

The supervision activities of the NSA aims at understanding to which extent the principles of the risk regulation regime are followed by the RUs and IMs.

The supervision process should be closely linked with the certification/authorisation process, so that information gathered during supervision can feed into any renewed or amended certificate/authorisation of a particular subject, and vice-versa: any information from the certification/authorisation activities should feed into the planning of supervision activities. Knowledge from the supervision process should also be fed into the monitoring activities of the NSA to better understand how the safety levels are developing. In addition, it should be used as an information source when the NSA plans its work for the coming years.

The enforcement should reinforce the fulfilment of the overarching national transport policy (if any). The process should be publicly available and include a range of enforcement actions that are proportionate to the non-compliance. For example, enforcement action that forces the withdrawal of a train service does not support a transport policy seeking to promote rail travel and should therefore be reserved for non-compliances with a direct threat to safety. For this reason the NSA should be able to choose between different enforcement tools depending on the severity of the situation. The possibility to choose less severe enforcement instruments also has important effects on the incident reporting culture in the railway sector. But on the other hand there needs to be a balance so as to avoid a situation where it is possible to profit from non-compliance (i.e. the fines are lower than what the companies gain from continuing to deliberately breach the rules).

The risk-based approach which was outlined in sub-element 2.5 should here lead to supervision and enforcement activities to be focused on the areas within the railway system where the highest risks have been identified.

Element 4: Performing		
Sub-element 4.1: Supervision & Enforcement		
	A. INTERNAL ORGANISATION	
	The NSA does not have a supervision plan and/or a formalised enforcement policy.	
1 Ad hoc	Supervision activities, when conducted, do not rely on information coming from the conformity assessment/authorisation process. Safety performance of the railway player are not considered as well. Use of resources in the supervision activity is not planned nor prioritised. Decisions made during in the supervision process are not justified and transparent.	
	Enforcement actions, when taken, are not consistent nor proportionate to the risk level of the non-conformities detected; the NSA cannot	

As many re-certification of RUs will take place from 2019, the sub-element will be considered with high priority during the first 3-year cycle 2018-2020.

	demonstrate to have a consistent nor transparent decision-making process with regards to its enforcement actions.
	In general, there is no dialogues with the sector on the expectations of the NSA and complaints are not accepted or, if they are, there is no internal procedure to process them in a systematic way.
	The NSA does not feel accountable for its decisions and the lack of internal arrangements limits the possibility to audit or inspect it.
	B. CO-OPERATION WITH OTHER SAFETY CERTIFICATION BODIES, NSAS AND NIBS:
	The NSA does not have a procedure in place for providing the safety certification body or the relevant NSA(s) with the necessary information gathered on the performance of the SMS.
	The NSA does not have formalised agreements with other NSAs involved in the supervision of an infrastructure manager with cross-border infrastructure(s) or of a railway undertaking operating in more than one Member State.
	The NSA does not have a cooperation agreement in place with the Agency, the relevant NIBs, certification bodies for entities in charge of maintenance and other competent authorities in order to share information and to coordinate their response to any failure to comply with the safety regulatory framework.
	A. INTERNAL ORGANISATION:
	The NSA has a supervision plan which is not based on a risk-based strategy so no priorities are applied to the supervision process. The NSA does have a formalised enforcement policy, evidences of its implementation are not available.
	The Supervision activities rely on information coming from the conformity assessment and authorisation processes. This transfer of information is not structured nor formally described. There are evidences of some attempts to ensure transparency in decision making during supervision, by the way the NSA is not supported by a structured process.
2	Enforcement actions, when taken, are not consistent nor proportionate to the risk level of the non-conformities detected.
2 Initialising	The NSA acknowledge the need to plan and prioritise the use of resources in the supervision activity, nevertheless this is done without the support of a structured methodology.
	The NSA communicates with the sector trying to set expectations. This is done inconsistently as there is no formalised approach to support this activity. 1Complaints are accepted but there is no internal procedure to process them in a systematic way.
	Generally speaking the NSA does feel accountable for its decisions even if the lack of internal arrangements limits the possibility to audit or inspect its processes.
	B. CO-OPERATION WITH OTHER SAFETY CERTIFICATION BODIES, NSAS AND NIBS:
	The NSA does have a procedure in place for providing the safety certification body or the relevant NSA(s) with the necessary information

