

Moving Europe towards a sustainable and safe  
railway system without frontiers.

## Annex III bis

### *NSA Monitoring – Referential compliance audit*

This document is the reference document to be used to perform a compliance audit.

## 1. Method

To evaluate the capacity and the effectiveness of the NSA to perform and to take decisions, the audit team assesses whether the requirements listed below are met or not and whether the extent of deviation from the expected level constitutes an observation or a deficiency<sup>1</sup>. The audit team considers the context of the audited NSA, the outputs of the NSA activities (e.g. issued safety certificates and authorisations, supervision activities performed, etc.) and how the NSA is organised to deliver its “*performance and decision-making*” (Art. 33 of Regulation 2016/796). Documented evidence will be examined.

Below, the proposed list covers only the EU legislation currently in force. ERA will alter this referential in the future to reflect the changing legislative base over the next few years. The list will be updated at regular intervals as the legal base changes over the next few years. In order to avoid any gap in the applied referential, references to the legal texts shall be considered as dynamic<sup>2</sup>. For monitoring of NSAs in EEA EFTA States, the application of this referential will be adapted to EU/EEA legislation in force.

In some cases, the legal requirement is addressed to the Member States and not to the NSA. These are nevertheless mentioned when the provision has an important impact on the NSA. (For example, the Member State shall establish an NSA). The table below should not be read as granting additional responsibilities to NSA compared to those of the EU legal framework.

Complete texts are not quoted due to lack of space, only key provisions are listed.

The referential is organised by thematic set of criteria:

- General – NSA organisation
- NSA reporting
- NSA tasks on safety certification
- NSA tasks on safety authorisation
- NSA tasks on authorisation for the placing in service of fixed installation
- NSA tasks on vehicle authorisation for placing on the market and vehicle type authorisation
- NSA tasks on supervision
- NSA tasks on promoting the regulatory framework
- NSA tasks on recognition of AsBos or NSA acting as AsBo
- NSA tasks on train drivers directive
- NSA tasks relating to ECM
- NSA tasks when appointed as Notifying Authority for the assessment, notification and monitoring of CABs (NoBos)

---

<sup>1</sup> See Annex II – NSA Monitoring - Audit procedure.

<sup>2</sup> There will be some safety certificates which have been granted by an NSA before transposition of the new Directive has taken place which will expire afterwards. In such situations for the purposes of Monitoring Supervision ERA will take into account that the legal framework under which Supervision takes place until the expiration of such certificates will be that of the 3rd Railway Package and its associated regulations. In the most extreme case this means that a Certificate granted on 15th June 2020 for 5 years would not expire until 15th June 2025. During this period Supervision will need to be carried out under the arrangements set out in the CSM 1077/2010 and against the Conformity Assessment Criteria set out in 1158/2010.



2. Detailed set of criteria

EU legal framework for NSA organisation		
Topics	Legal requirements	Criteria
<p><b>The NSA is established and is organised and it manages its staff/resources competences in order to deliver its tasks</b></p> <p><i>These criteria are also applicable to all NSA processes detailed below.</i></p>	<p>RSD 2016/798, Art. 16 and 17 Reg. 2018/761, Art. 6.3 (a) to (c) Reg. 2018/763, Art. 13.2</p>	<ol style="list-style-type: none"> <li>1 Resources (staff and financial) are allocated to the tasks specified in Article 16 (2) and Article 17.</li> <li>2. Responsibilities for managing the tasks are in place.</li> <li>3. Staff are allocated to specific tasks and trained and managed.</li> <li>4. There is guidance for staff on the delivery of the NSA tasks.</li> <li>5. The NSA ensures that its staff has relevant experience                         <ol style="list-style-type: none"> <li>a/ knowledge of the relevant regulatory framework as it applies to specified tasks</li> <li>b/ knowledge of the functioning of the railway system</li> </ol> </li> <li>6. The national safety authorities put in place a competence management system which includes:                         <ol style="list-style-type: none"> <li>a/ the development of competence profiles for each job, position or role</li> <li>b/ the recruitment of staff in accordance with the established competence profiles</li> <li>c/ the maintenance, development and assessment of staff competence in accordance with the established competence profiles</li> <li>d/ in the case of teamwork, the competences may be shared amongst the team members for SC and SUP:</li> <li>e/ staff carrying out visits, inspections and audits shall also demonstrate knowledge of, and experience in interviewing skills.</li> </ol> </li> <li>7. The NSA has staff processes to manage competences needed in order to undertake the NSA tasks.</li> </ol>
<p><b>The NSA is independent</b></p> <p>These criteria are also applicable to the various all NSA processes detailed below.</p>	<p>RSD 2016/798, Art. 16</p>	<ol style="list-style-type: none"> <li>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. Provided that such independence is guaranteed, that authority may be a department within the national ministry responsible for transport matters or any other government department.</li> <li>2. The NSA has the necessary internal and external organisational capacity in terms of human and material resources.</li> <li>3. The independence of the NSA organisation and the NSA staff towards the industry is ensured (sufficient resources, absence of conflict of interest, internal process).</li> <li>4. Staff are aware of and follow the requirements. Conflict of</li> </ol>



