

Making the railway system
work better for society.

Annex III

NSA Monitoring – Referential Matrix audit

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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 the 3 points above 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 entirety.

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.

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 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, one of the tools the Agency is oriented to use, is 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.

THE STRUCTURE OF THE MATURITY MODEL

The NSA Monitoring Matrix is structured considering the applicable legal framework, to contextualise the evaluation in the EU railway system.

Each element below describes key components of the NSA organisation and processes which are essential for NSAs to achieve their main tasks (see Table 1).

Table 1. Elements and criteria for the NSA Monitoring Matrix

Elements	Criteria
1. NSA organisation	<ul style="list-style-type: none"> A. The NSA is established and is organised and it manages its staff/resources competences in order to deliver its tasks B. The NSA is independent C. The NSA takes decisions in line with decision making principles D. The NSA coordinates and cooperates
2. Reporting	<ul style="list-style-type: none"> A. Safety indicators B. Annual reports C. Reporting on the application of the CSM for Monitoring Regulation (EU) 1078/2012 D. Reporting on the CSM for Risk Evaluation and Assessment (Regulation (EU) 402/2013) E. Reporting on the CSM on Safety Management System Requirements (Regulation (EU) 2018/762)
3. Safety Certification	<ul style="list-style-type: none"> A. General B. Pre-engagement, receipt of the application and initial screen C. Detailed assessment D. Decision-making E. Closing assessment F. Specific provisions for the renewal or an update of a single safety certificate
4. Safety authorisation	<ul style="list-style-type: none"> A. General B. Pre-engagement, receipt of the application and initial screen C. Detailed assessment D. Decision-making E. Closing assessment F. Specific provisions for the renewal or an update of a single safety authorisation
5. Authorisation for the placing in service of fixed installations	<ul style="list-style-type: none"> A. General B. Processing the application C. Renewal/upgrading D. Decision making E. Review and appeal F. Link between supervision and APS of fixed installations
6. Authorisation of vehicles	<ul style="list-style-type: none"> A. General B. Pre-engagement C. Changes to an already authorised vehicle/ vehicle type D. Processing the application E. Decision-making and final documentation F. Review G. Link between supervision and vehicle authorisation for placing on the market and vehicle type authorisation.

7. Risk Assessment: recognition by the NSA of AsBos or NSA acting as AsBo	A. Recognition B. Information - Report C. Only where the NSA acts directly as Assessment Body D. Supervision/surveillance E. Use of ERA Recommendations For Use [RFUs]
8. NSA as Notifying Authority for CABs/NoBos	A. Responsibility B. Independence and impartiality C. Resources D. Confidentiality E. Information
9. NSA Supervision	A. Structured and auditable process B. Supervision strategy and plan C. Communicating the plan D. Delivering the supervision activities E. Outcomes of the supervision activities F. Reviewing the supervision activities G. Competence H. Decision Making I. Coordination and cooperation J. Reporting to the Agency
10. NSA tasks relating to ECM	A. NSA designated as ECM certification body B. NSA designated as ECM certification body C. Certification committee D. Activity Report E. Surveillance F. Requirements to be used by the NSA acting as recognition body
11. Train drivers	A. Issuance of a licence and sanctions B. Recognition/ accreditation and register C. Quality system
12. Promotion of the safety regulatory framework	A. Promote and contribute B. Coordinate and cooperate

THE LEVELS

Each element is evaluated taking into account various evidence - documents, reports and interviews. The evaluation is described in the NSA Monitoring audit Report taking into account the levels as reference.

The levels are not defined with the idea to set thresholds and pass-marks.

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.

Table 2. The measuring scale: levels and descriptions

Level	Performance	Description
1	<i>Ad hoc</i>	Tasks are not delivered or delivered in a random and unstructured way. Legal obligations are not complied with or may not be complied with in a systematic way.
2	<i>Initialising</i>	The creation of a structured way of delivering tasks has started, but structures and processes are not yet fully implemented entailing the risk that tasks are not delivered and legal obligations are not complied with.

3	<i>Implementing</i>	The processes that were created in order to deliver tasks in a structured way have been implemented. Tasks are delivered, legal obligations are met.
4	<i>Managing</i>	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	<i>Improved</i>	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)

Granting level 1 – ad hoc – to an element indicates that legal obligations are not complied with or may not be complied with in a systematic way. Therefore, generally granting a level 1 to an element would lead to the qualification of finding(s) as deficiency(ies).

Granting level 2 to an element – Initialising – indicates that there is the risk that tasks are not delivered and legal obligations are not complied with as structures and processes are not yet fully implemented. Therefore, generally granting a level 2 to an element would lead to the qualification of finding(s) as observation(s).

Qualification of findings as deficiencies and observations is performed in line with the audit procedure based on a risk evaluation.

As several observations considered together may lead to deficiency, in case several elements are granted level 2, this could lead to deficiency(ies).

The measuring scale with the 5 levels 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 audit 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 element, which are described in Appendix 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 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 look at how the NSA have structured and implemented their processes in conformity with the applicable legislation, which is one of the bases used to define the criteria detailed in Appendix I.

Appendix I: EXPLANATION OF THE MATRIX ELEMENTS

1. Organisation

Element 1: Organisation	
<p>1 Ad hoc</p>	<p>A. The NSA is established and is organised and it manages its staff/resources competences in order to deliver its tasks</p> <ol style="list-style-type: none"> 1. Resources (staff and financial) are not allocated to the tasks specified in Article 16 (2) and Article 17 of Directive 2016/798. 2. Responsibilities for managing the tasks are not in place. 3. Staff are not allocated to specific tasks and neither trained nor managed. 4. Staff does not receive guidance to deliver its activities. 5. The NSA does not ensure that its staff has relevant experience and knowledge of the relevant regulatory framework as it applies to specified tasks and knowledge of the functioning of the railway system. 6. The NSA has not put in place a competence management system which includes the following elements: <ul style="list-style-type: none"> - the development of competence profiles for each job, position or role - the recruitment of staff in accordance with the established competence profiles - the maintenance, development and assessment of staff competence in accordance with the established competence profiles - in the case of teamwork, the competences may be shared amongst the team members - for SC and SUP: staff carrying out visits, inspections and audits shall also demonstrate knowledge of, and experience in interviewing skills. 7. The NSA does not have staff processes to manage competences needed in order to undertake the NSA tasks. <p>B. The NSA is independent</p> <ol style="list-style-type: none"> 1. The NSA is not independent in its organization, legal structure and decision making from any railway undertaking, infrastructure manager, applicant or contracting entity and from any entity awarding public service contracts. In case the NSA is a department within the national ministry responsible for transport matters or any other government department, its independence is not ensured. 2. The NSA does not have the necessary internal and external organisational capacity in terms of human and material resources. 3. The independence of the NSA organisation and the NSA staff towards the industry is not ensured (e.g. insufficient resources, conflict of interests, lack of internal process). 4. Staff are not aware of and do not follow the requirements relating to independence. Conflict of interests are neither identified nor dealt with. 5. The legislation is not consistently applied, monitored and reviewed to ensure it meets the requirements. In case of issue, the NSA does not take any action at the MS level. 6. NSA tasks listed under Article 16 (2) of the Railway Safety Directive are transferred or subcontracted to IM, RU or contracting entity. If technical assistance is requested from the RU, IM or procurement authority, the NSA does not ensure that it does not affect its independence. The assistance involves making decisions on behalf of the NSA.

	<p>C. The NSA takes decisions in line with decision making principles</p> <ol style="list-style-type: none"> 1. The NSA does not carry out its tasks in an open, non-discriminatory and transparent way. 2. The NSA decisions and actions are not verified, monitored and reviewed to ensure that they remain open and transparent, and are applied in a non-discriminatory way. 3. The NSA does not allow all parties to be heard and it gives reasons for its decisions. 4. The legislation (or process) does not ensure that all parties can be heard and that the NSA gives reasons for its decisions. It is continually monitored and reviewed to ensure that it meets the requirements. 5. Staff are not aware of and do not follow the requirements to ensure that decisions are open, transparent and applied in a non-discriminatory way. 6. The NSA does not respond promptly to all requests and information from the RU/IM without delay and does not adopt all decisions within four months after all requested information has been provided. 7. The NSA does not communicate its requests for information without delay and does not adopt all decisions within four months after all requested information has been provided. 8. Applicants are not given help and guidance in order for them to know what is expected from them. 9. The NSA does not publish necessary information for the RU/IM/ECM/training centers on how it carries out its activities. 10. RUs/IMs/ECM/training centers are not informed as early as possible about any problem or deficiencies. 11. Where appropriate (if it is in the NSA tasks, depending on the national legal framework), in the process of developing the regulatory framework, the NSA does not consult all persons involved and interested parties, including RU, IM, manufactures and maintenance providers, users and staff representatives. 12. The NSA is not free to carry out all inspections, audits and investigations that are needed for the accomplishment of its tasks and it is not granted access to all relevant documents and to premises, installations and equipment of IMS and RUs and, where necessary, of any actor referred to in Article 4 of the Directive 2016/798. 13. There are no means for applicants to make a complaint and to lodge a judicial appeal against any decision made by the NSA and this is not communicated to the IM/RU/ECM/ training centers. <p>D. The NSA coordinates and cooperates</p> <ol style="list-style-type: none"> 1. . The NSA does not conduct an active exchange of views and experience for the purpose of harmonizing their decision-making criteria with relevant parties. For example, the NSA cannot show its active involvement in the NSA Network nor it cannot show that it shares urgent safety-relevant information with relevant parties. 2. The NSA cannot show how this helps with the harmonisation of their decision making process.
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<p>2 Initialising</p>	<p>A. The NSA is established and is organised and it manages its staff/resources competences in order to deliver its tasks</p> <ol style="list-style-type: none"> 1. Resources (staff and financial) are not fully allocated to the tasks specified in Article 16 (2) and Article 17 of Directive 2016/798. 2. Responsibilities for managing the tasks are not fully in place. 3. Staff are partially allocated to specific tasks and are trained and managed in a limited and not fully structured manner. 4. Staff receives limited guidance to deliver its activities. 5. The NSA does not fully ensure that its staff has relevant experience and knowledge of the relevant regulatory framework as it applies to specified tasks and knowledge of the functioning of the railway system. 6. The NSA has started putting in place a competence management system which includes the following elements: <ul style="list-style-type: none"> - the development of competence profiles for each job, position or role - the recruitment of staff in accordance with the established competence profiles - the maintenance, development and assessment of staff competence in accordance with the established competence profiles - in the case of teamwork, the competences may be shared amongst the team members - for SC and SUP: staff carrying out visits, inspections and audits shall also demonstrate knowledge of, and experience in interviewing skills. <p>But the competence management system is not fully set up and implemented in a systematic manner.</p> <ol style="list-style-type: none"> 7. The NSA has some staff processes to manage competences needed in order to undertake the NSA tasks. <p>B. The NSA is independent</p> <ol style="list-style-type: none"> 1. The NSA is not fully independent in its organization, legal structure and decision making from any railway undertaking, infrastructure manager, applicant or contracting entity and from any entity awarding public service contracts. In case the NSA is a department within the national ministry responsible for transport matters or any other government department, its independence is not fully ensured (e.g. lack of independence in priority settings and resource management). 2. The NSA does not systematically have the necessary internal and external organisational capacity in terms of human and material resources. 3. The independence of the NSA organisation and the NSA staff towards the industry is partly ensured (e.g. insufficient resources, conflict of interests, lack of internal process). 4. Staff are partly aware of and follow the requirements relating to independence. Conflict of interests are identified and dealt with in some cases only. 5. The legislation is partly applied, monitored and reviewed to ensure it meets the requirements. In case of issue, the NSA does not systematically take any action at the MS level. 6. NSA tasks listed under Article 16 (2) of the Railway Safety Directive are in some cases transferred or subcontracted to IM, RU or contracting entity without systematically ensuring the NSA independence. If technical assistance is requested from the RU, IM or procurement authority, the NSA does not systematically ensure that it does not affect its independence. The assistance could involve in some cases making decisions on behalf of the NSA.
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	<p>C. The NSA takes decisions in line with decision making principles</p> <ol style="list-style-type: none"> 1. The NSA does not systematically carry out its tasks in an open, non-discriminatory and transparent way. 2. The NSA decisions and actions are not systematically verified, monitored and reviewed to ensure that they remain open and transparent, and are applied in a non-discriminatory way. 3. The NSA does not systematically allow all parties to be heard and it gives reasons for its decisions. 4. The legislation (or process) does not systematically ensure that all parties can be heard and that the NSA gives reasons for its decisions. It is continually monitored and reviewed to ensure that it meets the requirements. 5. Staff aware of follow the requirements in relation to ensure that decisions are open, transparent and applied in a non-discriminatory way. 6. The NSA does not systematically respond promptly to all requests and information from the RU/IM without delay and does not systematically adopt all decisions within four months after all requested information has been provided. This is not fully monitored and nor reviewed to ensure it is correctly applied and meets the requirements. 7. The NSA does not communicate its requests for information without delay and does not adopt all decisions within four months after all requested information has been provided. This is neither monitored nor reviewed to ensure that it is correctly applied and it meets the requirements. 8. Applicants are not systematically given help and guidance in order for them to know what is expected from them. 9. The NSA does not systematically publish necessary information for the RU/IM/ECM/training centers on how it carries out its activities. 10. RUs/IMs/ECM/training centers are not systematically informed as early as possible about any problem or deficiencies. 11. Where appropriate (if it is in the NSA tasks, depending on the national legal framework), in the process of developing the regulatory framework, the NSA does not systematically consult all persons involved and interested parties, including RU, IM, manufactures and maintenance providers, users and staff representatives. 12. The NSA is always free to carry out all inspections, audits and investigations that are needed for the accomplishment of its tasks and it is not always granted access to all relevant documents and to premises, installations and equipment of IMS and RUs and, where necessary, of any actor referred to in Article 4 of the Directive 2016/798. 13. There are not systematically means for applicants to make a complaint and to lodge a judicial appeal against any decision made by the NSA and this is not always communicated to the IM/RU/ECM/ training centers. <p>D. The NSA coordinates and cooperates</p> <ol style="list-style-type: none"> 1. The NSA does not systematically conduct an active exchange of views and experience for the purpose of harmonizing their decision-making criteria with relevant parties. For example, the NSA has a limitative involvement in the NSA Network and it does not systematically share urgent safety-relevant information with relevant parties. 2. The NSA can show limitative evidence of how this helps with the harmonisation of their decision making process. This is not systematically monitored and reviewed to ensure that it is correctly applied and meets the requirements.
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<p>3 Implementing</p>	<p>A. The NSA is established and is organised and it manages its staff/resources competences in order to deliver its tasks</p> <ol style="list-style-type: none"> 1. Resources (staff and financial) are allocated to the tasks specified in Article 16 (2) and Article 17 of Directive 2016/798. 2. Responsibilities for managing the tasks are in place. 3. Staff are allocated to specific tasks and are trained and managed. 4. Staff receives guidance to deliver its activities. 5. The NSA ensures that its staff has relevant experience and knowledge of the relevant regulatory framework as it applies to specified tasks and knowledge of the functioning of the railway system. 6. The NSA has put in place a competence management system which includes the following elements: <ul style="list-style-type: none"> - the development of competence profiles for each job, position or role - the recruitment of staff in accordance with the established competence profiles - the maintenance, development and assessment of staff competence in accordance with the established competence profiles - in the case of teamwork, the competences may be shared amongst the team members - for SC and SUP: staff carrying out visits, inspections and audits shall also demonstrate knowledge of, and experience in interviewing skills. 7. The NSA has staff processes to manage competences needed in order to undertake the NSA tasks. <p>B. The NSA is independent</p> <ol style="list-style-type: none"> 1. The NSA is independent in its organization, legal structure and decision making from any railway undertaking, infrastructure manager, applicant or contracting entity and from any entity awarding public service contracts. In case the NSA is a department within the national ministry responsible for transport matters or any other government department, its independence is ensured. 2. The NSA has the necessary internal and external organisational capacity in terms of human and material resources. 3. The independence of the NSA organisation and the NSA staff towards the industry is ensured (e.g. sufficient resources, conflict of interests, lack of internal process). 4. Staff are aware of and follow the requirements relating to independence. Conflict of interests are identified and dealt with. 5. The legislation is applied, monitored and reviewed to ensure it meets the requirements. In case of issue, the NSA takes action at the MS level. 6. NSA tasks listed under Article 16 (2) of the Railway Safety Directive may not be transferred or subcontracted to IM, RU or contracting entity. If technical assistance is requested from the RU, IM or procurement authority, the NSA ensures that it does not affect its independence. The assistance does not involve making decisions on behalf of the NSA. <p>C. NSA takes decisions in line with decision making principles</p> <ol style="list-style-type: none"> 1. The NSA carries out its tasks in an open, non-discriminatory and transparent way. 2. The NSA decisions and actions are verified, monitored and reviewed to ensure that they remain open and transparent, and are applied in a non-discriminatory way. 3. The NSA allows all parties to be heard and it gives reasons for its decisions. 4. The legislation (or process) ensures that all parties can be heard and that the NSA gives reasons for its decisions.
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	<ol style="list-style-type: none"> 5. Staff are aware of follow the requirements in relation to ensure that decisions are open, transparent and applied in a non-discriminatory way. 6. The NSA responds promptly to all requests and information from the RU/IM without delay and adopts all decisions within four months after all requested information has been provided. 7. The NSA communicates its requests for information without delay and adopts all decisions within four months after all requested information has been provided. This monitored and reviewed to ensure that it is correctly applied and it meets the requirements. 8. Applicants are given help and guidance in order for them to know what is expected from them. 9. The NSA does not systematically publish necessary information for the RU/IM/ECM/training centers on how it carries out its activities. 10. RUs/IMs/ECM/training centers are informed as early as possible about any problem or deficiencies. 11. Where appropriate (if it is in the NSA tasks, depending on the national legal framework), in the process of developing the regulatory framework, the NSA consults all persons involved and interested parties, including RU, IM, manufactures and maintenance providers, users and staff representatives. 12. The NSA is always free to carry out all inspections, audits and investigations that are needed for the accomplishment of its tasks and it is not always granted access to all relevant documents and to premises, installations and equipment of IMS and RUs and, where necessary, of any actor referred to in Article 4 of the Directive 2016/798. 13. There are means for applicants to make a complaint and to lodge a judicial appeal against any decision made by the NSA and this is communicated to the IM/RU/ECM/ training centers. <p>D. The NSA coordinates and cooperates</p> <ol style="list-style-type: none"> 1. The NSA conducts an active exchange of views and experience for the purpose of harmonizing their decision-making criteria with relevant parties. For example, the NSA shows its active involvement in the NSA Network and it shares urgent safety-relevant information with relevant parties. 2. The NSA helps with the harmonisation of their decision making process. This is monitored and reviewed to ensure that it is correctly applied and meets the requirements.
<p style="text-align: center;">4</p> <p style="text-align: center;">Managing</p>	<p>A. The NSA is established and is organised and it manages its staff/resources competences in order to deliver its tasks</p> <p>As for Level 3, plus: The NSA performs controls and reviews to ensure that the requirements relating to resources in terms of staff, including its competence management system, and financial aspects are well managed. The NSA takes corrective actions when needed.</p> <p>B. The NSA is independent</p> <p>As for Level 3, plus: The NSA performs controls and reviews to ensure its independence. It has processes in place with are established and reviewed. The NSA takes corrective actions when needed.</p> <p>C. NSA takes decisions in line with decision making principles</p> <p>As for Level 3, plus: The NSA performs controls and reviews of its decisions to check that these are in line with decision making principles. It has processes in place which are established and</p>

	<p>reviewed. The NSA takes corrective actions when needed.</p> <p>D. The NSA coordinates and cooperates As for Level 3, plus: The NSA performs controls and reviews its processes for conducting exchange of views and experience for the purpose of harmonizing their decision-making criteria with relevant parties. The NSA also performs controls and reviews its processes to support the harmonisation of NSAs decision making process. The NSA takes corrective actions when needed.</p>
<p>5 Improving</p>	<p>A. The NSA is established and is organised and it manages its staff/resources competences in order to deliver its tasks As for Level 4, plus: The NSA continuously strives to improve the management of its resources in terms of staff, including its competence management system, and financial aspects are well managed to improve efficiency.</p> <p>B. The NSA is independent As for Level 4, plus: The NSA continuously strives to improve its independence. It has processes in place and their is efficiency improved.</p> <p>C. NSA takes decisions in line with decision making principles As for Level 4, plus: The NSA continuously strives to improve its decisions to ensure that these are in line with decision making principles. It has processes in place and their is efficiency improved.</p> <p>E. The NSA coordinates and cooperates As for Level 4, plus: The NSA continuously strives to improve its processes for conducting exchange of views and experience for the purpose of harmonizing their decision-making criteria with relevant parties. The NSA also continuously strives to improve s its processes to support the harmonisation of NSAs decision making process.</p>

2. Reporting

Element 2.: Reporting	
<p>1 Ad hoc</p>	<p>A. Safety indicators 1. CSIs are not implemented. 2. Some monitoring is carried out but the collection of data is random or done in unstructured way. The data are rarely analysed and there are no purposeful reactions to findings.</p> <p>B. Annual reports 1. The NSA does not monitor formally the performance of the sector and therefore does not produce any annual report. 2. There is no follow-up on the annual reporting from RUs and IMs.</p> <p>C. Reporting on the application of the CSM for Monitoring Regulation (EU) 1078/2012 NSA does not report as required by Article 19 of Directive (EU) 2016/798, on the application of CSM for Monitoring by the railway undertakings, infrastructure managers, and as far as it is aware of it, by the entities in charge of maintenance.</p>