	gathered on the performance of the SMS. There is no evidence of a systematic implementation of this arrangement.
	The NSA does not have formalised agreements with other NSAs involved in the supervision of an infrastructure manager with cross-border infrastructure(s) or of a railway undertaking operating in more than one Member State. There is no evidence of a systematic implementation of this arrangement.
	The NSA does not have a cooperation agreement in place with the Agency, the relevant NIBs, certification bodies for entities in charge of maintenance and other competent authorities in order to share information and to coordinate their response to any failure to comply with the safety regulatory framework. There is no evidence of a systematic implementation of this arrangement.
3 Implementing	 A. INTERNAL ORGANISATION: The NSA has a Supervision plan and strategy; The NSA has an enforcement policy is in place, proportionated to the enforcement tools available; There are evidences of the implementation of the Supervision plan and strategy. This is to ensure that activities are targeted primarily at those activities which the NSA believes give rise to the most serious risks or where the hazards are least well-controlled; The supervision plans, strategies and techniques are linked with the certification and authorization process and they are risk-based; The NSA has a methodology in place to ensure proportionality between enforcement and risk. There is evidence that actions taken by NSA, to achieve compliance or bring RUs and IMS to account for not meeting their legal obligations, are proportionate to any risks to safety or to the potential seriousness of any non-compliance, including any actual or potential harm; The NSA has a methodology to place to have a consistent decision making process to ensure that a similar approach, in similar circumstances to achieve similar ends, are adopted. There are evidences of the application of such methodology; For the supervision process, the NSA has a methodology to decide on its priorities and on the use of its resources. The NSA has a methodology to allow railway undertakings and infrastructure managers understand what is expected of them (including what they should or should not do) and what they should expect from the NSA. The NSA has a acomplaints procedure. <i>B.</i> Co-OPERATION WITH OTHER SAFETY CERTIFICATION BODIEs, NSAS AND NIBS:
	 The NSA has a procedure in place (evidence provided) for providing the safety certification body or the relevant NSA(s) with the necessary

	 information gathered on the performance of the SMS. There are evidences of a systematic exchange of the following information: A description of major non-compliances The current status of the action plan or plans established by the railway undertaking or infrastructure manager to resolve major non-compliances referred to in point (a) and relevant actions that have been taken by the national safety authority to supervise resolution of these issues; An overview of the safety performance of the railway undertaking or infrastructure manager to resolve resoluting or infrastructure manager operating in its Member State; The current status of the action plan or plans established by the railway undertaking or infrastructure manager operating in its Member State; The current status of the action plan or plans established by the railway undertaking or infrastructure manager to resolve residual concerns from previous assessment. The NSA has formalised agreements with other NSAs involved in the supervision of an infrastructure manager with cross-border infrastructure(s) or of a railway undertaking operating in more than one Member State. The agreement includes provisions on how to regulate their approach to supervision, as referred to in Article 17(7) and Article 17(9) of Directive (EU) 2016/798 respectively, to ensure that any key
	 17(9) of Directive (EU) 2016/798 respectively, to ensure that any key information on the specific infrastructure manager or railway undertaking (particularly on known risks and its safety performance) is shared and used to target supervision activities on the areas of greatest risk for the whole operation. There are evidences of a systematic exchange of information. The NSA has a cooperation agreement in place with the Agency, the relevant NIBs, certification bodies for entities in charge of maintenance and other competent authorities in order to share information and to coordinate their response to any failure to comply with the safety regulatory framework. There are evidences of a systematic exchange of information.
	A. <u>Internal organisation:</u> Level 3, plus:
4 Managing	 The NSA has a Supervision plan and strategy, this is improved systematically using several sources of data (reactive); The enforcement policy is improved systematically using several sources of data (reactive); the need of new/different enforcement tools is verified periodically with the competent authority; The methodology to ensure that supervision activities are targeted is reviewed systematically and improved, if necessary, on the basis of its results; The link between Supervision and the certification/authorization process is monitored and improved, if necessary, on the basis of the return of experience; The methodology in place to ensure proportionality between enforcement and risk is monitored and continually improved, on the basis of experience; The methodology in place to ensure a consistent decision making process is monitored and continually improved on the basis of experience; The methodology adopted by the NSA to set priorities and to allocate resources – in the supervision activity - is monitored and continually improved;