		<p>interests are identified and dealt with.</p> <p>5. The legislation is consistently applied, monitored and reviewed to ensure it meets the requirements. In cases where it is not applied, appropriate action is taken by the MS.</p> <p>6. NSA tasks listed under Article 16 (2) of the Railway Safety Directive may not be transferred or subcontracted to any IM, RU or contracting entity. If technical assistance is requested from the RU, IM or procurement authority, the NSA needs to show that this does not affect its independence; and the assistance does not involve making any decisions on behalf of the NSA.</p>
<p><b>The NSA takes decisions in line with decision making principles</b></p> <p>These criteria are also applicable to the various NSA processes.</p>	<p>RSD 2016/798, Art. 18 Reg 2018/763, Annex II, 5 decision-making</p>	<ol style="list-style-type: none"> <li>1. The NSA carries out its tasks in an open, non-discriminatory and transparent way.</li> <li>2. The NSA decisions and actions are continuously verified, monitored and reviewed to ensure that they remain open and transparent, and are applied in a non-discriminatory way.</li> <li>3. The NSA allows all parties to be heard and it gives reasons for its decisions.</li> <li>4. The legislation (or process) ensures that all parties can be heard and that the NSA gives reasons for its decisions is continually monitored and reviewed to ensure that it meets the requirements.</li> <li>5. Staff are aware of and follow the requirements in relation to ensure that decisions are open, transparent and applied in a non-discriminatory way.</li> <li>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. This is monitored and reviewed to ensure it is correctly applied and meets the requirements.</li> <li>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 is monitored and reviewed to ensure that it is correctly applied and it meets the requirements.</li> <li>8. Applicants are given enough help and guidance in order for them to know what is expected from them.</li> <li>9. The NSA publishes any necessary information for the RU/IM/ECM/training centers on how it carries out its activities.</li> <li>10. RUs/IMs/ECM/training centers informed as early as possible about any problem or deficiencies.</li> <li>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.</li> <li>12. The NSA is free to carry out all inspections, audits and</li> </ol>



		<p>investigations that are needed for the accomplishment of its tasks and it is 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.</p> <p>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>
<p><b>The NSA coordinates and cooperates</b></p>	<p>RSD 2016/798, Art. 18(4)</p>	<p>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 can show its active involvement in the NSA Network or it can show that it shares urgent safety-relevant information with relevant parties.</p> <p>2. The NSA can show how this 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>