	<p>D. Reporting on the CSM for Risk Evaluation and Assessment (Regulation (EU) 402/2013) NSA does not report, as required by Article 19 of Directive (EU) 2016/798, on the experience of the proposers with the application of this Regulation, and, where appropriate, its own experience.</p> <p>E. Reporting on the CSM on Safety Management System Requirements (Regulation (EU) 2018/762) NSA does not report, as required by Article 19 of Directive (EU) 2016/798, on the experience of the application of this Regulation, and, where appropriate, its own experience.</p>
<p style="text-align: center;">2 Initialising</p>	<p>A. Safety indicators 1. 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. 2. The NSA has started to formalise the monitoring safety data within the system.</p> <p>B. Annual reports 1. The NSA produces the annual report and sends it to the Agency within the set deadline or not. The annual report does not provide all mandatory information requested by legal obligation. 2. The annual reporting from RUs and IMs is partly taken into account in drawing up its annual report.</p> <p>C. Reporting on the application of the CSM for Monitoring Regulation (EU) 1078/2012 NSA reports some of the information as required by Article 19 of Directive (EU) 2016/798, on the application of CSM for Monitoring by the railway undertakings, infrastructure managers, and as far as it is aware of it, by the entities in charge of maintenance.</p> <p>D. Reporting on the CSM for Risk Evaluation and Assessment (Regulation (EU) 402/2013) NSA reports some of the information, as required by Article 19 of Directive (EU) 2016/798, on the experience of the proposers with the application of this Regulation, and, where appropriate, its own experience.</p> <p>E. Reporting on the CSM on Safety Management System Requirements (Regulation (EU) 2018/762) NSA reports some of the information, as required by Article 19 of Directive (EU) 2016/798, on the experience of the application of this Regulation, and, where appropriate, its own experience.</p>
<p style="text-align: center;">3 Implementing</p>	<p>A. Safety indicators 1. CSI's are fully implemented. The NSA uses CSTs and NRVs as input to evaluate the safety level of the member state. 2. The NSA collects the safety data within the system but does not verify yet that RUs and IMs are delivering reliable data.</p> <p>B. Annual reports 1. The NSA produces in a structured, consistent and timely way the annual report (using an agreed harmonised template) and provides the mandatory information requested by legal obligation. The annual report is sent to the Agency and to all actors in the sector (including manufacturers, consumers associations, etc.). 2. The annual reporting from RUs and IMs is taken into account in drawing up its annual report.</p>

	<p>C. Reporting on the application of the CSM for Monitoring Regulation (EU) 1078/2012 NSA provides information as required by Article 19 of Directive (EU) 2016/798, on the application of CSM for Monitoring by the railway undertakings, infrastructure managers, and as far as it is aware of it, by the entities in charge of maintenance.</p> <p>D. Reporting on the CSM for Risk Evaluation and Assessment (Regulation (EU) 402/2013) NSA provides information, as required by Article 19 of Directive (EU) 2016/798, on the experience of the proposers with the application of this Regulation, and, where appropriate, its own experience.</p> <p>E. Reporting on the CSM on Safety Management System Requirements (Regulation (EU) 2018/762) NSA provides information, as required by Article 19 of Directive (EU) 2016/798, on the experience of the application of this Regulation, and, where appropriate, its own experience.</p>
<p style="text-align: center;">4 Managing</p>	<p>A. Safety indicators 1. The NSA plans activities/initiatives in accordance with the safety performance of RUs/IMs. 2. The NSA analyses the safety data within the system and verifies that RUs and IMs are delivering reliable data.</p> <p>B. Annual reports As for level 3, plus: 1. In the annual report, the NSA plans activities/initiatives in order to improve the safety railway system. Proposals to improve the EU legal framework are not made yet. 2. The NSA analyses the safety data of the annual reports from RUs/IMs to target and prioritise its activities accordingly.</p> <p>C. Reporting on the application of the CSM for Monitoring Regulation (EU) 1078/2012 NSA analyses the information on the application of CSM for Monitoring by the railway undertakings, infrastructure managers, and as far as it is aware of it, by the entities in charge of maintenance giving a reliable picture of the situation in the country.</p> <p>D. Reporting on the CSM for Risk Evaluation and Assessment (Regulation (EU) 402/2013) NSA analyses the information on the experience of the proposers with the application of the CSM for Risk Evaluation and Assessment, and, where appropriate, its own experience, giving a reliable picture of the situation in the country.</p> <p>E. Reporting on the CSM on Safety Management System Requirements (Regulation (EU) 2018/762) NSA analyses the information on the experience of the application of this CSM on SMS, and, where appropriate, its own experience, giving a reliable picture of the situation in the country.</p>
<p style="text-align: center;">5 Improved</p>	<p>A. Safety indicators 1. The analyses of CSIs is done on risk based approach and is a source to proactively define its strategy, operational activities and goals. 2. The NSA plans dissemination and training to help the sector in the analyses of the safety data within the system for improving their standardisation and homogenisation.</p>

	<p>B. Annual reports As for level 4, plus:</p> <ol style="list-style-type: none"> 1. The NSA analyses the information from different sources to proactively define on risk based approach its strategy, operational activities and goals which are communicated to the sector and provides proposals to improve the EU legal framework. 2. The NSA analyses the data of the annual reports from RUs/IMs to target and prioritise its activities (e.g the supervision) in accordance with the safety performance of the RUs/IMs and with the risk profile of the activities. <p>C. Reporting on the application of the CSM for Monitoring Regulation (EU) 1078/2012 NSA reviews the changes of the sector experience about the application of the methodology of CSM for Monitoring by the railway undertakings, infrastructure managers, and as far as it is aware of it, by the entities in charge of maintenance, putting in place initiatives for improvements.</p> <p>D. Reporting on the CSM for Risk Evaluation and Assessment (Regulation (EU) 402/2013) NSA reviews the changes of the sector experience about the application of the methodology of the CSM for Risk Evaluation and Assessment, putting in place initiatives for improvements.</p> <p>E. Reporting on the CSM on Safety Management System Requirements (Regulation (EU) 2018/762) NSA reviews the changes of the sector experience about the application of the methodology of CSM on SMS, putting in place initiatives for improvements.</p>
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3. Safety Certification

Element 3: Safety certification	
<p>1 Ad hoc</p>	<p>A. General</p> <ol style="list-style-type: none"> 1. The NSA, whether safety certification body or not, does not have a structured and auditable process for the complete activity and it does not check and review its performance. There is no process and no established internal arrangements or procedures for managing the safety assessment process against the Requirements of the relevant CSM. Safety Certificates are not issued using OSS and the required templates. 2. The NSA does not have a system for ensuring that staff involved in assessments have the required competences as described in Reg. 2018/763. 3. There is no NSA application Guide or there is a Guide but it is incomplete, e.g. it does not explain clearly the process of safety certification for an applicant for the cases where the NSA is the Safety Certification Body and for the cases where the NSA role is more limited because the Agency is the Safety Certification Body; Border Stations and what requirements it will apply to those stations within its own territory are not specified. <p>B. Pre-engagement, receipt of the application and initial screen</p> <ol style="list-style-type: none"> 1. Whether acting as safety certification body or not, <ul style="list-style-type: none"> - the NSA process for the scrutiny of Safety Certificate applications is not able to be completed within the timescales. - the NSA concerned with the intended area of operation does not check that the evidence for the type, extent and intended area of operation is clearly identified. - the NSA does not review a sufficient sample of the application for its own part, to check that its content is understandable. 2. When the NSA is acting as the safety certification body, <ul style="list-style-type: none"> - it does not accept pre-engagements when requested by the applicant and does not provide any requested clarification in the context of pre-engagement. - it does not assign competent resources to deliver the assessment process. - it does not perform a proper initial screen to check whether the application contains the necessary information. 3. When the Agency is the safety certification body, the NSA fails to coordinate with the Agency to decide whether there are areas in which, for their respective part, further information is necessary. <p>C. Detailed assessment</p> <ol style="list-style-type: none"> 1. Whether acting as safety certification body or not, <ul style="list-style-type: none"> - The NSA does not meet the timeframe for taking a decision on issuing the single safety certificate. - It does not assess the applicant’s responses giving no information on whether response is satisfactory or not. - The NSA does not request supplementary information or make site visits to RUs under assessment. - The NSA is not impartial and proportionate and does not provide documented reasons for conclusions reached. It is not transparent in how it judges the severity of each identified issue.

	<ul style="list-style-type: none"> - Type 4 issues are not resolved to the satisfaction of the safety certification body (either the Agency or the NSA) and do not lead to an update of the relevant application file. - Residual concerns (Type 3 issues) are not defined and agreed for supervision. <p>2. When acting as safety certification body,</p> <ul style="list-style-type: none"> - The assessment is not based on evidence that the SMS requirements, TSI OPE and relevant notified national rules have been met. It focuses on national rules only. <ul style="list-style-type: none"> - In a case where the application could be rejected or could take more time than the allowed timeframe for assessment to reach a decision, the NSA does not take any contingency measure to manage the process. <p>3. When part of an assessment team, the NSA does not focus on the assessment of the national rules.</p> <p>D. Decision-making</p> <p>The NSA, when acting as the safety certification body,</p> <ul style="list-style-type: none"> - does not issue a decision on whether to issue a single safety certificate based on the conclusions of the completed assessment or does not do it within the required timeframe. - is not clear about any decision made to restrict or reject a safety certificate. - does not inform the applicant about its decisions in good time and when certificate is to be issued with conditions or restrictions of use, it does not give adequate reasons for the decision. In addition, it does not notify the applicant of the procedure to request a review or an appeal against the decision. <p>E. Closing assessment</p> <p>1. The NSA, whether acting as safety certification body, or not,</p> <ul style="list-style-type: none"> - does not record and justify in writing all findings and opinions using OSS. - does not base its decisions whether to accept or reject applications on the evidence provided by the applicant against each of the Requirements set out in Regulation 2018/762 Annex I. <p>2. The NSA, when acting as the safety certification body, does not complete the administrative closure by ensuring that all documents and records are reviewed, organised and archived.</p> <p>F. Specific provisions for the renewal or an update of a single safety certificate</p> <p>1. The NSA, whether safety certification body or not,</p> <ul style="list-style-type: none"> - In the case of a renewal application (received before the expiry date of validity of an existing certificate), does not check the detail of changes to the evidence submitted in the previous application or requires a complete reassessment of the application file. - does not consider results of past supervision activities (as referred in Reg. 2018/761, Art.5) to prioritise or target the relevant SMS requirements and notified national rules upon which to assess the renewal application. - does not take a proportionate approach to the reassessment, based on the nature of the changes proposed. <p>2. The NSA, when acting as the safety certification body, after receiving an application for an update, does not complete the assessment in due time and it extends the validity period of the single safety certificate.</p>
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	<p>3. The NSA does not start the update process for a safety certificate, when the safety certification body receives the notification by an RU of a substantial change proposed to the type, area and extent of operation with the applicant.</p>
<p style="text-align: center;">2 Initialising</p>	<p>A. General</p> <p>1. The NSA, whether safety certification body or not, has a process for the complete activity but it is only partially structured and is not completely auditable. There are occasional checks and reviews but this is not part of a structured and regular process. The NSA does have a process for managing safety assessment against the requirements of the relevant CSM however, it is not structured and there are gaps. Safety Certificates are issued using the OSS but there are nationally imposed requirements in the templates used.</p> <p>2. The NSA has a system for ensuring that staff involved in assessments are competent, but it is incomplete.</p> <p>3. There is an NSA application Guide, but it does not clearly explain the process of safety certification for the cases where the NSA role is more limited because the Agency is the Safety Certification Body. The Guide includes specifications on border stations but the applicable requirements are not clear or are no different to those an applicant would need to apply if they wanted to access to the whole member state.</p> <p>B. Pre-engagement, receipt of the application and initial screen</p> <p>1. Whether acting as safety certification body or not,</p> <ul style="list-style-type: none"> - the NSA process for the scrutiny of Safety Certificate applications is not always completed within the timescale. - the NSA concerned with the intended area of operation does not systematically check that the evidence for the type, extent and intended area of operation is clearly identified. - the NSA sometimes reviews a sufficient sample of the application for its own part, to check that its content is understandable. <p>2. When the NSA is acting as the safety certification body,</p> <ul style="list-style-type: none"> - it generally accepts pre-engagements when requested by the applicant and provides any requested clarification in the context of pre-engagement but there are gaps. - it assigns resources to deliver the assessment but they may not be sufficient or do not have the sufficient level of competence. - it does perform an initial screen to check whether there is the basic information, but this is based on National Rules rather than EU Regulation. <p>3. When the Agency is the safety certification body, the NSA does coordinate with the Agency to decide whether there are areas in which further information is needed. But when further information is necessary, this is not timely managed and exchanges are not straightforward.</p> <p>C. Detailed assessment</p> <p>1. Whether acting as safety certification body or not,</p> <ul style="list-style-type: none"> - The NSA does not always meet the timeframe for taking a decision on issuing the single safety certificate. - It does not assess the applicant’s responses giving little information on whether response is satisfactory or not. - The NSA does request some supplementary information and/or makes some site visits to RUs that are being assessed. But this is not done each time deemed needed.

	<ul style="list-style-type: none"> - The NSA is generally impartial and proportionate and does provide some documented reasons for conclusions reached. The NSA is not very transparent in how it judges the severity of each identified issue. - Type 4 issues are only partially resolved to the satisfaction of the certification body (either the Agency or the NSA) and sometimes lead to an update of the relevant application file. - Residual concerns (Type 3 issues) are only partially / in some cases defined and agreed for supervision. <p>2. When acting as safety certification body,</p> <ul style="list-style-type: none"> - The assessment is based on a confusing mix of evidence that the SMS requirements, TSI OPE and relevant notified national rules have been met. There are significant overlaps between the different legal bases. - The NSA, in a case where the application could be rejected or it will take a longer time than the allowed timeframe for assessment to reach a decision, takes few contingency measures to manage the process. <p>3. When part of an assessment team, the detailed assessment of the application partially uses the SMS and TSI OPE requirements but tends to address this through a focus on specific national rules which duplicate those requirements thereby creating conflicts when the Agency is the safety certification body.</p> <p>D. Decision-making</p> <p>The NSA, when acting as the safety certification body,</p> <ul style="list-style-type: none"> - issues a decision on whether to issue a single safety certificate based on the conclusions of the completed assessment but often not within the required timeframe. - is sometimes not clear about any decisions made to restrict or reject a safety certificate. - sometimes does not inform the applicant about its decisions in good time and when Certificate is to be issued with conditions or restrictions of use it does not give adequate reasons for the decision and does not notify the applicant of the procedure to request a review or an appeal against the decision. <p>E. Closing assessment</p> <p>1. The NSA, whether acting as safety certification body, or not,</p> <ul style="list-style-type: none"> - partially records and justifies in writing findings and judgements using OSS. - sometimes does not base its decisions whether to accept or reject applications on the evidence provided by the applicant against each of the Requirements set out in Regulation 2018/762 Annex I. <p>2. The NSA, when acting as the safety certification body, sometimes does not complete administrative closure by ensuring that all documents and records are reviewed, organised and archived.</p> <p>F. Specific provisions for the renewal or an update of a single safety certificate</p> <p>1. The NSA, whether safety certification body or not,</p> <ul style="list-style-type: none"> - In the case of a renewal application (received before the expiry date of validity of an existing certificate), it partially checks the detail of changes to the evidence submitted in the previous application. The NSA often requires a complete reassessment of the application file for update even though there is no justification for this. - sometimes considers results of past supervision activities (as referred in Regulation 2018/761, Art.5) to prioritise or target the relevant SMS requirements and notified national rules upon which to assess the renewal application.
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	<ul style="list-style-type: none"> - sometimes takes a proportionate approach to the reassessment, based on the nature of the changes proposed. <ol style="list-style-type: none"> 2. The NSA when acting as the safety certification body, after receiving an application for an update completes the assessment and sometimes extends the validity period of the single safety certificate. 3. The NSA sometimes does not start the update process for a safety certificate, when the safety certification body, receives the notification by an RU of a substantial change proposed to the type, area and extent of operation with the applicant.
<p style="text-align: center;">3 Implementing</p>	<p>A. General</p> <ol style="list-style-type: none"> 1. The NSA, whether safety certification body or not, has a process for the complete activity which is structured and auditable. It checks and reviews its own performance as part of a structured and regular review. The NSA has a process for managing the safety assessment process against the Requirements of the relevant CSM which is structured and auditable. Safety Certificates are issued using the OSS and use the EU templates. 2. The NSA has a competence management system which ensures that staff involved in assessments are competent. 3. There is an NSA application Guide which explains clearly the process of safety certification for both the cases where the NSA is the Safety Certification Body and for the cases where its role is more limited because the Agency is the Safety Certification Body. It specifies Border Stations and the requirements which it will apply to those stations within its own territory. <p>B. Pre-engagement, receipt of the application and initial screen</p> <ol style="list-style-type: none"> 1. Whether acting as safety certification body or not, <ul style="list-style-type: none"> - the NSA process for the scrutiny of Safety Certificate applications is completed within the timescale. - The NSA concerned with the intended area of operation checks that the evidence for the type, extent and intended area of operation is clearly identified. - The NSA reviews a sufficient sample of the application for its own part, to check that its content is understandable. 2. When the NSA is acting as safety certification body, <ul style="list-style-type: none"> - it accepts pre-engagements when requested by the applicant and provides any requested clarification in the context of pre-engagement. - it does assign sufficient and competent resources to deliver the assessment process. - it performs an initial screen to check whether there is the basic information. 3. When the Agency is the safety certification body, the NSA does coordinate with the Agency to decide whether there are areas in which, for their respective part, further information is needed. <p>C. Detailed assessment</p> <ol style="list-style-type: none"> 1. Whether acting as safety certification body or not, <ul style="list-style-type: none"> - The NSA meets the timeframe for taking a decision on issuing the single safety certificate. - It assesses the applicant’s responses giving information on whether response is satisfactory or not. - The NSA requests supplementary information and/or makes site visits to RUs that are being assessed as needed.

	<ul style="list-style-type: none"> - The NSA is impartial and proportionate and provides documented reasons for conclusions reached. It is transparent in how it judges the severity of each identified issue. - Type 4 issues are resolved to the satisfaction of the safety certification body (either the Agency or the NSA) and lead to an update of the relevant application file. - Residual concerns (Type 3 issues) are defined and agreed for supervision. <p>2. When acting as safety certification body,</p> <ul style="list-style-type: none"> - The detailed assessment of the application uses the SMS and TSI OPE requirements as well as National Rules with the correct balance between them. In case of identified issues these are communicated to the appropriate regulatory body. - The NSA, in a case where the application could be rejected or it will take a longer time than the allowed timeframe for assessment to reach a decision, takes contingency measures to manage the process. <p>3. When part of an assessment team, the NSA focuses on the assessment of the national rules. In case of identified issues these are communicated to the appropriate regulatory body.</p> <p>D. Decision-making</p> <p>The NSA, when acting as safety certification body,</p> <ul style="list-style-type: none"> - issues a decision on whether to issue a single safety certificate based on the conclusions of the completed assessment in the required timeframe. - is clear about any decisions made to restrict or reject a safety certificate. informs the applicant about its decisions in good time and when Certificate is to be issued with conditions or restrictions of use it gives adequate reasons for the decision and notifies the applicant of the procedure to request a review or an appeal against the decision. <p>E. Closing assessment</p> <p>1. The NSA, whether acting as safety certification body, or not,</p> <ul style="list-style-type: none"> - records and justifies in writing findings and judgements using OSS. - bases its decisions whether to accept or reject applications on the evidence provided by the applicant against each of the Requirements set out in Regulation 2018/762 Annex I. <p>2. The NSA, when acting as the safety certification body, completes administrative closure by ensuring that all documents and records are reviewed, organised and archived.</p> <p>F. Specific provisions for the renewal or an update of a single safety certificate</p> <p>1. The NSA, whether safety certification body or not,</p> <ul style="list-style-type: none"> - In the case of a renewal application (received before the expiry date of validity of an existing certificate), checks the detail of changes to the evidence submitted in the previous application. - considers results of past supervision activities (as referred in Regulation 2018/761, Art.5) to prioritise or target the relevant SMS requirements and notified national rules upon which to assess the renewal application - takes a proportionate approach to the reassessment, based on the nature of the changes proposed. <p>2. The NSA when acting as the safety certification body, after receiving an application for an update completes the assessment.</p> <p>3. The NSA starts the update process for a safety certificate, when the safety certification body, receives the notification by an RU of a substantial change proposed to the type, area and extent of operation.</p>
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<p>4 Managing</p>	<p>A. General As for level 3, plus:</p> <ol style="list-style-type: none"> 1. The NSA SSC process, whether safety certification body or not, is structured and auditable and reviewed regularly. The NSA process for managing the safety assessment process against the Requirements of the relevant CSM is structured and auditable and reviewed regularly. 2. The NSA competence management system is regularly reviewed to ensure it remains up to date. 3. The NSA application Guide including Border Stations requirements is regularly reviewed to ensure that the requirements remain current. <p>B. Pre-engagement, receipt of the application and initial screen As for level 3, plus:</p> <ol style="list-style-type: none"> 1. Whether acting as safety certification body or not, <ul style="list-style-type: none"> - The NSA actively monitors progress and makes sure that all applications are managed within the correct timescales. - The NSA concerned with the intended area of operation pro-actively engages with the applicant to check that the evidence for the type, extent and intended area of operation is clearly identified. - The NSA reviews a sufficient sample of the application for its own part, to check that its content is understandable and meets the standard to allow it to proceed to the next stage. 2. When the NSA is acting as the safety certification body, <ul style="list-style-type: none"> - it promotes engagement with the applicant to make sure that the process runs smoothly and provides any requested clarification in the context of pre-engagement. - it actively works to make sure to maintain needed staff and their competence. - it performs an initial screen raising appropriate issues of concern. 3. When the Agency is the safety certification body, the NSA coordinates with the Agency in a timely, effective and efficient way. <p>C. Detailed assessment As for level 3, plus:</p> <ol style="list-style-type: none"> 1. Whether acting as safety certification body or not, <ul style="list-style-type: none"> - The NSA regularly reviews the assessments to ensure that the timeframes will always be met. - The NSA regularly reviews the dialogue with its applicants to ensure that there is a proper understanding in the sector as to what is required. - The NSA regularly reviews its decision-making process (impartial, proportionate, documented reasons, transparency). - Lessons from the resolution of Type 4 issues are learnt and communicated to assessors. - Lessons are learnt as to the most appropriate way to structure type 3 issues for ongoing supervision. 2. When acting as safety certification body, <ul style="list-style-type: none"> - The detailed assessment of the application uses the SMS and TSI OPE requirements as well as National Rules with the correct balance between them. The NSA is reviewing the information regularly and updating its assessors accordingly. In case of identified issues these are communicated to the appropriate regulatory body and followed up. - When the NSA takes appropriate contingency measures to manage the process, these are regularly reviewed and lessons are learnt.
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	<p>3. When part of an assessment team, the NSA focuses on the assessment of the national rules and adequately coordinates with the Agency as safety certification body. In case of identified issues these are communicated to the appropriate regulatory body and followed up.</p> <p>D. Decision-making As for level 3, plus: The NSA, when acting as the safety certification body, regularly reviews</p> <ul style="list-style-type: none"> - progress with assessments to make sure that it meets the required timeframes. - decisions on restrictions and revocations to make sure that they are consistent and decisions are open transparent to the applicant and applied in a non-discriminatory way. - its procedures when the certificate is to be issued with conditions or restrictions of use. <p>E. Closing assessment As for level 3, plus:</p> <ol style="list-style-type: none"> 1. The NSA, whether acting as safety certification body, or not, regularly reviews <ul style="list-style-type: none"> - assessments findings and opinions to ensure that there is consistency of approach and findings within the NSA. - decisions whether to accept or reject applications to ensure that they are consistent and well managed. 2. The NSA, when acting as the safety certification body, regularly reviews and updates its procedure for administrative closure. <p>F. Specific provisions for the renewal or an update of a single safety certificate As for level 3, plus:</p> <ol style="list-style-type: none"> 1. The NSA, whether safety certification body or not, <ul style="list-style-type: none"> - In the case of a renewal application (received before the expiry date of validity of an existing certificate), systematically checks the detail of changes to the evidence submitted in the previous application along with any outstanding Type 2 or Type 3 issues from the previous application to make sure that these have been properly covered. - systematically considers results of past supervision activities upon which to assess the renewal application and takes these fully into account when deciding on the outcome of the assessment. - takes a proportionate approach to the reassessment, based on the nature of the changes proposed. 2. The NSA when acting as the safety certification body, after receiving an application for an update completes the assessment in a fair and proportionate manner and reviews such applications on a regular basis to ensure consistency of approach. 3. The NSA starts the update process for a safety certificate, when the safety certification body, receives the notification by an RU of a substantial change proposed to the type, area and extent of operation and coordinates with the safety certification body.
	<p>A. General As for level 4, plus:</p> <ol style="list-style-type: none"> 1. To improve its SSC processes and increase its efficiency, the NSA is looking to engage with other NSAs and authorities. 2. The NSA is looking to engage with other bodies to improve the CMS and learn from best practice.