	 The NSA monitors its methodology to ensure transparency in the decision making process and improves it, when necessary, on the basis of experience; The NSA monitors and improves (on experience) its methodology to allow railway undertakings and infrastructure managers understand what is expected of them (including what they should or should not do) and what they should expect from the NSA. The NSA is accountable for its decisions in accordance with Article 18(3) of Directive (EU) 2016/798: The NSA has internal arrangements against which they can be held to account, which is monitored and improved when possible; The NSA has a complaints procedure, which is monitored and improved when possible.
	 B. <u>CO-OPERATION WITH OTHER SAFETY CERTIFICATION BODIES, NSAs AND NIBS:</u> The NSA monitors the effectiveness of the procedure set up to exchange information and improves it, when possible, on the basis of experience. The NSA monitors the formalised agreements with other NSAs involved in the supervision of an infrastructure manager with cross-border infrastructure(s) or of a railway undertaking operating in more than one Member State. The agreements are then improved on the basis of the experience gained in their implementation.
	• The NSA monitors and propose improvements (on experience) to the cooperation agreements in place with the Agency, the relevant NIBs, and certification bodies.
	A. INTERNAL ORGANISATION:
5 Improving	 Level 4, plus: The NSA has a Supervision plan and strategy, these are improved systematically using several sources of data and through risk assessment (proactive); The enforcement policy is improved systematically using several sources of data and risk assessment (proactive); the need of new/different enforcement tools is verified periodically with the competent authority, with a risk based approach; The review of the methodology to ensure that supervision activities are targeted is reviewed with a risk-based approach; The link between Supervision and the certification/authorization process is monitored and improved, if necessary, with a risk based approach; The methodology in place to ensure proportionality between enforcement and risk is monitored and continually improved, with a risk based approach.
	 The methodology in place to ensure a consistent decision making process is monitored and continually improved with a risk-based approach; The methodology adopted by the NSA to set priorities and to allocate resources – in the supervision activity - is monitored and continually improved with a risk-based approach; The NSA monitors its methodology to ensure transparency in the decision making process and improves it, when necessary, on the basis of experience;

 The NSA monitors and improves, with a risk-based approach, its methodology to allow railway undertakings and infrastructure managers understand what is expected of them (including what they should or should not do) and what they should expect from the NSA. The NSA is accountable for its decisions in accordance with Article 18(3) of Directive (EU) 2016/798: - The NSA has a complaints procedure, which is monitored and improved when possible, with a risk-based approach;
 C. CO-OPERATION WITH OTHER SAFETY CERTIFICATION BODIES, NSAs AND NIBS: The NSA monitors the effectiveness of the procedure set up to exchange information and improves it, when possible, with a risk-based approach. The NSA monitors the formalised agreements with other NSAs involved in the supervision of an infrastructure manager with cross-border infrastructure(s) or of a railway undertaking operating in more than one Member State. The NSA monitors and propose improvements (risk-based approach. The NSA monitors and propose improvements (risk-based) to the cooperation agreements in place with the Agency, the relevant NIBs, and certification bodies.

4.2 Certification & Authorisation

This sub-element covers the activities of the NSA in relation to certification and authorisation. In the EU risk regulation regime it is the industry creating the risks that should manage them and the role for the NSA is to review the capability of RUs and IMs to do so by evaluating their Safety Management System. This is the highest form of control over an industry in a risk regulation regime: a formal demonstration of safety needs to be made by the subject and accepted by the regulator before operations are permitted to start. In addition to an assessment of an RU's/IM's capability to manage the risks of its own operations, the certification process should address the RU's/IM's knowledge of the wider system and how it intends to cooperate with the other parties in it. Best practice in certification/authorisation processes include a link with the supervision activities to determine that the issues captured during the certification/authorisation process are followed up.

The point "Support to the sector" can be better assessed if the RUs and IMs are involved in the process.

Note: this sub-element will be progressively adapted to the entry into force of the 4th package, directives 2016/797 and 2016/798 and their derived legal acts. Therefore the priority will be low during the first 3-years cycle 2018-2020.