EU legal framework for NSA reporting		
Topics	Legal requirements	Criteria
<b>Reporting CSIs</b>	RSD (EU) 2016/798 Article 5 and 19 (a)	<ol style="list-style-type: none"> <li>1. CSIs are collected in the Member State by the NSA.</li> <li>2. The definitions used for the CSIs are consistent with the ones stated in the Annex I of the Directive (EU) 2016/798.</li> <li>3. The operational scope of the CSIs refers to train operations and shunting.</li> </ol> <p>The year N report includes data from year N-1.</p>
<b>Production and delivery of the Annual Report</b>	RSD (EU) 2016/798 Article 16 and Article 19	<ol style="list-style-type: none"> <li>1. The NSA is regularly producing and delivering the annual report sending it to the Agency by 30 September of each year.</li> <li>2. The Annual report shall include information concerning NSA activities in the preceding year.</li> <li>3. The annual report shall include information on the development of railway safety, including an aggregation at Member State level of the CSIs in accordance with art 5 (1) and Annex 1 of Directive (EU) 2016/798.</li> <li>4. The annual report shall include information on important changes in legislation and regulation concerning railway safety (if any).</li> <li>5. The annual report shall include information on the development of safety certification and safety authorisation.</li> <li>6. The annual report shall include information on results of and experience relating to the supervision of infrastructure managers and railway undertakings;</li> <li>7. The annual report shall include information on the derogations (if any) that have been decided in accordance with Article 15 of Directive (EU) 2016/798 (Alternative measures to certify ECMs).</li> <li>8. The annual report shall include information on the experience of the railway undertakings and infrastructure managers on the application of the relevant CSMs.</li> </ol>
<b>Reporting on the application of the CSM for Monitoring Regulation (EU) 1078/2012</b>	RSD (EU) 2016/798 Article 19 (f)	<ol style="list-style-type: none"> <li>1. Each national safety authority shall report, in its annual safety report referred to 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.</li> </ol>
<b>Reporting on the CSM for Risk Evaluation and Assessment</b>	RSD (EU) 2016/798 Article 19 (f)	<ol style="list-style-type: none"> <li>1. Each national safety authority shall report, in its annual safety report referred to 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.</li> </ol>



<b>(Regulation (EU) 402/2013)</b>		
<b>Reporting on the CSM on Safety Management System Requirements (Regulation (EU) 2018/762)</b>	RSD (EU) 2016/798 Article 19 (f)	1. Each national safety authority shall report, in its annual safety report referred to Article 19 of Directive (EU) 2016/798, on the experience of the application of this Regulation, and, where appropriate, its own experience.

EU legal framework for Safety Certification 4th RP		
Topics	Legal requirements	Criteria
<b>General</b>	Reg 2016/798, Art. 10 and 11 Reg 2018/763, Annex II Reg 2018/763, Art. 13 Reg 2018/763, Art. 3 Reg. 2018/762 Commission Recommendation 2019/780 Competences: Reg. 2018/763, Art. 13; Commission Recommendation 2019/780, points 35-36).	<ol style="list-style-type: none"> <li>1. The NSA, whether safety certification body or not, has a structured and auditable process for the complete activity. The safety assessment process shall be iterative (See Appendix of Reg. 2018/763).</li> <li>2. The NSA has a process and establishes internal arrangements or procedures for managing the safety assessment process against the Requirements of the relevant CSM.</li> <li>3. The NSA checks its own performance for the process in 1 above.</li> <li>4. The NSA process referred to in 1 above is periodically reviewed.</li> <li>5. The process in 1 above is appropriate to the risks, character and extent of the operations of individual applicants.</li> <li>6. The process in 1 above is based on the overall capability of the applicant to operate safely as described in its SMS.</li> <li>7. Safety Certificates are issued using OSS and the required templates.</li> <li>8. The NSA ensures that staff involved in assessments have the required competences as described in Reg. 2018/763.</li> <li>9. The NSA, acting as the safety certification body or when delivering safety authorisation, is responsible for the planning implementation and monitoring of the assessment works it carries out. In case it is safety certification body, it is also responsible for the setting up of coordination arrangements which are necessary.</li> <li>10. The NSA application Guide explains 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.</li> <li>11. The NSA should in its guide specify what are the Border Stations and what requirements it will apply to those stations within its own territory.</li> </ol>
<b>Pre-engagement, receipt of the application and initial screen</b>	Reg 2018/763, Annex II and Art. 6 Annex II, 3, Initial screen	<ol style="list-style-type: none"> <li>1. The process for the scrutiny of Safety Certificate applications is capable of being completed within the timescale set out in Reg 2018/763, Art. 6 and Annex II./ Commission Recommendation 2019/780.</li> <li>2. When the NSA is acting as the safety certification body, <ul style="list-style-type: none"> <li>- it accepts pre-engagements when requested by the applicant and provides any requested clarification in the context of pre-engagement.</li> <li>- it formally and promptly acknowledges the receipt of the application</li> <li>- it assigns competent resources to deliver the assessment process</li> </ul> </li> </ol>