<p style="text-align: center;">5</p> <p style="text-align: center;">Improving</p>	<p>3. To improve its application Guide including Border Stations requirements, the NSA engages with other NSAs and relevant organisations to improve the information and the presentation of it to applicants.</p> <p>B. Pre-engagement, receipt of the application and initial screen</p> <p>As for level 4, plus:</p> <ol style="list-style-type: none"> 1. Whether acting as safety certification body or not, <ul style="list-style-type: none"> - The NSA is actively monitoring all SSC applications and communicates with other NSAs to improve the efficiency of the process. - The NSA concerned with the intended area of operation pro-actively engages with the applicant to check that the evidence for the type, extent and intended area of operation is clearly identified. The NSA seeks to provide accurate information in its Guide on how applicants should present information and regularly reviews this. - The NSA cross checks across all applications and with others to ensure that its decisions are consistent. 2. When the NSA is acting as the safety certification body, <ul style="list-style-type: none"> - The NSA reviews the pre-engagement process regularly and engages with others e.g. NSAs and ERA to make sure that they follow best practices. - The NSA actively pursues best practices in competence management. - The NSA actively seeks to learn from others how the initial screen process can be improved. 3. When the Agency is the safety certification body, the NSA is proactive in its coordination with the Agency to decide whether there are areas in which, for their respective part, further information is necessary, and this is done in a timely and effective way. <p>C. Detailed assessment</p> <p>As for level 4, plus:</p> <ol style="list-style-type: none"> 1. Whether acting as safety certification body or not, <ul style="list-style-type: none"> - The NSA proactively reviews assessments and improve its SSC process to ensure that the timeframes will always be met. - The NSA regularly reviews the dialogue with its applicants to ensure that there is a proper understanding in the sector as to what is required. The NSA acts proactively to inform the sector of its findings. - The NSA continuously seeks to improve its decision-making process (impartial, proportionate, documented reasons, transparency) and seeks for stakeholders feedbacks and performs benchmarking with other NSAs. - The NSA proactively seeks lessons to be learnt from the resolution of Type 4 issues are and communicates to assessors. - Lessons are learnt as to the most appropriate way to structure type 3 issues for ongoing supervision by both the NSA in question and other NSAs. 2. When acting as safety certification body, <ul style="list-style-type: none"> - The NSA actively and regularly monitors the detailed assessment against the SMS, TSI OPE and National Rules and updating as necessary. Possible issues are proactively checked and the relevant regulatory body is informed. - When the NSA takes appropriate contingency measures to manage the process, these are proactively reviewed and lessons are learnt and communicated to other authorities as appropriate. 3. When part of an assessment team, the NSA focuses on the assessment of the national rules and proactively coordinates with the Agency as safety certification
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	<p>body. Possible issues are proactively checked and the relevant regulatory body is informed.</p> <p>D. Decision-making As for level 4, plus: The NSA, when acting as the safety certification body,</p> <ul style="list-style-type: none"> - proactively reviews progress with assessments to make sure that it meets the required timeframes. - proactively reviews decisions on restrictions and revocations to make sure that they are consistent, open transparent to the applicant and applied in a non-discriminatory way. - proactively reviews its procedures to in case the certificate is to be issued with conditions or restrictions of use. <p>E. Closing assessment As for level 4, plus:</p> <ol style="list-style-type: none"> 1. The NSA, whether acting as safety certification body, or not, proactively reviews <ul style="list-style-type: none"> - assessments findings and judgements to ensure that there is consistency of approach and findings within the NSA. The NSA consult with other NSAs to ensure that similar decisions are made for cross border companies. - decisions whether to accept or reject applications to ensure that they are consistent and well managed. 2. The NSA, when acting as the safety certification body, proactively and systematically reviews and updates its procedure for administrative closure to ensure that they remain fit for purpose. <p>F. Specific provisions for the renewal or an update of a single safety certificate As for level 4, plus:</p> <ol style="list-style-type: none"> 1. The NSA, whether safety certification body or not, <ul style="list-style-type: none"> - In the case of a renewal application (received before the expiry date of validity of an existing certificate), pro-actively checks the detail of changes to the evidence submitted in the previous application along with any outstanding Type 2 or Type 3 issues from the previous application to make sure that these have been properly covered. - proactively considers results of past supervision activities including where relevant the results of supervision by other NSAs upon which to assess the renewal application and takes these fully into account when deciding on the outcome of the assessment. 2. The NSA when acting as the safety certification body, after receiving an application for an update completes the assessment in a fair and proportionate manner and proactively reviews such applications on a regular basis to ensure consistency of approach. 3. The NSA starts the update process for a safety certificate, when the safety certification body, receives the notification by an RU of a substantial change proposed to the type, area and extent of operation and proactively coordinates with the safety certification body.
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4. Safety authorisation

Sub-element 4: Safety authorisation	
<p>1 Ad hoc</p>	<p>A. General</p> <ol style="list-style-type: none"> 1. The NSA does not have a structured and auditable process for the complete activity and it does not check and review its performance. There is no process and no established internal arrangements or procedures for managing the safety authorisation process against the Requirements of the relevant CSM. Safety Authorisations are not issued using the recommended standard model for safety authorisation or are not issued at all. 2. The NSA does not have a system for ensuring that staff involved in safety authorisation have the required competences. 3. There is no NSA application Guide or there is a guide but it does not explain clearly the process of safety authorisation. Where there is cross border infrastructure, the NSA does not cooperate with other NSAs to issue the SA and therefore there is no requirement in the guide. <p>B. Pre-engagement, receipt of the application and initial screen</p> <ol style="list-style-type: none"> 1. The process for the scrutiny of Safety authorisation applications is not able to be completed within the timescale set out in Commission Recommendation 2019/780. 2. The NSA does not: <ul style="list-style-type: none"> - accept pre-engagements when requested by the applicant or provide any requested clarification in the context of pre-engagement. - assign competent resources to deliver the assessment process - perform a proper initial screen to check whether the basic information is there. 3. When assessing the IM’s capacity to operate trains, infrastructure inspection vehicles, on-track machines or other special vehicles, including the use of contractors where relevant, the NSA refers to National Rules rather than Regulation 2018/762, in particular its points 1, 5.1, 5.2 and 5.5. 4. The NSA does not review a sufficient sample of the application for its own part, to check that its content is understandable. <p>C. Detailed assessment</p> <ol style="list-style-type: none"> 1. The assessment is not based on evidence that the SMS requirements and relevant notified national rules have been met. It focuses on national rules only. 2. The timeframe for taking a decision on issuing the safety authorisation is not met by the NSA. 3. The NSA does not request supplementary information or make site visits to the IM under assessment. 4. The NSA does not assess the applicant’s responses giving no information on whether response is satisfactory or not. 5. The NSA is not impartial and proportionate and does not provide documented reasons for conclusions reached. It is not transparent in how it judges the severity of each identified issue. 6. Type 4 issues are not resolved and do not lead to an update of the relevant application file. 7. Residual concerns (Type 3 issues) are not clearly defined and agreed for supervision.

	<p>8. The NSA, in a case where the application could be rejected or it will take a longer time than the allowed timeframe for assessment to reach a decision, does not take any contingency measures to manage the process.</p> <p>D. Decision-making</p> <ol style="list-style-type: none"> 1. The NSA, based on the conclusions of the completed assessment, does not issue a decision on whether to issue a safety authorisation or not within the required timeframe. 2. The NSA is not clear about any decision made to restrict or reject a safety authorisation. 3. The NSA does not inform the applicant about its decisions in due time. Where the Safety Authorisation is to be issued with conditions or restrictions of use, it does not inform the applicant in due time and does not give adequate reasons for the decision and does not notify the applicant of the procedure to request a review or an appeal against the decision. <p>E. Closing assessment</p> <ol style="list-style-type: none"> 1. The NSA does not record and justify in writing all findings and judgements. 2. Decisions on whether to accept or reject applications are not based on the evidence provided by the applicant against each of the Requirements set out in Commission Recommendation 2019/780. 3. The NSA does not complete the administrative closure by ensuring that all documents and records are reviewed, organised and archived. <p>F. Specific provisions for the renewal or an update of a safety authorisation</p> <ol style="list-style-type: none"> 1. In the case of a renewal application (received before the expiry date of validity of an existing safety authorisation), the NSA does not check the detail of changes to the evidence submitted in the previous application or requires a complete reassessment of the application file. 2. The NSA does not consider results of past supervision activities (as referred in Regulation 2018/761, Art.5) to prioritise or target the relevant SMS requirements and notified national rules upon which to assess the renewal application. 3. The NSA does not take a proportionate approach to the reassessment, based on the nature of the changes proposed. 4. The NSA does not start the update process for a safety authorisation, when it receives the notification by an IM of a substantial change proposed to the character and extent of operation with the applicant. 5. The NSA receives the notification by an IM of a substantial change proposed to the infrastructure, the signalling, any energy supply used in connection with the infrastructure, signalling or energy supply in accordance with Art 12(2) of RSD 2016/798 but does not require the update of the safety authorisation. 6. The NSA after receiving an application for an update completes the assessment and extends the validity period of the safety authorisation.
<p style="text-align: center;">2</p> <p>Initialising</p>	<p>A. General</p> <ol style="list-style-type: none"> 1. The NSA has a process for the complete activity but it is only partially structured and is not completely auditable. There are occasional checks and reviews but this is not part of a structured and regular process. The NSA does have a process for managing safety authorisation assessment against the requirements of the relevant CSM however, it is not structured and there are gaps. 2. Safety Authorisations are issued using nationally imposed templates. The NSA has a system for ensuring that staff involved in assessments are competent, but it is incomplete.

	<p>3. There is an NSA application Guide but it does not cover all aspects of the process. It specifies some cross-border infrastructure but the requirements which apply are not clear.</p> <p>B. Pre-engagement, receipt of the application and initial screen</p> <p>1. The process for the scrutiny of safety authorisation applications is not always completed within the timescale set out in Commission Recommendation 2019/780.</p> <p>2. The NSA:</p> <ul style="list-style-type: none"> - generally accepts pre-engagements when requested by the applicant and provides any requested clarification in the context of pre-engagement but there are gaps. - does assign resources to deliver the assessment process, but they may not be sufficient or do not have the sufficient level of competence - does perform an initial screen to check whether there is the basic information, but this is based on National Rules rather than EU Regulation. <p>3. The NSA does not check that the evidence for the character and extent of the operation is clearly identified.</p> <p>4. The NSA sometimes reviews a sufficient sample of the application for its own part, to check that its content is understandable.</p> <p>C. Detailed assessment</p> <p>1. The detailed assessment of the application partially uses the SMS requirements but tends to address this through a focus on specific national rules which duplicate those requirements. The assessment is based on a confusing mix of evidence that the SMS requirements, and relevant notified national rules have been met. There are significant overlaps between the two.</p> <p>2. The timeframe for taking a decision on issuing the safety authorisation is sometimes not met by the NSA.</p> <p>3. The NSA does request some supplementary information and/or makes some site visits to IMs that are being assessed. But this is not done each time deemed needed.</p> <p>4. The NSA does not assess the applicant's responses giving little information on whether response is satisfactory or not.</p> <p>5. The NSA is generally impartial and proportionate and does provide some documented reasons for conclusions reached. The NSA is not very transparent in how it judges the severity of each identified issue.</p> <p>6. Type 4 issues are only partially resolved to the satisfaction of the NSA and sometimes lead to an update of the relevant application file.</p> <p>7. Residual concerns (Type 3 issues) are only partially defined and agreed for supervision.</p> <p>8. The NSA in a case where the application could be rejected or it will take a longer time than the allowed timeframe for assessment to reach a decision, takes few contingency measures to manage the process.</p> <p>D. Decision-making</p> <p>1. The NSA, based on the conclusions of the completed assessment issues a decision on whether to issue a safety authorisation but often not within the required timeframe.</p> <p>2. The NSA is sometimes not clear about any decisions made to restrict or reject a safety certificate.</p> <p>3. The sometimes does not inform the applicant about its decisions in good time. Where the Certificate is to be issued with conditions or restrictions of use, the NSA sometimes does not inform the applicant in good time and does not give</p>
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	<p>adequate reasons for the decision and does not notify the applicant of the procedure to request a review or an appeal against the decision.</p> <p>E. Closing assessment</p> <ol style="list-style-type: none"> 1. The NSA partially records and justifies in writing findings and judgements. 2. Decisions on whether to accept or reject applications are sometimes not based on the evidence provided by the applicant against each of the Requirements set out in Reg 2018/762 Annex II. 3. The NSA sometimes does not complete administrative closure by ensuring that all documents and records are reviewed, organised and archived. <p>F. Specific provisions for the renewal or an update of a safety authorisation</p> <ol style="list-style-type: none"> 1. In the case of a renewal application (received before the expiry date of validity of an existing safety authorisation), the NSA partially checks the detail of changes to the evidence submitted in the previous application. The NSA often requires a complete reassessment of the application file for an update even though there is no justification for this. 2. The NSA does not systematically consider results of past supervision activities upon which to assess the renewal application. 3. The NSA sometimes does not take a proportionate approach to the reassessment, based on the nature of the changes proposed. 4. The NSA receives the notification by an IM of a substantial change proposed to the infrastructure, the signalling, any energy supply used in connection with the infrastructure, signalling or energy supply in accordance with Art 12(2) of RSD 2016/798 but does not always require the update of the safety authorisation. 5. The NSA sometimes does not start the update process for a safety authorisation when it receives the notification by an IM of a substantial change proposed to the character and extent of operation 6. The NSA after receiving an application for an update completes the assessment and sometimes extends the validity period of the safety authorisation.
<p style="text-align: center;">3 Implementing</p>	<p>A. General</p> <ol style="list-style-type: none"> 1. The NSA has a process for the complete activity which is structured and auditable. It checks and reviews its own performance as part of a structured and regular review. <p>NSA has a process for managing the safety authorisation process against the Requirements of the relevant CSM which is structured and auditable.</p> <ol style="list-style-type: none"> 2. The NSA has a competence management system which ensures that staff involved in authorisation are competent. 3. There is an NSA application Guide which clearly explains the process of safety authorisation. It specifies cross border infrastructure and the requirements which apply within its own territory. <p>B. Pre-engagement, receipt of the application and initial screen</p> <ol style="list-style-type: none"> 1. The process for the scrutiny of safety authorisation applications is completed within the timescale set out in Commission Recommendation 2019/780. 2. The NSA: <ul style="list-style-type: none"> - accepts pre-engagements when requested by the applicant and provides any requested clarification in the context of pre-engagement. - assigns sufficient and competent resources to deliver the assessment process. - it performs an initial screen to check whether there is the basic information.

	<p>3. The NSA checks that the evidence for the character and extent of operation is clearly identified.</p> <p>4. The NSA reviews a sufficient sample of the application for its own part, to check that its content is understandable.</p> <p>C. Detailed assessment</p> <p>1. The assessment is based on a mix of evidence that the SMS requirements, TSI OPE and relevant notified national rules have been met. The assessment uses the SMS requirements as well as National Rules with the correct balance between them. In case of identified issues these are communicated to the appropriate regulatory body.</p> <p>2. The timeframe for taking a decision on issuing the safety authorisation is met by the NSA.</p> <p>3. The NSA does request supplementary information and/or makes site visits to IMs that under assessment.</p> <p>4. The NSA assesses the applicant’s responses giving information on whether response is satisfactory or not.</p> <p>5. The NSA is impartial and proportionate and provides some documented reasons for conclusions reached. It is transparent in how it judges the severity of each identified issue.</p> <p>6. Type 4 issues are resolved to the satisfaction the NSA and lead to an update of the relevant application file.</p> <p>7. Residual concerns (Type 3 issues) are defined and agreed for supervision.</p> <p>8. The NSA in a case where the application could be rejected or it will take a longer time than the allowed timeframe for assessment to reach a decision, takes contingency measures to manage the process.</p> <p>D. Decision-making</p> <p>1. The NSA based on the conclusions of the completed assessment issues a decision on whether to issue a safety authorisation within the required timeframe.</p> <p>2. The NSA is clear about any decisions made to restrict or reject a safety authorisation.</p> <p>3. The NSA does inform the applicant about its decisions in good time. Where the Safety Authorisation is to be issued with conditions or restrictions of use, the NSA informs the applicant in good time and gives adequate reasons for the decision and notifies the applicant of the procedure to request a review or an appeal against the decision.</p> <p>E. Closing assessment</p> <p>1. The NSA records and justifies in writing findings and judgements.</p> <p>2. Decisions on whether to accept or reject applications are based on the evidence provided by the applicant against each of the Requirements set out in Reg 2018/762 Annex I.</p> <p>3. The NSA completes administrative closure by ensuring that all documents and records are reviewed, organised and archived.</p> <p>F. Specific provisions for the renewal or an update of a safety authorisation</p> <p>1. In the case of a renewal application (received before the expiry date of validity of an existing safety authorisation), the NSA checks the detail of changes to the evidence submitted in the previous application.</p> <p>2. The NSA does systematically consider results of past supervision activities upon which to assess the renewal application.</p> <p>3. The NSA takes a proportionate approach to the reassessment, based on the nature of the changes proposed.</p>
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	<p>4. The NSA starts the update process for a safety authorisation, when it receives the notification by an IM of a substantial change proposed to the character and extent of operation</p> <p>5. The NSA after receiving an application for an update completes the assessment.</p>
<p style="text-align: center;">4 Managing</p>	<p>A. General As for level 3, plus:</p> <ol style="list-style-type: none"> 1. The NSA SA process is reviewed regularly. <p>The NSA process for managing the safety assessment process against the Requirements of the relevant CSM is structured and auditable and reviewed regularly.</p> <ol style="list-style-type: none"> 2. The NSA competence management system is regularly reviewed to ensure it remains up to date. 3. There is an NSA application Guide which clearly explains the process of safety authorisation. It specifies in its Guide cross border infrastructure and the requirements which it will apply within its own territory. The Guide and the cross-border infrastructure arrangements and requirements are regularly reviewed to ensure that they remain current. <p>B. Pre-engagement, receipt of the application and initial screen As for level 3, plus:</p> <ol style="list-style-type: none"> 1. The NSA actively monitors progress and makes sure that all applications are managed within the correct timescales. 2. The NSA: <ul style="list-style-type: none"> - promotes engagement with the applicant to make sure that the process runs smoothly and provides any requested clarification in the context of pre-engagement. - actively works to make sure to maintain needed staff and their competence. - performs an initial screen raising appropriate issues of concern. 3. The NSA engages with the applicant to check that the evidence for the character and extent of the operation is clearly identified. 4. The NSA reviews a sufficient sample of the application for its own part, to check that its content is understandable and meets the standard to allow it to proceed to the next stage. <p>C. Detailed assessment As for level 3, plus:</p> <ol style="list-style-type: none"> 1. The detailed assessment of the application uses the SMS requirements as well as National Rules with the correct balance between them. The NSA is reviewing the information regularly and updating its assessors accordingly. In case of identified issues these are communicated to the appropriate regulatory body and followed up. 2. The assessments are regularly reviewed to ensure that the timeframes will always be met. 3. The NSA regularly reviews the dialogue with its applicants to ensure that there is a proper understanding in the sector as to what is required. 4. The NSA regularly reviews its decision-making process (impartial, proportionate, documented reasons, transparency). 5. Lessons from the resolution of Type 4 issues are learnt and communicated to assessors. 6. Lessons are learnt as to the most appropriate way to structure Residual concerns (Type 3 issues) for ongoing supervision.