Element 4: Performing		
	Sub-element 4.2: Certification & Authorization	
1 Ad hoc	 A. ACTIVITIES AND PLANS: Assessment is delivered, i.e. the NSA issues safety certificates and safety authorisations, but there are no processes in place. There are no formalised decision making criteria, therefore RUs/IMs are not always treated consistently. Part A and Part B are assessed separately and there is no link between the two. No initial assessment is undertaken of the summary of the SMS before proceeding to the full assessment. There is no link to supervision activities. B. CO-OPERATION WITH OTHER NSAS: There is rarely any co-operation or co-ordination with other NSAs or it is ad hoc. C. SUPPORT TO THE SECTOR: No guidance is issued. It is unclear to the RUs/IMs on which base certificates and authorisations are issued and they therefore do not know what material to provide in their application. There are no instructions for dealing with complaints. 	
2 Initialising	 A. <u>ACTIVITIES AND PLANS:</u> The NSA has identified the need and started the work to put a process in place which ensures: a consistent delivery of certificates/authorisations (including decision making criteria) a proper quality management of the certification process a link with the supervision process that the assessment is proportionate to the size of the RU/IM a link between Part A and Part B certificates an initial assessment of the SMS summary before the full assessment is done B. <u>CO-OPERATION WITH OTHER NSAS:</u> The NSA is starting to put structures in place for assessment co-operation and co-ordination with other NSAs. C. <u>SUPPORT TO THE SECTOR:</u> Guidance is under development. There are some instructions for dealing with complaints. 	
3 Implementing	A. <u>ACTIVITIES AND PLANS</u> : There are clear work processes and procedures which set out how Part A and Part B certificates and authorisations are assessed in a consistent way (decision making criteria are available and published) ensuring equal treatment of applicants across the EU. The processes are auditable and	

	 consistently applied. The assessment is accurate and its scope is proportionate in general. There is a link between the outcome of the assessment with supervision and back from supervision to the reassessment. B. <u>CO-OPERATION WITH OTHER NSAs:</u> The NSA has a procedure for co-operation with NSAs that have issued the Part A certificate, which is actively applied in order to deal with cross border applications. C. <u>SUPPORT TO THE SECTOR:</u> Guidance on the requirements for Part A and Part B certificates is available to RUs and IMs and can be easily attained by anyone wanting to submit an application. New entrants and cross border RUs are given help in the application process, particularly the Part B. There is a procedure in place for dealing with questions and complaints.
4 Managed	 A. <u>ACTIVITIES AND PLANS:</u> As for Level 3, plus: The CSM for Conformity Assessment is fully applied. The assessment process is regularly reviewed based on experience, with the aim to ensure that it stays fit for purpose. Assessment decisions are also regularly reviewed to ensure that the decision-making criteria are consistently applied and remain fit for purpose. B. <u>CO-OPERATION WITH OTHER NSAS:</u> As for Level 3, plus: The NSA actively applies and reviews the procedure for cross border applications based on experience in order to ensure that it stays fit for purpose. The NSA shares information with the other NSAs on any information risks/ problems. The Part B assessment is minimal in relation to the Part A. C. <u>SUPPORT TO THE SECTOR:</u> As for Level 3, plus: RUS/IMs are fully aware of the procedures that the NSA uses. The applicants know exactly what stage their application is, who to contact and they are actively informed of any problems/issues/non conformities at an early stage so that these can be rectified quickly. The interaction with applicants is regularly reviewed based on experience in order to ensure that it stays fit for purpose.
5 Improving	 A. <u>ACTIVITIES AND PLANS:</u> As for Level 4, plus: The assessment process and decision making criteria are proactively improved, involving consultation with the sector and looking for best practice. There are well functioning links with the supervision activities. The NSA actively looks for ways to streamline its activities so that more time is spent on supervision than the assessment itself. Resources are focused on delivering assessment effectively and efficiently. B. <u>CO-OPERATION WITH OTHER NSAS:</u> As for Level 4, plus: The NSA proactively improves the procedure for cross border applications. The NSA shares best practice with the other NSAs. C. <u>SUPPORT TO THE SECTOR:</u> As for Level 4, plus: From information through the supervision activities the RUs/IMs are well prepared for when their certificate and authorization needs to be reassessed so that the process is minimal, cost effective and helps them to improve their SMS processes. The interaction with applicants is continuously improved.