	<p>7. When the NSA takes appropriate contingency measures to manage the process, these are regularly reviewed and lessons are learnt.</p> <p>D. Decision-making As for level 3, plus: The NSA regularly reviews:</p> <ol style="list-style-type: none"> 1. progress with assessments to make sure that it meets the required timeframes. 2. decisions on restrictions and revocations to make sure that they are consistent and decisions are transparent to the applicant. 3. its procedures when the certificate is to be issued with conditions or restrictions of use. <p>E. Closing assessment As for level 3, plus:</p> <ol style="list-style-type: none"> 1. The NSA regularly reviews findings and judgements to ensure that there is consistency of approach and findings within the NSA. 2. The NSA regularly reviews decisions whether to accept or reject applications to ensure that they are consistent and well managed. 3. The NSA regularly reviews and updates its procedures to ensure that they remain fit for purpose. <p>F. Specific provisions for the renewal or an update of a safety authorisation As for level 3, plus:</p> <ol style="list-style-type: none"> 1. In the case of a renewal application (received before the expiry date of validity of an existing authorisation), systematically checks the detail of changes to the evidence submitted in the previous application along with any outstanding type 2 or Type 3 issues from the previous application to make sure that these have been properly covered. 2. The NSA systematically considers results of past supervision activities upon which to assess the renewal application and takes these fully into account when deciding on the outcome of the assessment. 3. The NSA immediately starts the update process for a safety authorisation, when it receives the notification by an IM of a substantial change proposed to the type, area and extent of operation. 4. The NSA after receiving an application for an update completes the assessment in a fair and proportionate manner and reviews such applications on a regular basis to ensure consistency of approach.
<p style="text-align: center;">5 Improving</p>	<p>A. General As for level 4, plus:</p> <ol style="list-style-type: none"> 1. To improve its SA processes and increase its efficiency, the NSA is looking to engage with other NSAs and authorities. 2. The NSA is looking to engage with other bodies to improve the CMS and learn from best practice. 3. To improve its application Guide including cross border infrastructure and the requirements, the NSA engages with other NSAs and relevant organisations to improve the information and the presentation of it to applicants. <p>B. Pre-engagement, receipt of the application and initial screen As for level 4, plus:</p> <ol style="list-style-type: none"> 1. The NSA is actively monitoring all SA applications and communicates with other NSAs to improve the efficiency of the process. 2. The NSA: <ul style="list-style-type: none"> - reviews the process regularly and engages with others e.g. NSAs and ERA to make sure that they follow best practice.

	<ul style="list-style-type: none"> - actively pursues best practice in competence management. - actively seeks to learn from others how the process can be improved. <p>3. The NSA pro-actively engages with the applicant to check that the evidence for the character and extent of operation is clearly identified. The NSA seeks to provide accurate information in its Guide on how applicants should present information and regularly reviews this.</p> <p>4. The NSA cross checks across all applications and with others to ensure that its decisions are consistent.</p> <p>C. Detailed assessment As for level 4, plus:</p> <ol style="list-style-type: none"> 1. The detailed assessment of the application uses the SMS requirements as well as National Rules with the correct balance between them. The NSA is actively monitoring the information regularly and updating as necessary. 2. The authorisation is clearly based on evidence that the SMS requirements, and relevant notified national rules have been met. The balance of the assessment requirements is regularly reviewed and any issues communicated to the appropriate regulatory body. 3. Type 4 issues are always resolved to the satisfaction of the NSA and lead to an update of the relevant application file. The NSA proactively seeks lessons to be learnt from the resolution of Type 4 issues and communicates to assessors. 4. Residual concerns (type 3 issues) are clearly defined and agreed for supervision. Lessons are learnt as to the most appropriate way to structure such issues for ongoing supervision by both the NSA in question and other NSAs. 5. The timeframe for taking a decision on issuing the safety authorisation is always met by the NSA. The assessments are regularly reviewed to ensure that the time frames will always be met. 6. The NSA acting as the safety authorisation body or not assesses the applicant’s responses giving information on whether response is satisfactory or not. The NSA regularly reviews the dialogue with its applicants to ensure that there is a proper understanding in the sector as to what is required. The NSA acts proactively to inform the sector of its findings. 7. The NSA in a case where the application could be rejected or it will take a longer time than the allowed timeframe for assessment to reach a decision, takes appropriate contingency measures to manage the process and these are proactively reviewed and lessons are learnt and communicated to other authorities as appropriate. 8. When the NSA takes appropriate contingency measures to manage the process, these are proactively reviewed and lessons are learnt and communicated to other authorities as appropriate. <p>D. Decision-making As for level 4, plus: The NSA</p> <ol style="list-style-type: none"> 1. proactively reviews progress with assessments to make sure that it meets the required timeframes. 2. proactively reviews decisions on restrictions and revocations to make sure that they are consistent. 3. proactively reviews its procedures to in case the authorisation is to be issued with conditions or restrictions of use. <p>E. Closing assessment As for level 4, plus:</p>
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	<ol style="list-style-type: none"> 1. The NSA proactively reviews assessments to ensure that there is consistency of approach and findings within the NSA. The NSA consult with other NSAs to ensure that similar decisions are made for cross border infrastructures. 2. The NSA proactively reviews decisions whether to accept or reject applications to ensure that they are consistent and well managed. 3. The NSA proactively and systematically reviews and updates its procedure for administrative closure to ensure that they remain fit for purpose. <p>F. Specific provisions for the renewal or an update of a safety authorisation</p> <p>As for level 4, plus:</p> <ol style="list-style-type: none"> 1. In the case of a renewal application (received before the expiry date of validity of an existing authorisation), proactively checks the detail of changes to the evidence submitted in the previous application along with any outstanding Type 2 or Type 3 issues from the previous application to make sure that these have been properly covered. 2. The NSA proactively considers results of past supervision activities upon which to assess the renewal application and takes these fully into account when deciding on the outcome of the assessment. 3. The NSA after receiving an application for an update completes the assessment in a fair and proportionate manner and proactively reviews such applications on a regular basis to ensure consistency of approach.
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5. Authorisation for the placing in service of fixed installations

Sub-element 5: Authorisation for the placing in service of fixed installations	
<p>1 Ad hoc</p>	<p>A. General</p> <ol style="list-style-type: none"> 1. The NSA does not issue authorisation for placing in service (APS) of fixed installations before those subsystems are allowed to be placed in service. 2. The NSA does not have the necessary organisational capacity (resources, competence, processes, procedures etc.) to perform the task to issue APS of fixed installations. 3. The NSA does not provide to the applicants, free of charge, an application guidance document that contains detailed guidance on how to obtain APS of fixed installations including <ul style="list-style-type: none"> - a description and explanation of the requirements for APS for fixed installations; and - a list of the required documents to be provided by the applicant to the NSA <p>B. Processing the application</p> <ol style="list-style-type: none"> 1. The NSA does not process the applications for APS of fixed installations in accordance with the application guidance document provided to the applicants. 2. The NSA does not check before issuing APS for fixed installations that the file provided by the applicant provides documentary evidence of: <ul style="list-style-type: none"> - EC Declarations of verification (ECDofV) for the subsystems; - Technical compatibility of the subsystem with the system they are being integrated into on the basis of TSIs, national rules and registers; - Safe integration of the subsystems on the basis of TSIs, national rules and CSMs; and - For CCS subsystems including trackside ERTMS equipment the positive decision of the Agency. 3. The NSA does not inform the applicant within one month of the receipt of the application that the file is complete or asks for relevant supplementary information. 4. The NSA does not verify the completeness, relevance and consistency of the file and when applicable the compliance with the positive decision issued by the Agency for trackside ERTMS equipment. 5. In processing the APS application, the NSA does not take into account any decision of non application of TSI granted according to Art 7 of Directive (EU) 2016/797. 6. The NSA does not issues the APS for fixed installations or informs the applicant of its negative decision within a pre-determined time that does not exceed 4 months from receipt of all relevant information. <p>C. Renewal/upgrading</p> <ol style="list-style-type: none"> 1. The NSA does not process the file for renewal or upgrading of fixed installations in accordance with the application guidance document provided to the applicants. 2. The NSA does not inform the applicant within one month of the receipt of the file that it is complete and does not ask for relevant supplementary information. 3. In case of ERTMS trackside equipment, the NSA does not cooperate with the Agency when examining the file. 4. The criteria applied by the NSA to evaluate if a new authorisation is required, or not, is not on the basis of if: <ul style="list-style-type: none"> - The overall safety level may be adversely affected;

	<ul style="list-style-type: none"> - It is required by the national implementation plan; and - Changes are made to the values of the parameters on the basis the APS was issued. <p>5. The NSA does not take the decision that a new authorisation is required or not within a pre-determined time that does not exceed 4 months from receipt of all relevant information.</p> <p>D. Decision making</p> <ol style="list-style-type: none"> 1. The decision-making criteria described to the applicant in the application guidance document are not applied by the NSA. 2. The issued decision is not duly substantiated by the NSA. 3. The NSA does not conduct an active exchange of views and experience with other NSAs in order to harmonise their decision-making criteria. 4. The NSA does not check that ERADIS has been updated as appropriate before delivering the APS for fixed installations. <p>E. Review and appeal</p> <ol style="list-style-type: none"> 1. The decisions for APS of fixed subsystems are not subject to judicial review. 2. The NSA does not review its decisions for APS of fixed subsystems and confirms or reverses its decision within 2 months from receipt of the applicants request. <p>F. Link between supervision and APS of fixed installations</p> <ol style="list-style-type: none"> 1. The NSA does not supervise that the fixed installation subsystems are in compliance with the essential requirements. 2. The NSA does not ensure that there is a link between APS of fixed installations and supervision in order to transfer relevant information.
<p style="text-align: center;">2 Initialising</p>	<p>A. General</p> <ol style="list-style-type: none"> 1. The NSA does not systematically issue authorisation for placing in service (APS) of fixed installations before those subsystems are allowed to be placed in service. 2. The NSA is in some case does not have sufficient organisational capacity (resources, competence, processes, procedures etc.) to perform the task to issue APS of fixed installations. 3. The NSA does not provide to the applicants, free of charge, a complete application guidance document that contains detailed guidance on how to obtain APS of fixed installations including <ul style="list-style-type: none"> - A description and explanation of the requirements for APS for fixed installations; and - A list of the required documents to be provided by the applicant to the NSA - The Guidance may be incomplete or with errors. <p>B. Processing the application</p> <ol style="list-style-type: none"> 1. The NSA processes the applications for APS of fixed installations in accordance with the application guidance document provided to the applicants but not systematically. 2. The NSA does not systematically check before issuing APS for fixed installations that the file provided by the applicant provides documentary evidence of: <ul style="list-style-type: none"> - EC Declarations of verification (ECDofV) for the subsystems; - Technical compatibility of the subsystem with the system they are being integrated into on the basis of TSIs, national rules and registers; - Safe integration of the subsystems on the basis of TSIs, national rules and CSMs; and - For CCS subsystems including trackside ERTMS equipment the positive decision of the Agency.

	<ol style="list-style-type: none"> 1. The NSA does not systematically inform the applicant within one month of the receipt of the application that the file is complete or asks for relevant supplementary information. 2. The NSA does not systematically verify the completeness, relevance and consistency of the file and when applicable the compliance with the positive decision issued by the Agency for trackside ERTMS equipment. 3. In processing the APS application, the NSA does not take into account any decision of non application of TSI granted according to Art 7 of Directive (EU) 2016/797. 4. The NSA does not issue the APS for fixed installations or informs the applicant of its negative decision within a pre-determined time that does not exceed 4 months from receipt of all relevant information. <p>C. Renewal/upgrading</p> <ol style="list-style-type: none"> 1. The NSA does not systematically process the file for renewal or upgrading of fixed installations in accordance with the application guidance document provided to the applicants. 2. The NSA does not systematically inform the applicant within one month of the receipt of the file that it is complete and does not systematically ask for relevant supplementary information. 2. In case of ERTMS trackside equipment, the NSA does not systematically cooperate with the Agency when examining the file. 3. The criteria applied by the NSA to evaluate if a new authorisation is required, or not, is not systematically on the basis of if: <ul style="list-style-type: none"> - The overall safety level may be adversely affected; - It is required by the national implementation plan; and - Changes are made to the values of the parameters on the basis the APS was issued. 4. The NSA does not systematically take the decision that a new authorisation is required or not within a pre-determined time that does not exceed 4 months from receipt of all relevant information. <p>D. Decision making</p> <ol style="list-style-type: none"> 1. The decision-making criteria described to the applicant in the application guidance document are not systematically applied by the NSA. 2. The issued decision is not systematically substantiated by the NSA. 3. The NSA does not systematically conduct an active exchange of views and experience with other NSAs in order to harmonise their decision-making criteria. 2. The NSA does not systematically check that ERADIS has been updated as appropriate before delivering the APS for fixed installations. <p>E. Review and appeal</p> <ol style="list-style-type: none"> 1. The decisions for APS of fixed subsystems are not systematically subject to judicial review. 2. The NSA does not systematically review its decisions for APS of fixed subsystems and confirms or reverses its decision within 2 months from receipt of the applicants request. <p>F. Link between supervision and APS of fixed installations</p> <ol style="list-style-type: none"> 1. The NSA does not systematically supervise that the fixed installation subsystems are in compliance with the essential requirements. 2. The NSA does not systematically ensure that there is a link between APS of fixed installations and supervision in order to transfer relevant information.
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<p>3</p> <p>Implementing</p>	<p>A. General</p> <ol style="list-style-type: none"> 1. The NSA issue authorisations for placing in service (APS) of fixed installations before those subsystems are allowed to be placed in service and it has a process to support this. 2. The NSA has sufficient organisational capacity (resources, competence, processes, procedures and processes etc.) to perform the task to issue APS of fixed installations. 3. The NSA provides to the applicants, free of charge, a complete application guidance document that contains detailed guidance on how to obtain APS of fixed installations including <ul style="list-style-type: none"> - A description and explanation of the requirements for APS for fixed installations; and - A list of the required documents to be provided by the applicant to the NSA. - The NSA has a process to support this. <p>B. Processing the application</p> <ol style="list-style-type: none"> 1. The NSA processes the applications for APS of fixed installations in accordance with the application guidance document provided to the applicants and it has a process to support this. 2. The NSA checks before issuing APS for fixed installations that the file provided by the applicant provides documentary evidence of: <ul style="list-style-type: none"> - EC Declarations of verification (ECDofV) for the subsystems; - Technical compatibility of the subsystem with the system they are being integrated into on the basis of TSIs, national rules and registers; - Safe integration of the subsystems on the basis of TSIs, national rules and CSMS; and - For CCS subsystems including trackside ERTMS equipment the positive decision of the Agency. <p style="margin-left: 40px;">The NSA has a process to support this.</p> 3. The NSA informs the applicant within one month of the receipt of the application that the file is complete or asks for relevant supplementary information and it has a process to support this. 4. The NSA verifies the completeness, relevance and consistency of the file and when applicable the compliance with the positive decision issued by the Agency for trackside ERTMS equipment and it has a process to support this. 5. In processing the APS application, the NSA takes into account any decision of non application of TSI granted according to Art 7 of Directive (EU) 2016/797 and it has a process to support this. 6. The NSA issues the APS for fixed installations or informs the applicant of its negative decision within a pre-determined time that does not exceed 4 months from receipt of all relevant information and it has a process to support this. <p>C. Renewal/upgrading</p> <p>The NSA has supporting processes for the following requirements:</p> <ol style="list-style-type: none"> 1. The NSA processes the file for renewal or upgrading of fixed installations in accordance with the application guidance document provided to the applicants. 2. The NSA informs the applicant within one month of the receipt of the file that it is complete and asks for relevant supplementary information. 3. In case of ERTMS trackside equipment, the NSA cooperates with the Agency when examining the file. 4. The criteria applied by the NSA to evaluate if a new authorisation is required, or not, is on the basis of if:
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	<ul style="list-style-type: none"> - The overall safety level may be adversely affected; - It is required by the national implementation plan; and - Changes are made to the values of the parameters on the basis the APS was issued. <p>5. The NSA takes the decision that a new authorisation is required or not within a pre-determined time that does not exceed 4 months from receipt of all relevant information.</p> <p>D. Decision making The NSA has supporting processes for the following requirements:</p> <ol style="list-style-type: none"> 1. The decision-making criteria described to the applicant in the application guidance document are applied by the NSA. 2. The issued decision is duly substantiated by the NSA. 3. The NSA conducts an active exchange of views and experience with other NSAs in order to harmonise their decision-making criteria. 4. The NSA checks that ERADIS has been updated as appropriate before delivering the APS for fixed installations. <p>E. Review and appeal The NSA has supporting processes for the following requirements and relevant information is provided to applicants on how to ask for review or launch an appeal:</p> <ol style="list-style-type: none"> 1. The decisions for APS of fixed subsystems are subject to judicial review. 2. The NSA reviews its decisions for APS of fixed subsystems and confirms or reverses its decision within 2 months from receipt of the applicants request. <p>F. Link between supervision and APS of fixed installations The NSA has supporting processes for the following requirements:</p> <ol style="list-style-type: none"> 1. It supervises that the fixed installation subsystems are in compliance with the essential requirements. 2. It ensures that there is a link between APS of fixed installations and supervision in order to transfer relevant information.
<p style="text-align: center;">4 Managing</p>	<p>A. General As for Level 3, plus: The NSA takes corrective actions when needed and regularly checks and reviews its processes to ensure that:</p> <ul style="list-style-type: none"> - It issues authorisations for placing in service (APS) of fixed installations before those subsystems are allowed to be placed in service - it has sufficient organisational capacity (resources, competence, processes, procedures and processes etc.) to perform the task to issue APS of fixed installations - it provides to the applicants, free of charge, a complete application guidance document that contains detailed guidance on how to obtain APS of fixed installations. <p>B. Processing the application As for Level 3, plus: The NSA takes corrective actions when needed and regularly checks and reviews its processes to ensure that:</p> <ul style="list-style-type: none"> - it processes the applications for APS of fixed installations in accordance with the application guidance document provided to the applicants - it checks before issuing APS for fixed installations that the file provided by the applicant provides documentary evidence of: <ul style="list-style-type: none"> • EC Declarations of verification (ECDoFV) for the subsystems;

	<ul style="list-style-type: none"> • Technical compatibility of the subsystem with the system they are being integrated into on the basis of TSIs, national rules and registers; • Safe integration of the subsystems on the basis of TSIs, national rules and CSMS; and • For CCS subsystems including trackside ERTMS equipment the positive decision of the Agency. <ul style="list-style-type: none"> - it informs the applicant within one month of the receipt of the application that the file is complete or asks for relevant supplementary information. - it verifies the completeness, relevance and consistency of the file and when applicable the compliance with the positive decision issued by the Agency for trackside ERTMS equipment. - In processing the APS application, it takes into account any decision of non application of TSI granted according to Art 7 of Directive (EU) 2016/797. - it issues the APS for fixed installations or informs the applicant of its negative decision within a pre-determined time that does not exceed 4 months from receipt of all relevant information and it has a process to support this. <p>C. Renewal/upgrading As for Level 3, plus: The NSA takes corrective actions when needed and regularly checks and reviews its processes to ensure that:</p> <ul style="list-style-type: none"> - it processes the file for renewal or upgrading of fixed installations in accordance with the application guidance document provided to the applicants. - it informs the applicant within one month of the receipt of the file that it is complete and asks for relevant supplementary information. - In case of ERTMS trackside equipment, it cooperates with the Agency when examining the file. - The criteria applied by the NSA to evaluate if a new authorisation is required, or not, is on the basis of if: <ul style="list-style-type: none"> • The overall safety level may be adversely affected; • It is required by the national implementation plan; and • Changes are made to the values of the parameters on the basis the APS was issued. - It takes the decision that a new authorisation is required or not within a pre-determined time that does not exceed 4 months from receipt of all relevant information. <p>D. Decision making As for Level 3, plus: The NSA takes corrective actions when needed and regularly checks and reviews its processes to ensure that:</p> <ol style="list-style-type: none"> 1. The decision-making criteria described to the applicant in the application guidance document are applied by the NSA. 2. The issued decision is duly substantiated by the NSA. 3. The NSA conducts an active exchange of views and experience with other NSAs in order to harmonise their decision-making criteria. 4. The NSA checks that ERADIS has been updated as appropriate before delivering the APS for fixed installations.
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	<p>E. Review and appeal As for Level 3, plus: The NSA takes corrective actions when needed and regularly checks and reviews its processes (including communication of relevant information to applicants on how to ask for review or launch an appeal) to ensure that:</p> <ol style="list-style-type: none"> 1. The decisions for APS of fixed subsystems are subject to judicial review. 2. The NSA reviews its decisions for APS of fixed subsystems and confirms or reverses its decision within 2 months from receipt of the applicants request. <p>F. Link between supervision and APS of fixed installations As for Level 3, plus: The NSA takes corrective actions when needed and regularly checks and reviews its processes to ensure that:</p> <ol style="list-style-type: none"> 1. It supervises that the fixed installation subsystems are in compliance with the essential requirements. 2. 2. there is a link between APS of fixed installations and supervision in order to transfer relevant information.
<p style="text-align: center;">5 Improving</p>	<p>A. General As for Level 4, plus The NSA continuously strives to improve its processes to ensure that:</p> <ul style="list-style-type: none"> - It issues authorisations for placing in service (APS) of fixed installations before those subsystems are allowed to be placed in service - it has sufficient organisational capacity (resources, competence, processes, procedures and processes etc.) to perform the task to issue APS of fixed installations - it provides to the applicants, free of charge, a complete application guidance document that contains detailed guidance on how to obtain APS of fixed installations <p>B. Processing the application As for Level 4, plus The NSA continuously strives to improve its processes to ensure that:</p> <ul style="list-style-type: none"> - it processes the applications for APS of fixed installations in accordance with the application guidance document provided to the applicants - it checks before issuing APS for fixed installations that the file provided by the applicant provides documentary evidence of: <ul style="list-style-type: none"> • EC Declarations of verification (ECDofV) for the subsystems; • Technical compatibility of the subsystem with the system they are being integrated into on the basis of TSIs, national rules and registers; • Safe integration of the subsystems on the basis of TSIs, national rules and CSMs; and • For CCS subsystems including trackside ERTMS equipment the positive decision of the Agency. - it informs the applicant within one month of the receipt of the application that the file is complete or asks for relevant supplementary information. - it verifies the completeness, relevance and consistency of the file and when applicable the compliance with the positive decision issued by the Agency for trackside ERTMS equipment. - In processing the APS application, it takes into account any decision of non application of TSI granted according to Art 7 of Directive (EU) 2016/797.