4.3 Promoting the safety regulatory framework

As discussed in the introduction to basic-element 4, one of the cornerstones of a risk regulation regime is *behavioural change*. Enforcing the legal framework is one way of accomplishing behavioural change (see more about Enforcing in sub-element 4.1). Another tool is to promote the regime to the users. This basically means to actively advertise the benefits of the risk regulation regime as such. It is not enough to only mention once why the whole regime was put in place to start with. When carrying out the everyday tasks it can sometimes be forgotten why it is necessary to go through a big pile of documents or to check a large number of technical devices. The reason for doing these things need to be continuously reminded of so that it eventually becomes a natural part of how all the persons in the system think about the importance of their job. Only then can there be a solid safety culture within the system. The aspect of restating the benefits of the risk regulation regime is extra important in markets such as the EU railway market where new players may be introduced.

Element 4: Performing	
	Sub-element 4.3: Promoting the safety regulatory framework
1 Ad hoc	A. There is no information or guidance about the safety regulatory framework to the sector. The national and European legal framework is not clearly communicated.
2 Initiating	A. Some information and some guidance is provided. The importance of having a structured way to inform about the framework and its benefits has been identified and a process and strategy is under development. Some care is taken to share lessons learned from established safety recommendations.
3 Implementing	A. The process to promote the safety regulatory framework is defined and implemented. It includes information, guidance and dissemination, focusing not only on communicating the structure of the legal framework ("how") but also the philosophy behind it ("why"). The aim of these activities is to facilitate a correct and purposeful acceptance and execution of the safety management responsibilities of the RUs and IMs. There is a systematic sharing of lessons learned from established safety recommendations. Rules are shared with EU-wide sector (e.g. via Notif-IT database).
4 Managing	A. As for level 3, plus: The processes are regularly reviewed to ensure they stay fit for purpose. The NSA encourages and supports the sharing of best practices among the RUs and IMs. The NSA has a helpdesk/support for the individual RUs and IMs in need of guidance on specific issues.
5 Improving	A. As for level 4, plus: The processes are continuously improved taking on board the views of the sector and implementing best practice in promoting a legal framework. The promoting mechanism is recognised by all staff of the NSA as an important tool in achieving the goals of the RSD. The NSA actively invites the sector and other stakeholders to discussion fora about the safety regulatory framework with the aim to discuss shared problems, inform well in advance about possible legal changes, collect good ideas on how to improve the framework and spread best practices in applying it. The NSA actively contribute to the establishment of EU guidance material and acceptable means of compliance for the sector.

4.4 Authorisation of technical sub-systems

This sub-element will be progressively adapted to the entry into force of the 4th package, directives 2016/797 and 2016/798 and their derived legal acts. Therefore the priority will be low during the first 3-years cycle 2018-2020.

Element 4: Performing		
	Sub-element 4.4: Authorisation of technical sub-systems	
1 Ad hoc	Α.	
2 Initialising	Α.	
3 Implementing	Α.	
4 Managing	Α.	
5 Improving	Α.	

4.5 Monitoring the Sector

Monitoring concerns the third cornerstone of a risk regulation regime; *information gathering*. Together with the supervision activities and accident investigations, monitoring will give a general understanding of how well the risk regulation regime is functioning in practice. Through these activities it will be possible to evaluate whether the *behavioural change* tools need to be improved or if the regulatory framework (i.e. the *standard setting*) needs to be clarified.

Mainly, this sub-element addresses the role of the NSA in monitoring the performance of the sector. According to the EU risk regulation regime this should be done by using Common Safety Indicators (CSIs) and Common Safety Targets (CSTs). Monitoring also includes overseeing learning from accident investigations. The NSA should monitor that the RUs and IMs implement the safety recommendations from the NIB and the NIB should monitor that the NSA actually carries out this monitoring.

Monitoring is an important tool in a risk-based regime. By following the development of safety indicators it is possible to act on safety risks in a pro-active way. In a risk regulation regime such as the one for railways it can however be difficult to identify the problem areas since accidents are relatively few. Best practice under such circumstances is to look for patterns that can predict the indicators, i.e. to work with precursors. It could also be useful to analyse the information in the annual reports from the RUs and IMs, from supervision activities etc., in order to better understand in which direction the railway safety performance develops.