	<ul style="list-style-type: none"> - it issues the APS for fixed installations or informs the applicant of its negative decision within a pre-determined time that does not exceed 4 months from receipt of all relevant information and it has a process to support this. <p>C. Renewal/upgrading</p> <p>As for Level 4, plus</p> <p>The NSA continuously strives to improve its processes to ensure that:</p> <ul style="list-style-type: none"> - it processes the file for renewal or upgrading of fixed installations in accordance with the application guidance document provided to the applicants. - it informs the applicant within one month of the receipt of the file that it is complete and asks for relevant supplementary information. - In case of ERTMS trackside equipment, it cooperates with the Agency when examining the file. - The criteria applied by the NSA to evaluate if a new authorisation is required, or not, is on the basis of if: <ul style="list-style-type: none"> • The overall safety level may be adversely affected; • It is required by the national implementation plan; and • Changes are made to the values of the parameters on the basis the APS was issued. - It takes the decision that a new authorisation is required or not within a pre-determined time that does not exceed 4 months from receipt of all relevant information. <p>D. Decision making</p> <p>As for Level 4, plus</p> <p>The NSA continuously strives to improve its processes to ensure that:</p> <ol style="list-style-type: none"> 1. The decision-making criteria described to the applicant in the application guidance document are applied by the NSA. 2. The issued decision is duly substantiated by the NSA. 3. The NSA conducts an active exchange of views and experience with other NSAs in order to harmonise their decision-making criteria. 4. The NSA checks that ERADIS has been updated as appropriate before delivering the APS for fixed installations. <p>E. Review and appeal</p> <p>As for Level 4, plus:</p> <p>The NSA continuously strives to improve its processes its processes (including communication of relevant information to applicants on how to ask for review or launch an appeal) to ensure that:</p> <ol style="list-style-type: none"> 1. The decisions for APS of fixed subsystems are subject to judicial review. 2. The NSA reviews its decisions for APS of fixed subsystems and confirms or reverses its decision within 2 months from receipt of the applicants request. <p>F. Link between supervision and APS of fixed installations</p> <p>As for Level 4, plus:</p> <p>The NSA continuously strives to improve its processes its processes (including communication of relevant information to applicants on how to ask for review or launch an appeal) to ensure that:</p> <ol style="list-style-type: none"> 1. It supervises that the fixed installation subsystems are in compliance with the essential requirements. 2. it ensures that there is a link between APS of fixed installations and supervision in order to transfer relevant information.
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6. Authorisation of vehicles

Element 6: Authorisation of vehicles	
<p>1 Ad hoc</p>	<p>A. General</p> <ol style="list-style-type: none"> 1. The NSA does not have sufficient organisational capacity to perform all its tasks as the authorising entity and as the NSA for the area of use. 2. The NSAs does not have internal arrangements covering the necessary aspects for management of: the issuing of vehicle type authorisations, the issuing of vehicle authorisation for placing on the market, issuing of the assessment file to the authorising entity and providing the pre-engagement, or the relevant part of the pre-engagement. 3. The NSA has not put in place the cooperation agreement with the Agency and when applicable also a multilateral agreement. 4. The NSA has not published, free of charge, a guideline describing their language policy, communication provisions and when applicable the process for temporary authorisations. 5. The NSA, when applicable, has not developed the procedure to follow regarding cross-border agreements for the authorisations to cover stations in neighbouring Member States or the NSA has not published the procedure on its website. <p>B. Pre-engagement</p> <ol style="list-style-type: none"> 1. The NSA does not have a process that allows it to deliver in, a consistent and timely manner, the review of the pre-engagement application and the issuing of an opinion on the approach proposed by the applicant. 2. The NSA does not always provide pre-engagement, or the relevant part of the pre-engagement, when it is requested by the applicants and/ or it does not fully comply with the EU legal requirements. <p>C. Changes to an already authorised vehicle/ vehicle type</p> <ol style="list-style-type: none"> 1. The NSA, as authorising entity, does not have a process to ensure that after it has been notified of a change, the NSA in a consistent and systematic manner: <ul style="list-style-type: none"> - Identifies cases of wrong categorisation of a change or insufficiently substantiated information; and - Issues, when applicable and within 4 months, a reasoned decision in case of a wrong categorisation of a change or insufficiently substantiated information. <p>The NSA does not always perform the tasks related changes to an already authorised vehicle/ vehicle type.</p> <p>D. Processing the application</p> <ol style="list-style-type: none"> 1. The NSA does not have a process that ensures that it: <ul style="list-style-type: none"> - Within one month from the receipt of the application performs a completeness check of the application where it checks that the required information and documents are provided and that it is relevant in order to allow to perform the assessment. - When applicable, plans, organises and agrees with other involved NSAs on the necessary arrangements to take into account the classification of national rules. - Performs its assessment in accordance with Article 39 or 40 of Regulation (EU) 2018/545 and issues an assessment file for its scope of the assessment. - Takes into account information resulting from return of experience in the course of its assessment.

	<ul style="list-style-type: none"> - Records and categorises issues in the OSS issues log. The issues are re-evaluated and re-classified, when relevant, by the NSA following a response or action taken by the applicant. - As authorising entity checks in an independent manner that the process has been carried out correctly and covers the required aspects. <p>The NSA does not always perform its tasks relating to the processing of the application in compliance with the EU legislation.</p> <p>E. Decision-making and final documentation</p> <p>1. The NSA as authorising entity does not have a complete and structured process that ensures that:</p> <ul style="list-style-type: none"> - It provides sufficiently documented reasons for its decisions in a consistent manner; and - The issued decisions contain the required information and do not contain any time limited conditions for use and other restrictions unless the conditions in Article 46(6) of Regulation (EU) 2018/545 are fulfilled. <p>There is no review before issuing the decisions. The NSA issues:</p> <ul style="list-style-type: none"> - Inconsistent decisions; - Inconsistent or insufficient documented reasons for its decisions; - Decisions with missing or incorrect information; and/or - Decisions with time limited conditions for use and other restrictions that do not fulfil the conditions in Article 46(6) of Regulation (EU) 2018/545. <p>2. The NSA as authorising entity does not have a process for:</p> <ul style="list-style-type: none"> - Checking the consistency of the data provided by the applicant, completing the ERATV entry and making it available to the public. - Ensuring that ERADIS has been updated as appropriate before delivering a vehicle type authorisation and/or vehicle authorisation for placing on the market. <p>For authorisations issued by the NSA there is not always complete data in ERATV and ERADIS and/or it is not consistent and correct.</p> <p>F. Review</p> <p>The NSA as authorising entity does not have a review process.</p> <p>G. Link between supervision and vehicle authorisation for placing on the market and vehicle type authorisation.</p> <p>Suspension, revocation and amendment of an issued authorisation</p> <p>1. There is no link between the issuing of vehicle type authorisations and vehicle authorisation for placing on the market (including those cases where the Agency has issued the authorisation for the concerned area of use) and supervision in order to transfer information.</p> <p>2. The NSA as authorising entity does not have a process that ensures that when it takes a decision to revoke, suspend or amend a vehicle type authorisation it updates ERATV and it also ensures that ERADIS is updated accordingly.</p> <p>For decision to revoke, suspend or amend a vehicle type authorisation taken by the NSA there is not always complete data in ERATV and ERADIS and/or it is not consistent and correct.</p> <p>3. The NSA does not have a process that ensures that it informs the Agency, the concerned RUs and NSAs in a systematic and consistent manner when:</p> <ul style="list-style-type: none"> - It becomes aware that a vehicle/vehicle type when used as intended does not meet an applicable essential requirement - Revokes a vehicle authorisation for placing on the market
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	<p>4. The NSA does not have a process that ensures that it collects and shares information resulting from return of experience with the Agency and all other NSAs.</p>
<p style="text-align: center;">2 Initialising</p>	<p>A. General</p> <ol style="list-style-type: none"> 1. The NSA has the organisational capacity to perform most of its tasks as the authorising entity and as the NSA for the area of use. However, it does not always have a sufficient number of staff to cover the roles in OSS with the required independence for the check of the application of the process. The organisational capacity is not flexible and it is not sufficient to cover also peaks in the number of applications. 2. The NSAs has started to implement, its internal arrangements for managing: the issuing of vehicle type authorisations, the issuing of vehicle authorisation for placing on the market, issuing of the assessment file to the authorising entity and providing the pre-engagement, or the relevant part of the pre-engagement. However, it does not yet cover all necessary aspects. 3. The NSA has put in place the cooperation agreement with the Agency and when applicable also a multilateral agreement. The internal arrangements of the NSA do not take into account those agreements and the staff are not always aware of and/ or do not always apply the provisions of the agreements. 4. The NSA has started to develop and is planning to publish, free of charge, a guideline describing their language policy, communication provisions and when applicable the process for temporary authorisations or it has published a guideline that only covers some of the required topics. 5. The NSA, when applicable, has started to develop the procedure to follow regarding cross-border agreements for the authorisations to cover stations in neighbouring Member States and the NSA intends to publish the procedure on its website. <p>B. Pre-engagement</p> <ol style="list-style-type: none"> 1. The NSA is developing a process for pre-engagement to allow it to deliver in, a consistent and timely manner, the review of the pre-engagement application and the issuing of an opinion on the approach proposed by the applicant. However, the pre-engagement is currently not always delivered in a consistent and timely manner and the NSA relies mainly on the NSA staff’s own experience and professional judgement when issuing its opinion on the approach proposed by the applicant. 2. The NSA provides pre-engagement, or the relevant part of the pre-engagement when it is requested by the applicants, respecting the EU legal requirements, though it may not always be achieved in a timely manner. <p>C. Changes to an already authorised vehicle/ vehicle type</p> <ol style="list-style-type: none"> 1. The NSA, as authorising entity, is developing a process to ensure that after it has been notified of a change: <ul style="list-style-type: none"> - Identifies cases of wrong categorisation of a change or insufficiently substantiated information; and - Issues, when applicable and within 4 months, a reasoned decision in case of a wrong categorisation of a change or insufficiently substantiated information. <p>The NSA performs the tasks related to changes to an already authorised vehicle/ vehicle type. However, it is currently not done in in a consistent and systematic manner and the NSA relies mainly on the NSA staff’s own experience and professional judgement when delivering the task.</p>

	<p>D. Processing the application</p> <p>1. The NSA has started to develop and/ or has implemented parts of a process that ensures that it:</p> <ul style="list-style-type: none"> - Within one month from the receipt of the application performs a completeness check of the application where it checks that the required information and documents are provided and that it is relevant in order to allow to perform the assessment. - When applicable, plans, organises and agrees with other involved NSAs on the necessary arrangements to take into account the classification of national rules. - Performs its assessment in accordance with Article 39 or 40 of Regulation (EU) 2018/545 and issues an assessment file for its scope of the assessment. - Takes into account information resulting from return of experience in the course of its assessment. - Records and categorises issues in the OSS issues log. The issues are re-evaluated and re-classified, when relevant, by the NSA following a response or action taken by the applicant. - As authorising entity checks in an independent manner that the process has been carried out correctly and covers the required aspects. <p>The NSA performs the tasks relating to the processing of the application in compliance with the EU legislation. However, it is currently not done in a consistent and systematic manner and the NSA does not always perform its tasks in a timely manner. The NSA relies mainly on the NSA staff's own experience and professional judgement when delivering the task.</p> <p>E. Decision-making and final documentation</p> <p>1. The NSA as authorising entity is developing a decision-making process or has implemented parts of a decision-making process to ensure that:</p> <ul style="list-style-type: none"> - It provides sufficiently documented reasons for its decisions in a consistent manner; and - The issued decisions contain the required information and do not contain any time limited conditions for use and other restrictions unless the conditions in Article 46(6) of Regulation (EU) 2018/545 are fulfilled. <p>If there is an implemented decision-making process, it is not complete and structured and/or it does not ensure that the NSA delivers consistent decisions and documented reasons for the decisions containing the required information. The review before issuing decisions is insufficient. There are some limited cases where the NSA has issued:</p> <ul style="list-style-type: none"> - Inconsistent decisions; - Inconsistent or insufficiently documented reasons for its decisions; and/or - Decisions with missing or incorrect information; and/or - Decisions with time limited conditions for use and other restrictions that do not fulfil the conditions in Article 46(6) of Regulation (EU) 2018/545. <p>2. The NSA as authorising entity is developing and/ or has put in place parts of a process for:</p> <ul style="list-style-type: none"> - Checking the consistency of the data provided by the applicant, completing the ERATV entry and making it available to the public. - Ensuring that ERADIS has been updated as appropriate before delivering a vehicle type authorisation and/or vehicle authorisation for placing on the market.
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	<p>For authorisations issued by the NSA there is complete data in ERATV and ERADIS but it is not always consistent and/or correct.</p> <p>F. Review The NSA as authorising entity is developing a review process or it has implemented parts of a review process.</p> <p>G. Link between supervision and vehicle authorisation for placing on the market and vehicle type authorisation. Suspension, revocation and amendment of an issued authorisation</p> <ol style="list-style-type: none"> 1. There is a link between the issuing of vehicle type authorisations and vehicle authorisation for placing on the market (including those cases where the Agency has issued the authorisation for the concerned area of use) and supervision in order to transfer information. However, the link is not systematic and mainly relies on informal transfer of information. The NSA has started to develop a process for the systematic identification and transfer of information. 2. The NSA as authorising entity has started to develop a process that should ensure that when it takes a decision to revoke, suspend or amend a vehicle type authorisation it updates ERATV and it also ensures that ERADIS is updated accordingly. For decision to revoke, suspend or amend a vehicle type authorisation taken by the NSA there is complete data in ERATV and ERADIS but it is not always consistent and/or correct. 3. The NSA is developing, or has implemented parts of, a process that should ensure that it informs the Agency, the concerned RUs and NSAs in a systematic and consistent manner when: <ul style="list-style-type: none"> - It becomes aware that a vehicle/vehicle type when used as intended does not meet an applicable essential requirement - Revokes a vehicle authorisation for placing on the market 4. The NSA is developing, or has implemented parts of, a process that should ensure that it collects and shares information resulting from return of experience with the Agency and all other NSAs.
<p style="text-align: center;">3 Implementing</p>	<p>A. General</p> <ol style="list-style-type: none"> 1. The NSA has the organisational capacity to perform all its tasks as the authorising entity and as the NSA for the area of use. It has a sufficient number of staff to cover the roles in OSS with the required independence for the check of the application of the process. The organisational capacity is flexible and sufficient to cover also peaks in the number of applications. 2. The NSAs has implemented its internal arrangements that cover the necessary aspects for managing: the issuing of vehicle type authorisations, the issuing of vehicle authorisation for placing on the market, issuing of the assessment file to the authorising entity and providing the pre-engagement, or the relevant part of the pre-engagement. 3. The NSA has put in place and applies the provisions of the cooperation agreement with the Agency and when applicable also a multilateral agreement. The internal arrangements of the NSA take into account those agreements and the staff are aware of and apply the provisions of the agreements. 4. The NSA has published a guideline describing their language policy, communication provisions and when applicable the process for temporary authorisations. The guideline is made available free of charge. 5. The NSA has, when applicable, made publicly available on its website the procedure to follow regarding cross-border agreements for the authorisations to cover stations in neighbouring Member States.

	<p>B. Pre-engagement</p> <ol style="list-style-type: none"> 1. The NSA has implemented a complete and structured process for delivering pre-engagement in compliance with the EU legal requirements and it performs, in a consistent and timely manner, the review of the pre-engagement application and the issuing of an opinion on the approach proposed by the applicant. 2. The NSA provides pre-engagement, or the relevant part of the pre-engagement, when it is requested by the applicants, in a timely manner respecting the EU legal requirements. <p>C. Changes to an already authorised vehicle/ vehicle type</p> <ol style="list-style-type: none"> 1. The NSA, as authorising entity, has implemented a complete and structured process ensuring that after it has been notified of a change, the NSA in a consistent and systematic manner: <ul style="list-style-type: none"> - Identifies cases of wrong categorisation of a change or insufficiently substantiated information; and - Issues, when applicable and within 4 months, a reasoned decision in case of a wrong categorisation of a change or insufficiently substantiated information. <p>D. Processing the application</p> <ol style="list-style-type: none"> 1. The NSA has implemented a complete and structured process that ensures that it: <ul style="list-style-type: none"> - Within one month from the receipt of the application performs a completeness check of the application where it checks that the required information and documents are provided and that it is relevant in order to allow to perform the assessment. - When applicable, plans, organises and agrees with other involved NSAs on the necessary arrangements to take into account the classification of national rules. - Performs its assessment in accordance with Article 39 or 40 of Regulation (EU) 2018/545 and issues an assessment file for its scope of the assessment. - Takes into account information resulting from return of experience in the course of its assessment. - Records and categorises issues in the OSS issues log. The issues are re-evaluated and re-classified, when relevant, by the NSA following a response or action taken by the applicant. - As authorising entity checks in an independent manner that the process has been carried out correctly and covers the required aspects. <p>The NSA performs the tasks relating to the processing of the application in a consistent, systematic and timely manner in full compliance with the EU legislation.</p> <p>E. Decision-making and final documentation</p> <ol style="list-style-type: none"> 1. The NSA as authorising entity has implemented a complete and structured decision-making process that includes a review before issuing decisions. The NSA consistently delivers: <ul style="list-style-type: none"> - Sufficiently documented reasons for its decisions in a consistent manner; and - Decisions that contain the required information and do not contain any time limited conditions for use and other restrictions unless the conditions in Article 46(6) of Regulation (EU) 2018/545 are fulfilled. 2. The NSA as authorising entity has implemented a process for: <ul style="list-style-type: none"> - Checking the consistency of the data provided by the applicant, completing the ERATV entry and making it available to the public.
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	<ul style="list-style-type: none"> - Ensuring that ERADIS has been updated as appropriate before delivering a vehicle type authorisation and/or vehicle authorisation for placing on the market. <p>For authorisations issued by the NSA there is complete, correct and consistent data in ERATV and ERADIS.</p> <p>F. Review</p> <p>The NSA as authorising entity has implemented an impartial review process. The timeframe for the review is 2 months from the receipt of a request for review. The NSA ensures that the stakeholders are informed about the review process.</p> <p>G. Link between supervision and vehicle authorisation for placing on the market and vehicle type authorisation.</p> <p>Suspension, revocation and amendment of an issued authorisation</p> <ol style="list-style-type: none"> 1. The NSA has implemented a process that ensures that there is a systematic link between the issuing of vehicle type authorisations and vehicle authorisation for placing on the market (including those cases where the Agency has issued the authorisation for the concerned area of use) and supervision in order to identify and transfer relevant information. 2. The NSA as authorising entity has implemented a process and ensures that when it takes a decision to revoke, suspend or amend a vehicle type authorisation it updates ERATV and it also ensures that ERADIS is updated accordingly. <p>For decision to revoke, suspend or amend a vehicle type authorisation taken by the NSA there is complete, correct and consistent data in ERATV and ERADIS.</p> <ol style="list-style-type: none"> 3. The NSA has implemented a process that ensures that it informs the Agency, the concerned RUs and NSAs in a systematic and consistent manner when: <ul style="list-style-type: none"> - It becomes aware that a vehicle/vehicle type when used as intended does not meet an applicable essential requirement - Revokes a vehicle authorisation for placing on the market 4. The NSA has implemented a process that ensures that it collects and shares information resulting from return of experience with the Agency and all other NSAs.
<p style="text-align: center;">4</p> <p style="text-align: center;">Managing</p>	<p>A. General</p> <ol style="list-style-type: none"> 1. As for level 3 plus: The NSA regularly evaluates that it has the necessary organisational capacity to perform its tasks with the necessary independence and flexibility. If needed, the NSA takes the required actions to adjust its organisational capacity. 2. As for level 3 plus: The NSA reviews its internal arrangements regularly to ensure that the process supports the delivery of the tasks as required. The NSA revises its internal arrangements, when necessary. 3. As for level 3 plus: The NSA regularly reviews the provisions of the cooperation agreement with the Agency and when applicable also the multilateral agreement. The NSA initiates discussions with its counterpart(s) when a need for revision of the agreement(s) is identified. The NSA ensures that its internal arrangements reflect any changes made and that the staff are made aware and apply the changes. 4. As for level 3 plus: The NSA regularly reviews the guideline. The NSA revises the guideline, when necessary, and informs the stakeholders about the changes. 5. As for level 3 plus: The NSA regularly reviews the procedure to follow regarding cross-border agreements for the authorisations to cover stations in neighbouring Member States. The procedure is revised when necessary and the sector is informed about the changes.