Element 4: Performing		
	Sub-element 4.5: Monitoring the Sector	
1 Ad hoc	 A. <u>ANNUAL REPORTS:</u> The NSA does not monitor formally the performance of the sector and therefore does not produce any annual report. Moreover there is no follow-up on the annual reporting from RUs and IMs. B. <u>SAFETY INDICATORS:</u> Some monitoring is carried out but the data is random and rarely analysed. There are no purposeful reactions to findings. CSIs are not implemented. 	
2 Initialising	 A. <u>ANNUAL REPORTS</u>: The NSA sends annual reports to the Agency. The reports are not drafted systematically and they are not the result of a specific process. The annual reporting from RUs and IMs is not continuous and the NSA does not enforce it. However the need of a structured reporting system is identified and a process is being developed. B. <u>SAFETY INDICATORS</u>: The NSA has started to formalise the monitoring and analysis of safety data within the system. CSI's are partially collected and the NSA understands the importance of using them together with the CSTs in the annual report. However, data quality assurance is limited. 	
3 Implementing	A. <u>ANNUAL REPORTS</u> : The NSA reports in a structured, consistent and timely way (using an agreed harmonised template) using data from the annual reports of RUs and IMs. These data are also delivered systematically and on-time, as the NSA enforces the reporting activity of RUs and IMs.	
	B. <u>SAFETY INDICATORS</u> : The CSIs are fully implemented. The NSA uses CSTs and NRVs as input to evaluate the safety level of the member state. There is a process in place to ensure collection, analysis and quality of data (e.g. the	

	NSA verifies that RUs and IMs are delivering reliable data through the supervision).
4 Managing	 A. <u>ANNUAL REPORTS & SAFETY INDICATORS:</u> As for level 3, plus: The NSA analyses the data of the annual reports from RUs and IMs and CSIs to target and prioritise the supervision activity in accordance with the safety performance of the RU/IM or with the risk profile of the activity (e.g. shunting). The analysis and the plans are part of the annual report of the NSA, which goes beyond the list of issues in the harmonised template. The process used to manage annual reporting and safety indicators is regularly reviewed. The list of addressees of the annual report is extended to all actors in the sector (including manufacturers, consumers associations, etc.) and to entities responsible for safety in other transport modes and in other fields of industry. B. <u>SEE POINT A</u>
5 Improving	 A. <u>ANNUAL SAFETY REPORTS & SAFETY INDICATORS:</u> As for level 4, plus: The NSA analyses the data of the annual reports from RUs and IMs and CSIs, together with other inputs to proactively define its operational activities and goals which are communicated to the sector. The process used to manage annual reporting and safety indicators is regularly improved and proposals to improve the EU legal framework are made. B. <u>SEE POINT A</u>

5 Evaluating

The element is studying the willingness and capability of the NSA and to continuously study the results of its own actions and to implement changes when problems are identified. It also looks at how the organisation co-operate to ensure that the whole system is robust and efficient in supporting the overall transport policy.

This element has two sub-elements;

- 1. Monitoring;
- 2. Review.

Monitoring includes a set of control mechanisms which should be applied often enough to ensure that the there is a hands-on (almost day-to-day) understanding of how well the NSA performs. Reviews take place more seldom and looks at information from all the different monitoring activities in order to correct malfunctions in the NSA and improve its effectiveness.

5.1 Monitoring the NSA

The sub-element of "Monitoring the NSA" is closely related to the sub-element "Monitoring the sector" in basic element 4 above. But in this case the monitoring relates to the performance of the NSA itself rather than the performance of the sector in general.

Monitoring is an on-going measurement of activities to ensure that the senior management has a continuously up-dated knowledge about how well the organisation is performing in relation to its goals. Monitoring includes criteria related to auditing, investigating events, performance follow-up and reporting:

The criteria of *audit* looks at how the NSA ensure that its internal processes are being followed and that it is complying with their legal obligations. An audit can cover parts of a system or a whole system. An internal/external audit in the NSA can for example cover either the safety certification process or the whole management system (of which the safety certification process is only one process among many other processes).