	<p>B. Pre-engagement</p> <ol style="list-style-type: none"> 1. As for level 3 plus: The NSA regularly reviews the process and regularly follows-up that it delivers reviews and opinions for pre-engagement in a consistent and timely manner. Corrective actions are implemented, when needed. 2. As for level 3 plus: The NSA regularly follows-up that it provides pre-engagement, or the relevant part of the pre-engagement, in consistent and timely manner that meets the EU legal requirements. Corrective actions are implemented, when needed. <p>C. Changes to an already authorised vehicle/ vehicle type</p> <p>As for level 3 plus: The NSA, regularly reviews its process to ensure that it in a consistent and systematic manner delivers its tasks related to changes to an already authorised vehicle/ vehicle type. Corrective actions are implemented, when needed.</p> <p>D. Processing the application</p> <p>As for level 3 plus: The NSA regularly reviews its process and regularly follows-up that it delivers its tasks relating to the processing of the application in a consistent, systematic and timely manner and that it complies with the EU legal requirements. Corrective actions are implemented, when needed.</p> <p>E. Decision-making and final documentation</p> <ol style="list-style-type: none"> 1. As for level 3 plus: The NSA regularly follows-up that the documented reasons for its decisions are sufficient and consistent and the issued decisions contain the required information without any time limited conditions for use and other restrictions unless the conditions in Article 46(6) of Regulation (EU) 2018/545 are fulfilled. The decision-making process is regularly reviewed. Corrective actions are implemented, when needed. 2. As for level 3 plus: The NSA regularly follows-up that the registers (ERATV and ERADIS) contain the required information and regularly reviews its own process. Corrective actions are implemented, when needed. <p>F. Review</p> <p>As for level 3 plus: The NSA regularly reviews the process to ensure that it is delivered in an impartial and timely manner. Corrective actions are implemented, when needed.</p> <p>G. Link between supervision and vehicle authorisation for placing on the market and vehicle type authorisation.</p> <p>Suspension, revocation and amendment of an issued authorisation. As for level 3 plus:</p> <ol style="list-style-type: none"> 1. The NSA regularly reviews the process to ensure that it is delivered in an impartial and timely manner. Corrective actions are implemented, when needed. 2. The NSA regularly follows-up that ERATV and ERADIS are updated as required when the it takes decision to revoke, suspend or amend a vehicle type authorisation. Corrective actions are implemented, when needed. 3. The NSA regularly reviews the process and regularly follows-up that it informs the Agency, the concerned RUs and NSAs in a systematic and consistent manner when: <ul style="list-style-type: none"> - It becomes aware that a vehicle/vehicle type when used as intended does not meet an applicable essential requirement. - It revokes a vehicle authorisation for placing on the market. <p style="margin-left: 40px;">Corrective actions are implemented, when needed.</p> 4. The NSA regularly reviews the process and regularly follows-up that it collects and shares information resulting from return of experience with the Agency and all other NSAs. Corrective actions are implemented, when needed.
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<p style="text-align: center;">5 Improving</p>	<p>A. General As for level 4 plus:</p> <ol style="list-style-type: none"> 1. The NSA continuously strives to find efficiency gains to improve and optimise its organisational capacity. 2. The NSA continuously strives to improve its internal arrangements in order to deliver its tasks in a more effective and efficient way taking into account the needs and expectations of its stakeholders, including, when applicable, the Agency and other NSAs. 3. The NSA actively looks for opportunities to both improve the application of, and the provisions in, its cooperation and multilateral agreement(s) (if applicable) to ensure that it is as efficient and effective as possible for all involved parties. The NSA participates in and, when needed initiates, discussions and cooperation with its counterpart(s) with the aim to improve the agreement(s). 4. The NSA actively looks for opportunities for improvement of the guideline and collects feedback from the stakeholders with the aim to improve the guidance based on their needs. The NSA also uses this input to improve its internal arrangement and processes to better meet the needs of the stakeholders. 5. The NSA continuously strives to improve the procedure to follow regarding cross-border agreements for the authorisations to cover stations in neighbouring Member States. It looks to make the procedure better both with regards to the needs of the stakeholders and for the NSA to deliver the tasks in a more effective and efficient way. <p>B. Pre-engagement</p> <ol style="list-style-type: none"> 1. As for level 4 plus: The NSA continuously strives to improve the process to ensure that it delivers consistent and timely reviews and opinions for pre-engagement in an effective and efficient way. The NSA aims to shorten the time frames for delivering its tasks. The NSA follows-up that the issued opinions on the approach proposed by the applicant are well understood by the applicants and it actively collects feedback to improve the clarity of its issued opinions on the approach proposed by the applicant. 2. As for level 4 plus: The NSA continuously strives to improve so that it provides pre-engagement, or the relevant part of the pre-engagement, in an effective and efficient way meeting the expectations of the applicants. The NSA aims to shorten the time frames for delivering its tasks. The NSA actively collects and uses feedback on the process and its own performance from the stakeholders, including, when applicable, the Agency and other NSAs. <p>C. Changes to an already authorised vehicle/ vehicle type As for level 4 plus: The NSA is continuously looking for improvements in its own process and delivery of tasks related to changes to an already authorised vehicle/ vehicle type. The NSA pro-actively communicates with the stakeholders and provides the necessary information and support regarding the correct categorisation of changes.</p> <p>D. Processing the application As for level 4 plus: The NSA f continuously strives to improve its process so that it delivers its tasks relating to the processing of the application, in an effective and efficient way meeting the expectations of the applicants and, when applicable, the Agency and other involved NSAs. The NSA aims to shorten the time frames for delivering its tasks. The NSA actively collects and uses feedback on the process and its own performance from the stakeholders, including, when applicable, the Agency and other NSAs.</p>
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	<p>E. Decision-making and final documentation</p> <ol style="list-style-type: none"> 1. As for level 4 plus: The NSA follows-up that the documented reasons for its decisions are well understood by the applicants and it actively collects feedback to improve the clarity of its decisions. The NSA also actively looks for improvements in its decision-making process in order to ensure clear, complete and consistent decisions. 2. As for level 4 plus: The NSA actively looks for and implements improvements in the process. It actively informs and encourages other involved parties with regards to their responsibilities in relation to updating ERATV and ERADIS. <p>F. Review</p> <p>As for level 4 plus: The NSA looks for and implement improvements with regards to delivering the review process in an efficient, effective and impartial manner. The NSA aims to shorten the time frames for delivering its tasks. It actively seeks feedback from the stakeholders to find possible improvements that can be made.</p> <p>G. Link between supervision and vehicle authorisation for placing on the market and vehicle type authorisation.</p> <p>Suspension, revocation and amendment of an issued authorisation</p> <p>As for level 4 plus:</p> <ol style="list-style-type: none"> 1. The NSA actively looks for and implements improvements in the process. The NSA strives to ensure that it identifies and transfers the relevant information. The NSA seeks feedback from and cooperates with the Agency and other NSAs to ensure that the information is relevant and consistent also with their needs and approach. 2. The NSA actively looks for and implements improvements in the process. It actively informs and encourages other involved parties with regards to their responsibilities in relation to updating ERATV and ERADIS. 3. The NSA actively looks for and implements improvements in the process. It actively strives to ensure that the information is well received and the NSA provides support and cooperation as needed to the other involved parties. It seeks to collect feedback to improve its process. 4. The NSA actively seeks feedback from and cooperates with the Agency and other NSAs to ensure that the information is relevant and consistent also with their needs and approach.
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7. Risk assessment: recognition by the NSA of AsBos or NSA acting as AsBos

Element 7: Risk Assessment: recognition by the NSA of AsBos or NSA acting as AsBo	
<p>1 Ad hoc</p>	<p>A. Recognition</p> <ol style="list-style-type: none"> 1. Criteria defined in Reg. (EU) 402/2013, Annex II (e.g. organisation, methodology, ISO 17020:2012) for the AsBo recognition are: <ul style="list-style-type: none"> - not used (e.g. instead national requirements are used, whereas they are not allowed by Regulation 402/2013), or, - not used in a systematic way (e.g. criteria and requirements not consistently used for all companies seeking recognition). 2. Principles of recognition differ from the accreditation. Recognition does not equally follow the principles of Regulation 765/2008 and the ISO/IEC 17011 standard which are applied by national accreditation bodies. 3. During the certification of the management system, the accreditation or recognition of the in-house AsBo of the Applicant is not systematically accepted, although done in accordance with article 7. 4. The administrative procedure to follow in order to get the assessment body recognised does not exist. 5. The recognition body does not provide the relevant information on recognised Assessment Bodies to the Agency in the ERADIS database. <p>B. Information - Report</p> <ol style="list-style-type: none"> 1. NSA does not include in its annual report a section on the experience of the railway sector in the country with the application of the risk management process. 2. NSA does not give information in its annual report on its experience with the recognition of assessment bodies. <p>C. Only where the NSA acts directly as Assessment Body</p> <ol style="list-style-type: none"> 1. For its AsBo activities, the NSA does not, or not systematically, fulfil the requirements of Annex II and Articles 6(2) and 15(1) of Regulation (EU) 402/2013. 2. The NSA experts that act as AsBo on some projects are not always independent from the other functions of the NSA on the same project. 3. The NSA does not apply the structure defined in Annex III of Regulation 402/2013 for the independent safety assessment report when it acts as AsBo. The structure of the independent safety assessment report is different for every project. <p>D. Supervision/surveillance</p> <p>The NSA does not have a clear plan for the surveillance of the assessment bodies that it recognised. Surveillance is also sporadic and does not concern all recognised AsBos. There is no assurance of fulfilling the requirement in Article 11 of Regulation (EU) 402/2013.</p> <p>E. Use of ERA Recommendations For Use [RFUs]</p> <ol style="list-style-type: none"> 1. For the recognition role, the NSA is neither aware of the existence of, nor uses as inputs, the ERA RFUs for the recognition and surveillance of AsBos. 2. NSA acts as AsBo: the NSA does neither take part to the meetings of the AsBo Cooperation Group organised by ERA, nor follows the outcomes of that group. 3. NSA acts as AsBo: the NSA is neither aware of the existence nor implements the ERA RFUs applicable to the AsBos.
	<p>A. Recognition</p> <ol style="list-style-type: none"> 1. Start of using the criteria defined in Reg. (EU) 402/2013, Annex II (e.g. organisation, methodology, ISO 17020:2012). But structured processes are not yet fully implemented so that there is no assurance that criteria are systematically and consistently used for all companies seeking recognition.

<p style="text-align: center;">2 Initialising</p>	<ol style="list-style-type: none"> 2. The implementation of the principles of Regulation 765/2008 and ISO/IEC 17011 standard has started. But the processes are not yet fully structured and completely implemented so that recognition of AsBos does not yet equally follow the principles applied by national accreditation bodies. 3. Structured processes are not yet completely implemented to accept systematically, during the certification of the management system of the applicant, the accreditation or recognition of the in-house AsBo, although the applicant complies with article 7 of Regulation (EU) 402/2013. 4. The administrative procedure to follow in order to get the assessment body recognised is defined but still unclear. 5. The recognition body stated to provide the relevant information on recognised Assessment Bodies to the Agency in the ERADIS database. However, the process is not well structured and not systematically followed by the recognition body. <p>B. Information - Report</p> <ol style="list-style-type: none"> 1. NSA started to include in its annual report a section on the experience of the railway sector in the country with the application of the risk management process. But the information is not well structured and does not enable to draw a reliable picture of the situation in the country. 2. NSA gives some information in its annual report on its experience with the recognition of assessment bodies. <p>C. Only where the NSA acts directly as Assessment Body</p> <ol style="list-style-type: none"> 1. For its AsBo activities, the NSA started to document in a structured manner the demonstration of compliance with the requirements of Annex II and Articles 6(2) and 15(1) of Regulation (EU) 402/2013. But the process is not fully documented and not systematically applied. 2. The NSA has processes in place to ensure that the NSA experts which act as AsBo on a project are independent from the other functions of the NSA on the same project. However, those processes are not systematically applied for all projects. 3. The NSA does not apply the structure defined in Annex III of Regulation 402/2013 for the independent safety assessment report when it acts as AsBo. The NSA has its own structure for that report and applies it for every project. <p>D. Supervision/surveillance</p> <p>The NSA started to develop a structured plan for the surveillance of the assessment bodies that it recognised. However, the surveillance plan is not systematically used for the surveillance of all recognised AsBos. There is no assurance of fulfilling completely the requirement in Article 11 of Regulation 402/2013.</p> <p>E. Use of ERA Recommendations For Use [RFUs]</p> <ol style="list-style-type: none"> 1. For the recognition role, the NSA has started to use as inputs the ERA RFUs for the recognition and surveillance of AsBos. But this is not yet formalised in a process and is not systematically or fully applied. 2. NSA acts as AsBo: the NSA has started to take part to the meetings of the AsBo Cooperation Group organised by ERA, or to follow the outcomes of that group. But this is not yet systematic and the NSA is not aware of all decisions met in the group. 3. NSA acts as AsBo: the NSA has started to use the ERA RFUs agreed in the AsBo Cooperation Group. But there is not yet systematic process for their implementation.
	<p>A. Recognition</p> <ol style="list-style-type: none"> 1. Processes for using in a structured manner the criteria defined in Reg. (EU) 402/2013, Annex II (e.g. organisation, methodology, ISO 17020:2012) are

<p style="text-align: center;">3</p> <p style="text-align: center;">Implementing</p>	<p>implemented. Recognition tasks are delivered according to Regulation (EU) 402/2013.</p> <ol style="list-style-type: none"> 2. The processes that ensure compliance with the principles of Regulation 765/2008 and ISO/IEC 17011 standard are followed to deliver the recognition tasks. Recognition of AsBos is therefore equivalent to accreditation of AsBos. 3. Structured processes are completely implemented to accept systematically, during the certification of the management system of the applicant, the accreditation or recognition of the in-house AsBo, when the applicant complies with article 7 of Regulation (EU) 402/2013. 4. The administrative procedure to follow in order to get the assessment body recognised is well defined and clear. 5. The recognition body provides the relevant information on recognised Assessment Bodies to the Agency in the ERADIS database. The process is well structured and systematically applied by the recognition body. <p>B. Information - Report</p> <ol style="list-style-type: none"> 1. NSA includes in its annual report a section on the experience of the railway sector in the country with the application of the risk management process. The information is structured and understandable. 2. NSA provides in its annual report structured information concerning its experience with the recognition of assessment bodies. <p>C. Only where the NSA acts directly as Assessment Body</p> <ol style="list-style-type: none"> 1. For its AsBo activities, the NSA has a structured management system which demonstrates compliance with the requirements of Annex II and Articles 6(2) and 15(1) of Regulation (EU) 402/2013. The NSA systematically follows the provisions of its structured management system. 2. The NSA has processes in place and applies them systematically in order to ensure that the NSA experts which act as AsBo on a project are independent from the other functions of the NSA on the same project. 3. The NSA applies systematically the structure defined in Annex III of Regulation 402/2013 for the independent safety assessment report when it acts as AsBo. <p>D. Supervision/surveillance</p> <p>The NSA has a structured plan for the surveillance of the assessment bodies that it recognised. That plan is systematically used for the surveillance of all recognised AsBos.</p> <p>E. Use of ERA Recommendations For Use [RFUs]</p> <ol style="list-style-type: none"> 1. For the recognition role, the NSA has a structured process for using as inputs the ERA RFUs for the recognition and surveillance of AsBos. The process is systematically applied. 2. NSA acts as AsBo: the NSA takes part to the meetings of the AsBo Cooperation Group organised by ERA, or when it cannot attend the meetings, it follows the outcomes of that group. The NSA is aware of all decisions met in the group. 3. NSA acts as AsBo: the NSA has a formal process for the use of the ERA RFUs agreed in the AsBo Cooperation Group. The NSA systematically implements all RFUs.
	<p>A. Recognition</p> <ol style="list-style-type: none"> 1. The structured processes for the systematic use of the criteria defined in Reg. (EU) 402/2013, Annex II (e.g. organisation, methodology, ISO 17020:2012) are monitored and corrective action plans implemented (when necessary) to improve the recognition of AsBos and keep complying with Regulation (EU)402/2013. 2. The follow up of the processes that ensure both the compliance with the principles of Regulation (EU) 765/2008 and ISO/IEC 17011 standard, and the delivery of recognition of AsBos equally to the accredited AsBos, are monitored. Where

<p style="text-align: center;">4</p> <p>Managing</p>	<p>necessary, corrective action plans are implemented to improve the recognition of AsBos and keep it equivalent to accreditation of AsBos.</p> <ol style="list-style-type: none"> 3. The correct implementation of the structured processes for the systematic acceptance, during the certification of the management system of the applicant, of the accreditation or recognition of the in-house AsBo in compliance with article 7 of Regulation (EU) 402/2013, is monitored. Where necessary, corrective action plans are implemented to improve the acceptance of assessments already carried out by the accreditation or recognition body in compliance with Regulation (EU) 402/2013. 4. The administrative procedure to follow in order to get the assessment body recognised is monitored, and where necessary corrective action plans are implemented to improve the applications for the AsBo recognition. 5. The recognition body provides the relevant information on recognised Assessment Bodies to the Agency in the ERADIS database. The process is well structured, systematically applied, and monitored by the recognition body in order to proactively correct mistakes of encoding data. <p>B. Information - Report</p> <ol style="list-style-type: none"> 1. NSA includes in its annual report a section on the experience of the railway sector in the country with the application of the risk management process. The information is structured and understandable. It includes also a yearly monitoring of the changes and improvements of the sector experience with the methodology. 2. NSA provides in its annual report structured information concerning: <ul style="list-style-type: none"> - its experience with the recognition of assessment bodies; - necessary corrective actions to improve the observed deficiencies. <p>C. Only where the NSA acts directly as Assessment Body</p> <ol style="list-style-type: none"> 1. For its AsBo activities, the NSA has a structured management system which demonstrates compliance with the requirements of Annex II and Articles 6(2) and 15(1) of Regulation (EU) 402/2013. The NSA also monitors the correct implementation of the provisions of the structured management system, as well as its effectiveness, and where necessary takes corrective actions to improve the system. 2. The NSA has processes in place and applies them systematically to ensure that the NSA experts which act as AsBo on a project are independent from the other functions of the NSA on the same project. The NSA continually monitors the different functions of its staff on the same project and takes corrective actions whenever the AsBo functions of the NSA interfere with the other functions of the NSA on the same project. 3. The NSA monitors the systematic application of the structure defined in Annex III of Regulation (EU) 402/2013 for the independent safety assessment report, when it acts as AsBo. Based on the feedback, it complements the structure of the report with additional information to facilitate the mutual recognition of the report. <p>D. Supervision/surveillance</p> <p>The NSA has a structured plan for the surveillance of the assessment bodies that it recognised. The NSA monitors the systematic application of the surveillance plan and takes timely any necessary corrective actions in order to ensure continual compliance with Article 11 of Regulation (EU) 402/2013.</p> <p>E. Use of ERA Recommendations For Use [RFUs]</p> <ol style="list-style-type: none"> 1. For the recognition role, the NSA has a structured process for using as inputs the ERA RFUs for the recognition and surveillance of AsBos. The systematic use of the process is monitored and where necessary corrective actions are taken to improve the process.
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	<ol style="list-style-type: none"> 2. NSA acts as AsBo: the NSA takes part to the meetings of the AsBo Cooperation Group organised by ERA, or when it cannot attend the meetings, it follows the outcomes of that group. The NSA is aware of all decisions met in the group. The NSA monitors the agendas of meetings and sends the most relevant expert to the AsBo Cooperation meeting vs. the agenda of the day. 3. NSA acts as AsBo: the NSA has a formal process for the use of the ERA RFUs agreed in the AsBo Cooperation Group. The NSA systematically monitors the correct implementation of all RFUs and where necessary takes corrective actions to align with the applicable RFUs.
<p>5 Improved</p>	<p>A. Recognition</p> <ol style="list-style-type: none"> 1. The structured processes for the systematic use of the criteria defined in Reg. (EU) 402/2013, Annex II (e.g. organisation, methodology, ISO 17020:2012) are monitored and corrective action plans implemented (when necessary): <ul style="list-style-type: none"> - to improve the recognition of AsBos and keep complying with Regulation (EU) 402/2013; - to better deliver the recognition of AsBos, in a more effective and efficient manner. 2. The follow up of the processes that ensure both the compliance with the principles of Regulation (EU) 765/2008 and ISO/IEC 17011 standard, and the delivery of recognition of AsBos equally to the accredited AsBos, are monitored. Where necessary, corrective action plans are implemented: <ul style="list-style-type: none"> - to improve the recognition of AsBos and keep recognition equivalent to accreditation of AsBos; - to better deliver the recognition of AsBos, in a more effective and efficient manner. 3. The correct implementation of the structured processes for the systematic acceptance, during the certification of the management system of the applicant, of the accreditation or recognition of the in-house AsBo in compliance with article 7 of Regulation 402/2013, is monitored. Where necessary, corrective action plans are implemented: <ul style="list-style-type: none"> - to improve the acceptance of assessments already carried out by the accreditation or recognition body in compliance with Regulation (EU) 402/2013. - to liaise with the accreditation or recognition body for reporting the issues identified during the certification of the management system of the applicant concerning the non-conformities of the in-house AsBo. 4. The administrative procedure to follow in order to get the assessment body recognised is monitored, and where necessary corrective action plans are implemented: <ul style="list-style-type: none"> - to improve the effectiveness and efficiency for the applications for recognition. - to facilitate and shorten the time to get recognised. 5. The recognition body provides the relevant information on recognised Assessment Bodies to the Agency in the ERADIS database. The process is well structured, systematically applied, and monitored by the recognition body in order: <ul style="list-style-type: none"> - to proactively correct mistakes of encoding data. - to coordinate with the AsBo for reassessing its competencies before the validity of the previous recognition expires.

	<p>B. Information – Report</p> <ol style="list-style-type: none"> 1. NSA includes in its annual report a section on the experience of the railway sector in the country with the application of the risk management process. The information is structured and understandable. It includes also: <ul style="list-style-type: none"> - a yearly monitoring of the changes and improvements of the sector experience with the methodology. - a targeted planning of dissemination and training to help the sector with the understanding and implementation of Regulation (EU) 402/2013. 2. NSA provides in its annual report structured information concerning: <ul style="list-style-type: none"> - its experience with the recognition of assessment bodies; - necessary corrective actions to improve not only the observed deficiencies, but also the effectiveness and efficiency of recognition. <p>C. Only where the NSA acts directly as Assessment Body</p> <ol style="list-style-type: none"> 1. For its AsBo activities, the NSA has a structured management system which demonstrates compliance with the requirements of Annex II and Articles 6(2) and 15(1) of Regulation (EU) 402/2013. The NSA also monitors the correct implementation of the provisions of the structured management system, as well as its effectiveness, and where necessary takes corrective actions to improve: <ul style="list-style-type: none"> - the continual compliance with the requirements of Annex II and Articles 6(2) and 15(1) of Regulation (EU) 402/2013; - the effectiveness and efficiency of the management system. 2. The NSA has processes in place and applies them systematically to ensure that the NSA experts which act as AsBo on a project are independent from the other functions of the NSA on the same project. The NSA continually monitors the different functions of its staff on the same project and: <ul style="list-style-type: none"> - takes corrective actions whenever the AsBo functions of the NSA interfere with the other functions of the NSA on the same project. - actively works to get other domestic companies, with native language of the railway sector, to be accredited or recognised AsBos in the country. 3. The NSA monitors the systematic application of the structure defined in Annex III of Regulation 402/2013 for the independent safety assessment report, when it acts as AsBo. Based on the feedback from this monitoring: <ul style="list-style-type: none"> - the NSA improves the structure of the report with additional information to facilitate the mutual recognition of the report. - the NSA develops a step wise approach for better producing the report, being more effective and efficient in including on time any relevant information necessary for an easier understanding of the AsBo work and an faster mutual recognition of the report. <p>D. Supervision/surveillance</p> <p>The NSA has a structured plan for the surveillance of the assessment bodies that it recognised. The NSA monitors the systematic application of the surveillance plan, and :</p> <ul style="list-style-type: none"> - where necessary takes timely corrective actions in order to ensure continual compliance with Article 11 of Regulation 402/2013. - continually seeks for improving the surveillance of recognised AsBos to achieve it more effectively and efficiently. <p>E. Use of ERA Recommendations For Use [RFUs]</p> <ol style="list-style-type: none"> 1. For the recognition role, the NSA has a structured process for using as inputs the ERA RFUs for the recognition and surveillance of AsBos. The systematic use of the process is monitored, and where necessary corrective actions are taken either to improve the process or to carry it out in a better, more effective and efficient way.
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	<ol style="list-style-type: none"> 2. NSA acts as AsBo : the NSA takes part to the meetings of the AsBo Cooperation Group organised by ERA, or when it cannot attend the meetings, it follows the outcomes of that group. The NSA is aware of all decisions met in the group. The NSA monitors the agendas of meetings and: <ul style="list-style-type: none"> - sends the most relevant expert to the AsBo Cooperation meeting vs. the agenda of the day; - proposes subjects for the agenda, or challenges the priority order of the RFUs to be processed as early as possible. 3. NSA acts as AsBo: the NSA has a formal process for the use of the ERA RFUs agreed in the AsBo Cooperation Group. The NSA systematically monitors the correct implementation of all RFUs, and where necessary: takes corrective actions: <ul style="list-style-type: none"> - to align with the applicable RFUs; - to better implement, more effectively and more efficiently the RFUs; - to report to the AsBo Cooperation Group their experience with the implementation of RFUs for further improvement of the RFUs.
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8. NSA as Notifying Authority for CABs/NoBos

Element 8: NSA as Notifying Authority for CABs/NoBos	
<p style="text-align: center;">1 Ad hoc</p>	<p>A. Responsibility</p> <ol style="list-style-type: none"> 1. The NSA does not take full responsibility for the assessments and monitoring of CABs/NoBos [<i>if appropriate “carried out by a national accreditation body”</i>]. 2. The NSA does not have clear procedures for the assessment, notification, and monitoring of conformity assessment bodies vs. Directive (UE) 2016/797 requirements (Art. 30 to 34) and where relevant ERA assessment scheme 000MRA1044. 3. The NSA does not take proportionate actions (restrict, suspend or withdraw notification as appropriate), when a notified body no longer meets the Directive (UE) 2016/797 requirements in Articles 30 to 32. <p>B. Independence and impartiality</p> <ol style="list-style-type: none"> 1. The NSA has no demonstration of the absence of conflicts of interest with CABs/NoBos. 2. The NSA is not organised, and/or is not operated, to safeguard the objectivity and impartiality of its activities. 3. The NSA offers or provides activities that are performed by CABs, or the NSA provides consultancy services on a commercial or competitive basis. <p>C. Resources</p> <ol style="list-style-type: none"> 1. The NSA is not organised in such a way that decisions relating to notification of CABs are taken by competent persons different from those who carried out the assessment. 2. The NSA does not have at its disposal a sufficient number of competent personnel for the proper performance of its assessment, notification and monitoring tasks. 3. The NSA staff in charge of assessment, notification and monitoring of notified bodies does not have the competence for the assessment of the requirements in Art. 30 to 34 of the Interoperability Directive, the ERA accreditation scheme (optional) and the ISO 17065 standard (optional). 4. When based on accreditation, the NSA resources in charge of notification does not have competence in ISO 17065 and ERA accreditation scheme to be able to take full responsibility for the tasks performed by the accreditation body.

	<p>D. Confidentiality The NSA does not have mechanisms to safeguard the confidentiality of the information it obtains.</p> <p>E. Information</p> <ol style="list-style-type: none"> 1. The NSA does not inform the Commission of their procedures for the assessment, notification and monitoring of CABs and of any changes to those procedures. 2. The NSA does not notify CABs to the Commission and other MSs via <u>NANDO</u>.
<p>2 Initialising</p>	<p>A. Responsibility</p> <ol style="list-style-type: none"> 1. The NSA is aware (but unprepared or unorganised) to systematically take full responsibility for the assessments and monitoring carried out by a national accreditation body. 2. The NSA started to develop procedures for the assessment, notification, and monitoring of conformity assessment bodies vs. IOD requirements (Art. 30 to 34) and where relevant ERA assessment scheme 000MRA1044. But those procedures are not yet systematically implemented. 3. The NSA started to take proportionate actions (restrict, suspend or withdraw notification as appropriate), when a notified body no longer meets the IOD requirements in Articles 30 to 32. But the processes are not fully and systematically implemented. <p>B. Independence and impartiality</p> <ol style="list-style-type: none"> 1. The NSA has relationships with CABs that may lead to conflicts of interests. 2. The NSA is aware about the requirements (but is unprepared or unorganised) that it shall safeguard the objectivity and impartiality of its activities. 3. The NSA is aware (but it is unprepared or unorganised) that it shall not offer or provide activities that are performed by CABs, or that it shall not provide consultancy services on a commercial or competitive basis. <p>C. Resources</p> <ol style="list-style-type: none"> 1. The NSA is aware (but it is unprepared or unorganised) that decisions relating to notification of CABs shall be taken by competent persons different from those who carried out the assessment. 2. The NSA is aware about the requirements (but it is unprepared or unorganised) that it shall have at its disposal a sufficient number of competent personnel for the proper performance of its assessment, notification and monitoring tasks. 3. The NSA started the development of processes to ensure that the staff in charge of assessment, notification and monitoring of notified bodies has the necessary competence for the assessment of the requirements in Art. 30 to 34 of the Interoperability Directive, the ERA accreditation scheme (optional) and the ISO 17065 standard (optional). But this is not yet structured and systematically implemented. 4. When based on accreditation, the NSA started the development of processes to ensure that resources in charge of notification have competence in ISO 17065 and ERA accreditation scheme to be able to take full responsibility for the tasks performed by the accreditation body. But this is not yet structured and systematically implemented. <p>D. Confidentiality The NSA is aware (but it is unprepared or unorganised) that it shall safeguard the confidentiality of the information it obtains.</p>

	<p>E. Information</p> <ol style="list-style-type: none"> The NSA is aware (but it is unprepared or unorganised) and does not inform the Commission of their procedures for the assessment, notification and monitoring of CABs and of any changes to those procedures. The NSA has a process to notify CABs to the Commission and other MSs via <u>NANDO</u>. But it does not use it systematically.
<p style="text-align: center;">3 Implementing</p>	<p>A. Responsibility</p> <ol style="list-style-type: none"> The NSA has processes and implements them for taking full responsibility for the assessments and monitoring carried out by a national accreditation body. The NSA implements systematically its procedures for the assessment, notification, and monitoring of conformity assessment bodies vs. IOD requirements (Art. 30 to 34) and where relevant ERA assessment scheme 000MRA1044. The NSA takes proportionate actions (restrict, suspend or withdraw notification as appropriate), when a notified body no longer meets the IOD requirements in Articles 30 to 32. <p>B. Independence and impartiality</p> <ol style="list-style-type: none"> The NSA has identified (e.g. risk log) and mitigates possible risks deriving from relationships with CABs which may lead to conflicts of interests. The NSA has identified (e.g. risk log) and mitigates possible risks to the objectivity and impartiality of its activities. The NSA does not offer, does not provide activities that are performed by CABs, and does not provide consultancy services on a commercial or competitive basis. <p>C. Resources</p> <ol style="list-style-type: none"> The NSA has processes, and implements them, to ensure that decisions relating to notification of CABs are taken by competent persons different from those who carried out the assessment The NSA has at its disposal a sufficient number of competent personnel for the proper performance of its assessment, notification and monitoring tasks. The NSA has, and systematically uses, processes which ensure that the staff in charge of assessment, notification and monitoring of notified bodies has the necessary competence for the assessment of the requirements in Art. 30 to 34 of the Interoperability Directive, the ERA accreditation scheme (optional) and the ISO 17065 standard (optional). When based on accreditation, the NSA has, and systematically uses, processes which ensure that resources in charge of notification have competence in ISO 17065 and ERA accreditation scheme to be able to take full responsibility for the tasks performed by the accreditation body. <p>D. Confidentiality</p> <p>The NSA has processes to safeguard the confidentiality of the information it obtains.</p> <p>E. Information</p> <ol style="list-style-type: none"> The NSA has a process and systematically informs the Commission of their procedures for the assessment, notification and monitoring of CABs and of any changes to those procedures. The NSA has a process, and systematically uses it, to notify CABs to the Commission and other MSs via NANDO.
	<p>A. Responsibility</p> <ol style="list-style-type: none"> The NSA controls the outputs of processes in place, and where necessary reviews them, to be able to take full responsibility for the assessments and monitoring carried out by a national accreditation body.

<p style="text-align: center;">4 Managing</p>	<ol style="list-style-type: none"> 2. The NSA controls the effectiveness of its procedures, and where relevant reviews them, in order to help the NSA for the assessment, notification, and monitoring of conformity assessment bodies vs. IOD requirements (Art. 30 to 34) and where relevant ERA assessment scheme 000MRA1044 3. The NSA monitors its effectiveness in checking that the notified body keeps meeting the IOD requirements in Articles 30 to 32, and reviews its processes to take proportionate actions (restrict, suspend or withdraw notification as appropriate), where necessary. <p>B. Independence and impartiality</p> <ol style="list-style-type: none"> 1. The NSA has identified (e.g. risk log), mitigates and updates possible risks deriving from relationships with CABs which may lead to conflicts of interests. 2. The NSA has identified (e.g. risk log), mitigates and updates possible risks to the objectivity and impartiality of its activities. 3. The NSA controls its recognition activities, and reviews the processes to ensure that the NSA keeps not offering, not providing activities that are performed by CABs, and not providing consultancy services on a commercial or competitive basis. <p>C. Resources</p> <ol style="list-style-type: none"> 1. The NSA controls the implementation of the processes, and when needed reviews them, to ensure that decisions relating to notification of CABs are always taken by competent persons different from those who carried out the assessment. 2. The NSA controls, and when necessary reinforces its team, to ensure that it has at its disposal a sufficient number of competent personnel for the proper performance of its assessment, notification and monitoring tasks. 3. The NSA regularly controls, and takes corrective actions to ensure, that the staff in charge of assessment, notification and monitoring of notified bodies has the necessary competence for the assessment of the requirements in Art. 30 to 34 of the Interoperability Directive, the ERA accreditation scheme (optional) and the ISO 17065 standard (optional). 4. When based on accreditation, the NSA regularly controls, and takes corrective actions, to ensure that resources in charge of notification have competence in ISO 17065 and ERA accreditation scheme to take full responsibility for the tasks performed by the accreditation body. <p>D. Confidentiality</p> <p>The NSA controls the application of its processes, and where needed reviews them, to safeguard the confidentiality of the information it obtains.</p> <p>E. Information</p> <ol style="list-style-type: none"> 1. The NSA controls the effectiveness of the process, and where necessary revises it, to inform the Commission of their procedures for the assessment, notification and monitoring of CABs and of any changes to those procedures. 2. The NSA controls the process, and revises it where necessary, to notify CABs to the Commission and other MSs via NANDO.
<p style="text-align: center;">5 Improved</p>	<p>A. Responsibility</p> <ol style="list-style-type: none"> 1. The NSA controls the outputs of processes in place, where necessary reviews and improves them, to be able to take more efficiently the full responsibility for the assessments and monitoring carried out by a national accreditation body. 2. The NSA controls the effectiveness of its procedures, and where relevant reviews them, to improve the NSA efficiency in the assessment, notification, and monitoring of conformity assessment bodies vs. IOD requirements (Art. 30 to 34) and where relevant ERA assessment scheme 000MRA1044.

	<p>3. The NSA monitors the risks of a notified body no longer meeting the IOD requirements in Articles 30 to 32, and agrees with the NoBo on preventive actions plans to implement in order to avoid the NSA restricting, suspending or withdrawing the notification as appropriate.</p> <p>B. Independence and impartiality</p> <p>1. The NSA has identified (e.g. risk log), mitigates and continually updates possible risks deriving from relationships with CABs which may lead to conflicts of interests. Where necessary, the NSA takes actions to prevent such conflicts to occur.</p> <p>2. The NSA has identified (e.g. risk log), mitigates and continually updates possible risks to the objectivity and impartiality of its activities. Where necessary, the NSA takes corrective actions to control those risks.</p> <p>3. The NSA continually controls its recognition activities, and improves the processes that ensure that the NSA does not offer, does not provide activities that are performed by CABs, and does not provide consultancy services on a commercial or competitive basis. On the contrary, the NSA helps the CABs in keeping their competencies to meet the IOD requirements in Articles 30 to 32.</p> <p>C. Resources</p> <p>1. The NSA controls the implementation of the processes, and when needed revises them to improve their efficiency, to keep ensuring that decisions relating to notification of CABs are taken by competent persons different from those who carried out the assessment.</p> <p>2. The NSA processes follow up the staff competences and turn over, to ensure that the NSA has always at its disposal a sufficient number of competent personnel (where needed with redundant competences) for the proper performance of its assessment, notification and monitoring tasks, although some.</p> <p>3. The NSA continually monitors the effectiveness, and improves the efficiency, of the processes which ensure that the staff in charge of assessment, notification and monitoring of notified bodies has the necessary competence for the assessment of the requirements in Art. 30 to 34 of the Interoperability Directive, the ERA accreditation scheme (optional) and the ISO 17065 standard (optional).</p> <p>4. When based on accreditation, the NSA continually monitors the effectiveness, and improves the efficiency of the processes which ensure that resources in charge of notification have competence in ISO 17065 and ERA accreditation scheme to take full responsibility for the tasks performed by the accreditation body.</p> <p>D. Confidentiality</p> <p>The NSA continually controls the proper application of its processes, and where necessary regularly revises and improves them, to better safeguard the confidentiality of the information it obtains.</p> <p>E. Information</p> <p>1. The NSA controls the effectiveness of the process, reviews it and improves it, to inform the Commission of their procedures for the assessment, notification and monitoring of CABs and of any changes to those procedures.</p> <p>2. The NSA controls the process, revises it and improves it, to notify CABs to the Commission and other MSs via NANDO.</p>
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9. NSA Supervision

Element 9 NSA Supervision	
<p>1 Ad hoc</p>	<p>A. Structured and auditable process There is no supervision process in place. Results of supervision activities, if any, are not documented. The NSA supervision activities, if any, do not cover all relevant stakeholders and matters (ECM, when appropriate, train drivers activities, trackside, control-command and signalling, energy and infrastructure subsystems ensuring that they are in compliance with the essential requirements.)</p> <p>B. Supervision strategy and plan The NSA does not have a supervision strategy and/or plan. When performing supervision activities, the risk-based approach is not used. There are not enough resources to effectively implement the supervision plan . In addition, the supervision techniques are not described (e.g. audits/inspections) and no risk-based logic applies when selecting the most appropriate supervision techniques.</p> <p>C. Communicating the plan The NSA does not communicate the objectives of the supervision strategy. It does not explain the supervision plan and how it will be undertaken to the supervised entities and, when appropriate, more widely.</p> <p>D. Delivering the supervision activities The NSA does not give effect to the supervision plan. It does not check the effectiveness of the SMS of the relevant supervised entities. The NSA is constrained in the performance of its supervision activities. For example, it may not be free to perform all needed audits and inspections or be granted needed access (e.g. premises, installations, equipment).</p> <p>E. Outcomes of the supervision activities The NSA does not share the results of the supervision activities with the supervised entities and it does not give them reasons for its decisions. The NSA does not have an overview of the safety performance both at individual level (RU/IM) and at Member State level. The NSA does not use and share information on the performance of the SMS for SSC and SA. In case it is needed, the NSA does not take enforcement actions and, if it does, those enforcement actions are not proportionate.</p> <p>F. Reviewing the supervision activities The NSA does not review its supervision strategy and plan based on the safety performance.</p> <p>G. Competence The NSA does not have sufficient competent staff to perform supervision activities as required by Reg. 2018/761, art. 6 and the NSA does not have any system in place to manage competences.</p> <p>H. Decision Making The NSA does not have decision making criteria on how to evaluate the application of an SMS and on how to enforce compliance with the safety regulatory framework. The NSA does not have a complaint procedure available for the supervised entities.</p> <p>I. Coordination and cooperation The NSA does not coordinate supervision approach with relevant cross-border NSAs for the supervision of IM with cross-border infrastructure. The NSA has not</p>

	<p>developed arrangements for coordinated and joint supervision. The NSA does not have any cooperation arrangement with NIBs, certification bodies for ECM and other competence authorities or bodies.</p> <p>J. Reporting to the Agency The NSA does not report the results of supervision in its annual report submitted to the Agency, it does not report on the experience of the RU/IM in implementing the CSMs. The NSA does not report to the Agency when acting as authorising entity in case of detected risks identified during the supervision activities.</p>
<p style="text-align: center;">2 Initialising</p>	<p>A. Structured and auditable process The NSA has started developing a process for supervision activities. Some results of supervision activities are documented and structured. The NSA supervision activities do not cover yet all relevant stakeholders and matters.</p> <p>B. Supervision strategy and plan The NSA has started developing a supervision strategy and plan. However, the NSA may not yet target its activities at the areas of greatest risks taking into consideration various sources including results of past supervision activities, NIB reports and safety recommendations (e.g., the NSA may perform systematically the same supervision activities). The plan may not include sufficient resources for it to be fully effective and may not systematically select the most appropriate supervision techniques.</p> <p>C. Communicating the plan The NSA provides some communication to the supervised entities but not all the information is provided. For example, the NSA may give some information on the supervision plan and how the activities will be performed, but it may not communicate on the objectives of the supervision strategy.</p> <p>D. Delivering the supervision activities The NSA partly delivers planned supervision activities (without providing relevant justifications such as reprioritisation of activities). It does not fully check the effectiveness of the SMS of the relevant supervised entities (e.g. some individual or partial elements are checked but the NSA does not check its effectiveness as a whole). The NSA is generally not constrained in the performance of its supervision activities, it can relatively easily carry out all needed audits and inspections or be granted needed access (e.g. premises, installations, equipment).</p> <p>E. Outcomes of the supervision activities The NSA shares some results of the supervision activities with the supervised entities and provides them with some reasons for its decisions. But this is not done in a systematic way. The NSA is in the process of having an overview of the safety performance both at individual level (RU/IM) and at Member State level. (E.g. It may have an overview of some RUs/IMs but does not have a view at the MS level). The NSA has started using and sharing information on the performance of the SMS for SSC and SA. (E.g. there is a link between SC / SA assessment and supervision but no information or no sufficient information is provided to the Agency as certifying entity). The NSA may take some enforcement actions. However, these may not be proportionate or effective.</p> <p>F. Reviewing the supervision activities The NSA reviews to some extent its supervision strategy and plan based on the safety performance, but it is not done in a systematic manner.</p>

	<p>G. Competence The NSA has some competent staff to perform supervision activities as required by Reg. 2018/761, art. 6, but there may not be sufficient staffing level to perform planned activities or the staff may not be at the adequate level of competence. The NSA has started developing a system to manage competences.</p> <p>H. Decision Making The NSA is developing decision making criteria on how it evaluates the application of an SMS and on how it enforces compliance with the safety regulatory framework. But it may not communicate these. The NSA has a complaint procedure but may not communicate it.</p> <p>I. Coordination and cooperation The NSA has started coordinating supervision approach with relevant cross-border NSAs for the supervision of IM with cross-border infrastructure. The NSA is developing arrangements for coordinated and joint supervision. The NSA has started developing cooperation arrangement with NIBs, certification bodies for ECM and other competence authorities or bodies.</p> <p>J. Reporting to the Agency The NSA provides some information on the results of supervision in its annual report submitted to the Agency. It also provides some information in the annual report on the RU/IM in implementing the CSMs. The NSA provides some information to the Agency when acting as authorising entity in case of detected risks identified during the supervision activities.</p>
<p style="text-align: center;">3 Implementing</p>	<p>A. Structured and auditable process The NSA has developed a process for supervision activities. Results of supervision activities are documented and structured. The NSA supervision activities cover all relevant stakeholders and matters as legally required.</p> <p>B. Supervision strategy and plan The NSA has developed a supervision strategy and plan. The NSA targets its activities looking at the areas of greatest risks and taking into consideration various sources including results of past supervision activities, NIB reports and safety recommendations. The plan includes sufficient resources for it to be fully effective and selects the most appropriate supervision techniques, which are described and explained.</p> <p>C. Communicating the plan The NSA communicates the objectives of the supervision strategy. It explains the supervision plan and how it will be undertaken to the supervised entities and when appropriate more widely (for example setting up REX working groups).</p> <p>D. Delivering the supervision activities The NSA delivers planned supervision activities. It checks the effectiveness of the SMS of the relevant supervised entities. The NSA does not generally encounter any constraint in the performance of its supervision activities.</p> <p>E. Outcomes of the supervision activities The NSA shares results of the supervision activities with the supervised entities and provides them with some reasons for its decisions in a systematic way. The NSA has an overview of the safety performance both at individual level (RU/IM) and at Member State level. The NSA uses and shares information on the performance of the SMS for SSC and SA. The NSA takes proportionate enforcement actions.</p>

	<p>F. Reviewing the supervision activities The NSA reviews its supervision strategy and plan on the basis of the safety performance both at individual and Member State level and contributes at the Member State level to overcome any deficiency in the safety regulatory framework.</p> <p>G. Competence The NSA has sufficient competent staff to perform supervision activities. The NSA has developed and implements a Competence Management system.</p> <p>H. Decision Making The NSA has developed decision-making criteria on how it evaluates the application of an SMS and on how it enforces compliance with the safety regulatory framework. The NSA has developed a complaint procedure. The above documentation is publicly available and is communicated by the NSA to the sector who is made aware on how to use it.</p> <p>I. Coordination and cooperation The NSA is coordinating supervision approach with relevant cross-border NSAs for the supervision of IM with cross-border infrastructure. The NSA has arrangements for coordinated and joint supervision and implement these. The NSA has cooperation arrangement with NIBs, certification bodies for ECM and other competence authorities or bodies.</p> <p>J. Reporting to the Agency The NSA reports on the results of supervision in its annual report submitted to the Agency. It reports in the annual report on the RU/IM in implementing the CSMs. The NSA provides the adequate level of information to the Agency when acting as authorising entity in case of detected risks identified during the supervision activities.</p>
<p style="text-align: center;">4 Managing</p>	<p>A. Structured and auditable process As for Level 3, plus: The NSA has developed a process for supervision activities which is iterative and covers the need to continually improve. The NSA controls outputs of supervision activities and may take corrective actions.</p> <p>B. Supervision strategy and plan As for Level 3, plus: The NSA revises the supervision strategy and plan when needed (corrective actions).</p> <p>C. Communicating the plan As for Level 3, plus: The NSA provides extensive communication to the sector on the supervision strategy, its objectives and the supervision plans. It answers all queries and develops communication actions with proactive attitude. The NSA has developed a communication strategy.</p> <p>D. Delivering the supervision activities As for Level 3, plus: The NSA adequately delivers planned supervision activities and regularly reviews the supervision outputs to check their adequacy and if needed, the NSA takes corrective actions.</p> <p>E. Outcomes of the supervision activities As for Level 3, plus: The NSA regularly reviews the way it shares information and gives reasons for decisions. The NSA has an overview of the safety performance level and reviews it. It uses tools to support this such as the ERA management maturity level (or similar tools). The NSA uses and shares information on the performance of the SMS for SSC and SA and review the way it is done. The NSA takes proportionate enforcement actions and reviews these. The NSA has an enforcement strategy.</p>