The criteria of *investigating events* addresses the ability of the NSA organisation to learn from its own mistakes. Just like the RUs and IMs can improve their performance by investigating incidents and accidents, the NSA can improve their performance by investigating the internal actions that led up to a mistake (for example losing a document that was handed in during a certificate application or overlooking evidence in an accident investigation). The ability to investigate this type of incidents is closely linked with the sub-element of "Safety culture management" which was addressed in section 2.3 above. If the organisation has a blame culture it is unlikely that employees will report their mistakes to be evaluated for future learning.

Not only failure offers a source of knowledge. Successes can provide equal opportunities for learning and should therefore be studied too.

The criteria of *performance follow-up* investigates to what extent the NSA measure their activities. This could for example be monthly statistics collected by senior management in the NSA on how long it takes in average to issue a safety certificate. Senior management can then by comparing numbers over the months/years see if site arrival/certificate handling times have increased or decreased. But monitoring will not give any answers as to *why* the numbers have changed in one direction or another. In order to find that out it would be necessary to carry out a proper audit or review.

The criteria of *reporting* explores if the NSA have tools to pick up early warnings about undesired outcomes in the organisations.

Element 5: Evaluating

Sub-element 5.1: Monitoring the NSA

	A. Audit:
	There is little or no evidence of internal/external audits being carried out. Audits that are carried out are not planned or prioritised.
	B. INVESTIGATING EVENTS:
	The NSA does not or does very rarely investigate its own failures. When failures occur, the culture of the organisation is to find someone to blame.
1	C. <u>Performance follow-up:</u>
Ad hoc	Tasks are not regularly followed up by the line management chain which means that managers cannot intervene if the tasks are not being properly performed. The organisation therefore lacks means to analyse whether it is carrying out its activities in an effective and efficient way.
	D. <u>Reporting</u> :
	There is no process in place to collect warnings from staff about issues and undesired events in the organisation.
	The NSA does not have a process to contribute to the collection collect and report of safety alerts about malfunctioning in the railway system.
	A. <u>Audit:</u>
	Internal/external audits are being carried out even if they are not following any coordinated plan. The need of an organised approach is identified and a process is drafted.
	B. INVESTIGATING EVENTS:
	Internal undesired outcomes are investigated but there is little guidance on how or what to investigate.
	C. <u>Performance follow-up:</u>
2 Initialising	Some critical processes are followed up and some results are evaluated, but collection of data is isolated and uncoordinated. This leads to inconsistencies between different units of the NSA that have similar tasks. Not all managers understand the need to follow up tasks and so do not collect the requested data.
	D. <u>Reporting:</u>
	Some warnings from staff are collected but not all the employees understand the importance of reporting issues. Exchange of relevant safety information is therefore not structured, even if the importance of exchanging relevant information is recognised by the senior management. A process is being drafted.
3	A. <u>Audit:</u>
Implementing	

		The management system of the NSA includes an audit process which makes it possible for the organisation to check if it is complying with its legal obligations as well as its own operational, strategic and administrative processes. There is evidence of co-ordinated and planned internal audits. There are external audits of the NSA.
	В.	INVESTIGATING EVENTS:
		The NSA has a process in place for evaluating internal mistakes with the aim to improve performance. However, only immediate causes are investigated; the organisation does not seek to identify areas for wider improvement.
	C.	PERFORMANCE FOLLOW-UP:
		All processes are followed up and results are evaluated. The collection of data is systematic and consistent among the units. Managers on all levels understand the need to follow up tasks and so collect the requested data.
	D.	Reporting:
		There is a process in place to collect warnings from the staff which is used by all employees and managers. There is awareness in the organisation of the importance of reporting issues.
	Α.	Audit: As for Level 3, plus:
		Internal lead auditors (if any) are regularly trained and certified when applicable. The auditing process is regularly reviewed. The NSA activities are regularly audited by internal/external competent auditors. Audit activities are prioritised based on problems identified in the monitoring process.
	В.	INVESTIGATING EVENTS: As for level 3, plus:
4 Managing		The process also ensures the evaluation of success stories. The process for evaluating internal mistakes/success stories ensures improved performance in both the concerned unit and wider in other parts of the organisation. The range of incidents that are investigated includes not only direct mistakes but also disruptions to work and where expected outcomes are not achieved. The NSA applies effective tools to find issues and success stories to study for future learning. Complaints from the public/applicants are investigated and any necessary improvements made.
	C.	PERFORMANCE FOLLOW-UP: As for level 3, plus:
		Process follow-up is prioritised based on previous results and linked with the broader policy goals with the aim to investigate whether there is divergence from the goals. The process is reviewed systematically.
		The overall performance of the NSA is measured against clear key performance indicators.
	D.	<u>REPORTING</u> : As for level 3, plus:

	The process is being reviewed. The staff receives feedback on registered reports. Internal reporting is supported by a just culture. The NSA reports to the Ministry on a regular basis and it is expected to link its reports with objectives.
5 Improving	 A. <u>AUDIT</u>: As for Level 4, plus: All auditors are regularly trained and certified, when applicable. The auditing process is regularly improved taking best practices into account. Audit activities are prioritised with a risk-based approach. The internal/external audits of NSA are focused on evaluating the efficiency and effectiveness of the organisations. B. <u>INVESTIGATING EVENTS</u>: As for level 4, plus: The NSA openly shares lessons learned with other national/European government bodies. C. <u>PERFORMANCE FOLLOW-UP</u>: As for level 4, plus: Process follow up is prioritised based on risks (e.g. changes in the organisation). The process is continually improved. The NSA actively invites public examination of its activities. D. <u>REPORTING</u>: As for level 4, plus: The process is being improved. Critical activities and areas are identified by the management to be reported on. The NSA reports (to the Ministry) include an extensive analysis of railway system performance in relation to previous years.

5.2 Review

While an audit is a tool to check if something is done according to a defined set of policies, procedures or requirements, a review is a tool to check if the way in which a task is carried out is really ensuring that the objective of that task is fulfilled. The result of an audit will for example show if a certain procedure was followed or not. A review of the same procedure will instead show if the procedure is effective in meeting the organisation's objectives.

This sub-element of the Matrix checks if the NSA is analysing the results of all their monitoring activities (i.e. audits, investigation of events, performance follow-up and reporting) to ensure that it is organised in the most opportune way and if the NSA have chosen the most efficient procedures and control systems to manage their tasks.

The reviews should also include a structured definition, allocation and follow-up of improvement measures. In addition, any changes should be tested in an impact evaluation before they are decided and implemented, which is why it is not possible to reach Level 3 in this sub-element unless there is a change management process in place (i.e. Level 3 has been reached in sub-element 2.6).

Element 5: Evaluating			
Sub-element 5.2: Review			
1 Ad hoc	A. <u>REVIEW:</u> There is no process for carrying out performance reviews. As a result, there is no analysis of the findings from monitoring activities and the organisation/system undergoes few changes for improvement.		
2 Initialising	A. <u>Review:</u> The reviews carried out are not part of a systematic approach to improvement. They are often reactive and not planned as part of the management cycle. But the importance of a systematic review is understood and a process is being developed. Reviews give rise to simple improvement actions and changes to low levels of the management system.		
3 Implementing	A. <u>Review:</u> The management system of the NSA includes a process which prompts the organisation to review its processes as well as its whole management system to ensure that these are still supporting the organisation in reaching its defined targets. (In assigning the level, please consider SE 1.2). The process also makes sure that the necessary actions identified by reviews are implemented using the organisation's change management process.		
4 Managing	 A. <u>Review:</u> As for Level 3, plus: The review process itself is continuously reviewed to ensure that it stays fit for purpose. The aim of the process is to understand wider implications and opportunities for creating more effective strategies. Corrective actions have closure criteria and mechanisms for tracking their progress. Recommendations from reviews show that the wider implications are considered. 		



A. <u>REVIEW:</u>

As for Level 4, plus: The NSA continuously reviews its processes as well as its whole internal management system to ensure that it is continuously improved. The NSA is being reviewed by an external body and actively takes part in peer review type activities with other competent bodies. Inspiration for improvement comes from (among other things) internal and external good practice, internal and external feedback, lessons learned, monitoring and peer-to-peer auditing activities. Risk-based improvement plans systematically and effectively ensure that results from reviews are acted upon. Corrective actions are supported by senior management which links them with the objectives of the organisation.