	<p>F. Reviewing the supervision activities As for Level 3, plus: The NSA performs checks and may take corrective actions.</p> <p>G. Competence As for Level 3, plus: The NSA regularly reviews the competence of its staff and its Competence Management System and takes correctives actions.</p> <p>H. Decision Making As for Level 3, plus: The NSA regularly reviews its decision-making criteria and its complaint procedure (e.g. internal review, feedbacks from the sector, etc.)</p> <p>I. Coordination and cooperation As for Level 3, plus: The NSA regularly checks and reviews with the relevant NSAs the coordinated supervision approach for the supervision of IM with cross-border infrastructure and the joint supervision. It also checks and reviews with the relevant authorities or bodies the cooperation arrangement with NIBs, certification bodies for ECM and other competence authorities or bodies.</p> <p>J. Reporting to the Agency As for level 3, plus: The NSA regularly checks and reviews that its reporting in the NSA annual report and to the Agency when acting as authorising entity.</p>
<p>5 Improved</p>	<p>A. Structured and auditable process As for Level 4, plus: The NSA strives to continuously improve the supervision process for it to be more effective and efficient.</p> <p>B. Supervision strategy and plan As for Level 4, plus: The NSA continuously strives to improve its supervision strategy and plan and it is also constantly looking at emerging trends which could affect its supervision activities (e.g. safety culture, ERTMS implementation).</p> <p>C. Communicating the plan As for Level 4, plus: The NSA effectively and efficiently communicates its supervision strategy and plan to the sector. It continuously improves its communication strategy.</p> <p>D. Delivering the supervision activities As for Level 4, plus: The NSA continuously strives to improve the effectiveness and efficiency of the supervision activities.</p> <p>E. Outcomes of the supervision activities As for Level 4, plus: The NSA strives to continuously improve the effectiveness and efficiency of the outcomes of its supervision activities. For example, NSA improves its information sharing, its overview of the safety performance and its enforcement actions.</p> <p>F. Reviewing the supervision activities As for Level 4, plus: The NSA strives to continuously improve the review of the supervision activities.</p> <p>G. Competence As for Level 4, plus: The NSA continuously strives to improve the competence of its staff and its Competence Management system. In particular, the NSA tries to anticipate on future work evolution in order to update staff competence matching those future evolutions.</p> <p>H. Decision Making As for Level 4, plus: The NSA continuously strives to improve its decision-making criteria and its complaint procedure.</p> <p>I. Coordination and cooperation As for level 4, plus: the NSA continuously strives to improve its coordination and cooperation arrangements.</p>

	<p>J. Reporting to the Agency As for level 4, plus: The NSA continuously strives to improve its reporting in the NSA annual report and to the Agency when acting as authorising entity.</p>
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10. NSA tasks relating to ECM

Element 10 NSA tasks relating to ECM	
<p>1 Ad hoc</p>	<p>A. NSA designated as ECM certification body 1. The NSA does not meet the criteria defined in ECM Accreditation scheme ERA 1172/002 V3.1 and Annex I Regulation 2019/779 (e.g. organisation, independence, competence, impartiality, responsibility, openness, confidentiality, responsiveness to complaints, liability and financing). 2. The NSA, acting as certification body, does not deliver the two types of certification (ECM certificate and maintenance functions certificates) as defined in the Regulation (EU) 2019/779 and in the ECM certification scheme (version 1172/003 V1.1). 3. The NSA, acting as certification body, does not identify each decision on certification with the European Identification Number (EIN).</p> <p>B. Assessment team When acting as certification body, the NSA staff (assessment team) performing the certification of Entities in Charge of Maintenance and/or outsourced maintenance functions does not have, as a team, all the competences as required by the Sectorial accreditation/recognition scheme ERA 1172/002 V3.1:</p> <ul style="list-style-type: none"> - Knowledge of the European railway sector - Knowledge and skills addressing the maintenance of railway vehicle - Knowledge and skills addressing assessment principles, practices and techniques and knowledge of the specific standards related to them. - Language skills in accordance with the country of ECMs <p>C. Certification committee When acting as certification body, the NSA staff (certification committee) performing the certification of Entities in Charge of Maintenance and/or outsourced maintenance functions does not have, as a team, all the competences as required by the Sectorial accreditation/recognition scheme ERA 1172/002 V3.1:</p> <ul style="list-style-type: none"> - Knowledge of the European railway sector - Knowledge and skills addressing the maintenance of railway vehicles - Knowledge and skills addressing assessment principles, practices and techniques and knowledge of specific standards - Language skills in accordance with the country of ECMs <p>The members of the certification committee are not different from the members of the assessment team.</p> <p>D. Activity Report The NSA acting as certification body does not deliver an activity report every 3 years to the Agency.</p> <p>E. Surveillance The NSA acting as certification body does not verify the fulfilment of the requirements set out in Regulation (EU)2019/779, Annex II conducting site visits at least once every 12 months counting from the date of issuing the certificate.</p>

	<p>F. Requirements to be used by the NSA acting as recognition body The NSA, to recognise certification bodies, does not apply the sectorial scheme for accreditation-ERA-1172-002 V3-1. The NSA does not inform the Agency via ERADIS of the names of the recognised ECM certification bodies.</p>
<p style="text-align: center;">2 Initialising</p>	<p>A. NSA designated as ECM certification body</p> <ol style="list-style-type: none"> 1. The NSA partly meets the criteria defined in ECM Accreditation scheme ERA 1172/002 V3.1 and Annex I Regulation 2019/779 (e.g. organisation, independence, competence, impartiality, responsibility, openness, confidentiality, responsiveness to complaints, liability and financing). 2. The NSA, acting as certification body, delivers in some cases the two types of certification (ECM certificate and maintenance functions certificates) as defined in the Regulation (EU) 2019/779 and in the ECM certification scheme (version 1172/003 V1.1). 3. The NSA, acting as certification body, identifies in some decisions on certification with the European Identification Number (EIN). <p>B. Assessment team When acting as certification body, the NSA staff (assessment team) performing the certification of Entities in Charge of Maintenance and/or outsourced maintenance functions has, as a team, some of the competences as required by the Sectorial accreditation/recognition scheme ERA 1172/002 V3.1:</p> <ul style="list-style-type: none"> - Knowledge of the European railway sector - Knowledge and skills addressing the maintenance of railway vehicle - Knowledge and skills addressing assessment principles, practices and techniques and knowledge of the specific standards related to them. - Language skills in accordance with the country of ECMs <p>C. Certification committee When acting as certification body, the NSA staff (certification committee) performing the certification of Entities in Charge of Maintenance and/or outsourced maintenance functions has, as a team, some of the competences as required by the Sectorial accreditation/recognition scheme ERA 1172/002 V3.1:</p> <ul style="list-style-type: none"> - Knowledge of the European railway sector - Knowledge and skills addressing the maintenance of railway vehicle - Knowledge and skills addressing assessment principles, practices and techniques and knowledge of the specific standards related to them. - Language skills in accordance with the country of ECMs <p>The members of the certification committee are not systematically different from the members of the assessment team.</p> <p>D. Activity Report The NSA acting as certification body does not deliver as required an activity report every 3 years to the Agency.</p> <p>E. Surveillance The NSA acting as certification body sometimes verifies the fulfilment of the requirements set out in Regulation (EU)2019/779, Annex II conducting site visits at least once every 12 months counting from the date of issuing the certificate. But this is not done systematically.</p> <p>F. Requirements to be used by the NSA acting as recognition body The NSA, to recognise certification bodies, does not fully apply the sectorial scheme for accreditation-ERA-1172-002 V3-1. The NSA does not systematically inform the Agency via ERADIS of the names of the recognised ECM certification bodies.</p>

<p>3</p> <p>Implementing</p>	<p>A. NSA designated as ECM certification body</p> <ol style="list-style-type: none"> 1. The NSA meets the criteria defined in ECM Accreditation scheme ERA 1172/002 V3.1 and Annex I Regulation 2019/779 (e.g. organisation, independence, competence, impartiality, responsibility, openness, confidentiality, responsiveness to complaints, liability and financing) and it has developed relevant processes to ensure this. 2. The NSA, acting as certification body, delivers the two types of certification (ECM certificate and maintenance functions certificates) as defined in the Regulation (EU) 2019/779 and in the ECM certification scheme (version 1172/003 V1.1) and it has developed relevant processes for delivery. 3. The NSA, acting as certification body, identifies its decisions on certification with the European Identification Number (EIN). <p>B. Assessment team</p> <p>When acting as certification body, the NSA staff (assessment team) performing the certification of Entities in Charge of Maintenance and/or outsourced maintenance functions has, as a team, the competences as required by the Sectorial accreditation/recognition scheme ERA 1172/002 V3.1:</p> <ul style="list-style-type: none"> - Knowledge of the European railway sector - Knowledge and skills addressing the maintenance of railway vehicle - Knowledge and skills addressing assessment principles, practices and techniques and knowledge of the specific standards related to them. - Language skills in accordance with the country of ECMs <p>The NSA has a competence management system and processes in place to ensure that these competences requirements as ECM certification body are met.</p> <p>C. Certification Committee</p> <p>When acting as certification body, the NSA staff (certification committee) performing the certification of Entities in Charge of Maintenance and/or outsourced maintenance functions has, as a team, the competences as required by the Sectorial accreditation/recognition scheme ERA 1172/002 V3.1:</p> <ul style="list-style-type: none"> - Knowledge of the European railway sector - Knowledge and skills addressing the maintenance of railway vehicle - Knowledge and skills addressing assessment principles, practices and techniques and knowledge of the specific standards related to them. - Language skills in accordance with the country of ECMs <p>The NSA has a competence management system and processes in place to ensure that these competences requirements as ECM certification body are met.</p> <p>Members from the certification committee and the assessment team are different and there is a process to ensure this.</p> <p>D. Activity Report</p> <p>The NSA acting as certification body delivers as required an activity report every 3 years to the Agency and it has developed a process to ensure this.</p> <p>E. Surveillance</p> <p>The NSA acting as certification body verifies the fulfilment of the requirements set out in Regulation (EU)2019/779, Annex II conducting site visits at least once every 12 months counting from the date of issuing the certificate. The NSA has developed a process to ensure that the surveillance is systematically done.</p> <p>F. Requirements to be used by the NSA acting as recognition body</p> <p>The NSA, to recognise certification bodies, applies the sectorial scheme for accreditation-ERA-1172-002 V3-1. The NSA informs the Agency via ERADIS of the names of the recognised ECM certification bodies. The NSA has established processes to perform its tasks as recognition body.</p>
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<p style="text-align: center;">4</p> <p style="text-align: center;">Managing</p>	<p>A. NSA designated as ECM certification body As for Level 3, plus The NSA takes corrective actions when needed and regularly checks and reviews its processes to ensure that:</p> <ol style="list-style-type: none"> 1. It meets the criteria defined in ECM Accreditation scheme ERA 1172/002 V3.1 and Annex I Regulation 2019/779. 2. It adequately delivers the two types of certification (ECM certificate and maintenance functions certificates). 3. It adequately identifies its decisions on certification with the European Identification Number (EIN). <p>B. Assessment team As for Level 3, plus The NSA takes corrective actions when needed and regularly checks and reviews its competence management system and processes to ensure that competence requirements of the assessment team of the NSA acting as ECM certification body are met.</p> <p>C. Certification committee As for Level 3, plus The NSA takes corrective actions when needed and regularly checks and reviews</p> <ul style="list-style-type: none"> - its competence management system and processes to ensure that competence requirements of the certification committee of the NSA acting as ECM certification body are met. - its process to ensure that the certification committee members and the members from the certification committee. <p>D. Activity Report As for Level 3, plus: The NSA takes corrective actions when needed to improve its reporting. It regularly checks and reviews its reporting process for improvement.</p> <p>E. Surveillance As for Level 3, plus: The NSA takes corrective actions when needed to improve its surveillance activities. It regularly checks and reviews its surveillance process for improvement.</p> <p>F. Requirements to be used by the NSA acting as recognition body As for Level 3, plus: The NSA takes corrective actions when needed to improve the performance of its tasks as recognition body. It regularly checks and reviews its relevant processes to act as recognition body for improvement.</p>
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<p style="text-align: center;">5</p> <p style="text-align: center;">Improved</p>	<p>A. NSA designated as ECM certification body As for Level 4, plus The NSA continuously strives to improve its processes to ensure that:</p> <ol style="list-style-type: none"> 1. It meets the criteria defined in ECM Accreditation scheme ERA 1172/002 V3.1 and Annex I Regulation 2019/779. 2. It adequately delivers the two types of certification (ECM certificate and maintenance functions certificates) 3. It adequately identifies its decisions on certification with the European Identification Number (EIN). <p>B. Assessment team As for Level 4, plus The NSA continuously strives to improve its competence management system and processes to ensure that competence requirements of the assessment team of the NSA acting as ECM certification body are met.</p> <p>C. Certification Committee As for Level 4, plus The NSA continuously strives to improve</p> <ul style="list-style-type: none"> - its competence management system and processes to ensure that competence requirements of the certification committee of the NSA acting as ECM certification body are met. - its process to ensure that the certification committee members and the members from the certification committee. <p>D. Activity Report As for Level 4, plus: The NSA continuously strives to improve its reporting (e.g. it performs benchmarking).</p> <p>E. Surveillance As for Level 4, plus: The NSA continuously strives to improve its surveillance activities.</p> <p>F. Requirements to be used by the NSA acting as recognition body As for Level 4, plus: The NSA continuously strives to improve its tasks as recognition body.</p>
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11. Train Drivers

Element 11: Train drivers	
<p>1 Ad hoc</p>	<p>A. Issuance of a licence and sanctions Licences are issued to train drivers but no clear procedure has been developed so that it is not transparent for relevant stakeholders how to apply to get a licence. If more stringent requirements are applied, licences issued in other Member State need to fulfil additional requirements to get recognized. No anti-fraud measures nor penalties rules in case of infringement to the licensing scheme have been adopted. Suspension and withdrawal of licence is applied without clear criteria and on a case-by-case basis and no appeal procedure has been developed related to the issuance of a licence.</p> <p>B. Recognition/accreditation and register In case where the national legislation provides that the NSA is the competent authority: No criteria for recognition of relevant stakeholders (training centers, examiners, medical doctors, psychologists) have been developed. The recognition procedure is not existing. The various registers are not updated and does not contain the relevant information while the list of recognised bodies is not publicly available.</p> <p>C. Training/examination EU requirements are not integrated in the training scheme and applied.</p> <p>D. Quality system No quality system has been set up.</p> <p>E. Supervision No measure is set up to monitor the drivers’ certification process. There is never any onboard controls on the train drivers’ documentation. In case of delegation of tasks, the NSA does not ensure compliance with provisions of Art 19 2. – 6 of Directive 2007/59/EC.</p>
<p>2 Initialising</p>	<p>A. Issuance of a licence and sanctions A procedure to issue licences is set up but is not clearly communicated and transparent to all relevant stakeholders. If more stringent requirements are applied, licences issued in other Member States are recognized but the NSA regularly requests more information. Anti-fraud measures and penalties rules in case of infringement to the licensing scheme are adopted but are not always applied consistently. A procedure of suspension and withdrawal has been developed but is not applied consistently. The appeal procedure related to the issuance of a licence exists but is not clearly communicated to the relevant stakeholders.</p> <p>B. Recognition/accreditation and register In case where the national legislation provides that the NSA is the competent authority: Criteria for recognition of relevant stakeholders (training centers, examiners, medical doctors, psychologists) are developed but not for all stakeholders and not necessarily following the commission decision 2011/765/EU. A procedure of recognition is established following the Commission recommendation 2011/766/EU but is not used consistently. The list of recognised bodies is published but some parts of the information are not accessible.</p>

	<p>Register exists, contains the relevant information and is rightfully updated. However, staff of the NSA does not know the Internal Market Information system. Information is provided to the train driver when they so request it but it is not clear how to request information.</p> <p>C. Training/examination EU requirements are not fully integrated in the training scheme and applied.</p> <p>D. Quality system The NSA started to establish a quality system and a monitoring plan but the processes are not yet fully implemented.</p> <p>E. Supervision Some measures are set up to monitor the drivers’ certification process, but it may not be fully applied and monitored. There are some onboard controls of train drivers’ documentation but they are not incorporated into a structured inspection plan. In case of delegation of tasks, the NSA attempts to ensure compliance with provisions of Art 19 2. – 6 of Directive 2007/59/EC. But the delegation is not fully managed and controlled.</p>
<p style="text-align: center;">3 Implementing</p>	<p>A. Issuance of a licence and sanctions A procedure to issue licences is set up and is clearly communicated and transparent to all relevant stakeholders. If more stringent requirements are applied, it does not impact the recognition of licences issued in other Member State. Anti-fraud measures are adopted and applied. A procedure of suspension and withdrawal is developed and applied. A procedure to review the decision of the NSA (appeal procedure) related to the issuance of a licence exists. Penalties rules in case of infringement to the licensing scheme are established and used appropriately.</p> <p>B. Recognition/ accreditation and register In case where the national legislation provides that the NSA is the competent authority: Criteria for recognition are developed following the commission decision 2011/765/EU. A procedure of recognition is established following the Commission recommendation 2011/766/EU. The list of recognised bodies is published and accessible. Register exists, contains the relevant information and is rightfully updated. Knowledge about Internal Market Information system and use it appropriately. Information is provided to the train driver when they so request it.</p> <p>C. Training/examination EU requirements are fully integrated in the training scheme and applied.</p> <p>D. Quality system A quality system is set up with a monitoring plan developed.</p> <p>E. Supervision Measures are set up to monitor the drivers’ certification process which is applied and monitored. An inspection plan is established when train drivers’ documentation check onboard are organised. In case of delegation of tasks, the NSA ensures compliance with provisions of Art 19 2. – 6 of Directive 2007/59/EC. The delegation is not fully managed and controlled.</p>
	<p>A. Issuance of a licence and sanctions As for Level 3, plus: the procedure to deliver licences is checked and reviewed. The anti-fraud measures, the procedure of suspension and withdrawal, the appeal procedure and the penalties rules in case of infringement to the licensing scheme are regularly reviewed.</p>

<p style="text-align: center;">4</p> <p style="text-align: center;">Managing</p>	<p>B. Recognition/ accreditation and register As for Level 3, plus: In case where the national legislation provides that the NSA is the competent authority: The procedure of recognition and its criteria and regularly reviewed. The register is updated and improvement to the system are looked for.</p> <p>C. Training/examination As for Level 3, plus: The training scheme is checked and reviewed.</p> <p>D. Quality system As for Level 3, plus: The quality system and monitoring plan are regularly reviewed.</p> <p>E. Supervision As for Level 3, plus: Measures and plans are regularly reviewed. If relevant, delegation of tasks and performance of delegated tasks are regularly checked and reviewed.</p>
<p style="text-align: center;">5</p> <p style="text-align: center;">Improving</p>	<p>A. Issuance of a licence and sanctions As for Level 4, plus: The NSA is proactively organizing exchanges with the stakeholders to receive feedback on the procedures to seek better ways to deliver its tasks. The effect of sanctions are monitored and analysed in a structured way to check whether they are meeting the objectives.</p> <p>B. Recognition/accreditation and register As for Level 4, plus: The NSA regularly exchanges with other NSAs on the information contained in the register for continuous improvement.</p> <p>C. Training/examination As for Level 4, plus: The NSA seeks for continuous improvement of the training scheme.</p> <p>D. Quality system As for Level 4, plus: The activities associated with training, the assessment of skills and the updating of licences and certificates are subject of continuous monitoring and improvements are regularly adopted.</p> <p>F. Supervision As for Level 4, plus: Measures and plans are continuously monitored. If relevant, delegation of tasks and performance of delegated tasks are continuously monitored.</p>

12. Promotion of the safety regulatory framework

Element 12: Development of the safety regulatory framework	
1 Ad hoc	<p>A. Promote and contribute The NSA has no appropriate means to monitor the evolution of the safety regulatory framework. The NSA does not participate neither actively nor passively to the development of the safety regulatory framework nor to its promotion. The NSA maintains very basic relationship with all relevant stakeholders and interested parties.</p> <p>B. Coordinate and cooperate The NSA has no cooperation arrangements with NIBs, certification bodies for ECM and other competent authorities. The NSA does not share information with these bodies and does not coordinate its response, if any, to any failure to comply with the safety regulatory framework.</p>
2 Initialising	<p>A. Promote and contribute The NSA monitors the safety regulatory framework but does not disseminate the information to the staff in a structured way. The NSA organizes some communication on the safety regulatory framework and its view on it to the relevant stakeholders (emails/letters sent, ad hoc even organized) but this communication is not integrated in a structured plan. When requested, the NSA participates to the development of the safety regulatory framework including the system of national rules. In this case, the NSA organizes ad hoc consultation with some relevant stakeholders.</p> <p>B. Coordinate and cooperate The NSA has no formal cooperation arrangements with NIBs, certification bodies for ECM and other competent authorities but the NSA shares information. The NSA also communicates its response to any failure to comply with the safety regulatory framework with relevant organisations.</p>
3 Implementing	<p>A. Promotes and contribute The NSA monitors, promotes and where appropriate develops the safety regulatory framework including the system of national rules. In practice, the NSA has a process and can show that it provides information and guidance about the safety regulatory framework to the sector, that rules are shared, that lessons learnt from safety recommendations are shared, that it provides guidance and support to individual stakeholders when needed. In its process, the NSA consults all stakeholders and interested parties, including IMs, RUs, manufacturers and maintenance providers, users and staff representatives. The promotion of the safety regulatory framework is planned and based on yearly priorities. The NSA publishes and communicates to relevant stakeholders its views on the effectiveness of the safety regulatory framework. The NSA contributes when necessary with its views and any proposals to its Member State to overcome any deficiencies in the safety regulatory framework</p> <p>B. Coordinate and cooperate The NSA has cooperation arrangements with NIBs, certification bodies for ECM and other competent authorities in order to share information and to coordinate their response to any failure to comply with the safety regulatory framework.</p>
4 Managing	<p>A. Promote and contribute As for Level 3, plus: The NSA review how well its promotion on the safety regulatory framework is positively received by the relevant stakeholders. It proactively communicates its view to its Member State to overcome any deficiency detected in the safety regulatory framework.</p> <p>B. Coordinate and cooperate</p>

	As for Level 3, plus: The cooperation agreements are regularly reviewed to include any emerging topics in the framework of sharing information.
5 Improved	A. Promote and contribute As for Level 4, plus: The NSA establishes clear priorities to foster the implementation within its Member State. The NSA anticipates future legal evolution and gathers the relevant stakeholders to prepare them and exchange on emerging topics. B. Coordinate and cooperate As for Level 4, plus: The NSA coordinates with the relevant organisations to improve working relationships and seek ways to deliver its tasks in a better, more effective and efficient way.