		<p>It performs an initial screen to check whether there is the basic information, sufficient evidence, sufficient internal cross-references, information from supervision.</p> <p>6. The NSA concerned with the intended area of operation checks that the evidence to the type, extent and intended area of operation is clearly identified.</p> <p>7. When the Agency is the safety certification body, the NSA coordinates with the Agency to decide whether there are areas in which, for their respective part, further information is necessary. If yes, further information may be promptly asked to the extent they deem reasonably necessary to support their assessment.</p> <p>8. The NSA shall review a sufficient sample of the application for its own part, to check that its content is understandable. If it is clearly not, the NSA (when relevant with the Agency as certification body) shall decide for its own part whether it needs to be updated by the applicant where necessary in conjunction with the Agency.</p>
<p><b>Detailed assessment</b></p>	<p>Reg 2018/763, Annex II Art. 6, and Art 10 Annex II, 4, detailed assessment Reg 2018/763, Art 12 – Categorisation of issues Regulation (EU) 2019/773 (STI OPE)</p>	<ol style="list-style-type: none"> <li>1. Where appropriate the NSA shall accept valid certificates of compliance provided by the applicant as evidence that certain SMS requirements are met.</li> <li>2. After the completion of the initial screen, the safety certification body and the NSA concerned with the intended area of operation shall process, each for their own part, the detailed assessment of the application using the SMS requirements, TSI OPE and relevant notified national rules.</li> <li>3. The NSA exercises its professional judgement, is impartial and proportionate, and provides documented reasons for conclusions reached.</li> <li>4. The NSA, either when acting as the certification body or not and in coordination where appropriate with each neighbouring member state shall be authorised to undertake visits and inspections on the sites of the RU and audit as part of the assessment. It may request supplementary information.</li> <li>5. The assessment shall determine whether the safety management system requirements, the TSI OPE and relevant notified national rules are met or whether further information shall be requested. The assessment is based on evidence that the SMS requirements, TSI OPE and relevant notified national rules have been met from the outputs of the SMS processes using where appropriate sampling methods.</li> <li>6. Any type 4 issue shall be resolved to the satisfaction of the certification body (either the Agency or the NSA) and lead to an update of the relevant application file.</li> <li>7. Residual concerns (Type 3 issues) are deferred for consideration to supervision</li> </ol>



		<p>8. The NSA shall be transparent in how it judges the severity of each identified issue. When identifying an issue, it shall be specific and help the applicant understand the level of detail expected in the response. To this end it shall take the steps described in Annex II, 4.7 of Reg. 2018/763.</p> <p>9. The timeframe for taking a decision on issuing the single safety certificate may be extended with the agreement of the applicant and only until the required information has been submitted in the case of type 1 issues, type 4 issues or multiple type 3 issues. The decision is taken with the certification body in coordination with the relevant NSA.</p> <p>10. The NSA either acting as the certification body or not assesses the applicant’s responses, explaining why a response is considered as not satisfactory (where relevant), identifying further information or demonstration required.</p> <p>11. The NSA when acting as the certification body, 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, may take contingency measures.</p> <p>12. The NSA whether acting as the certification body or not, completes the assessment when it is concluded that either the application meets all requirements or that further progress is unlikely in securing satisfactory responses to outstanding matters and in the latter case the NSA takes appropriate action to reject or restrict the application.</p>
<b>Decision-making</b>	Reg 2018/763, Annex II, 5	<p>1. The NSA, when acting as the safety certification body, based on the conclusions of the completed assessment issues a decision whether to issue a single safety certificate or not. It may issue the single safety certificate even if there are some residual concerns, however, all type 4 issues shall be resolved during the assessment.</p> <p>2. The NSA, when acting as the safety certification body may decide to restrict the scope of the single safety certificate by identifying restrictions or conditions of use if these address type 4 issue. The single safety certificate is updated on request of the applicant after all residual concerns have been addressed. Where the NSA is not the certification body, it supports the certification body.</p> <p>3. The NSA as the certification body informs the applicant about its decision and the single safety certificate is issued as appropriate. In case the issue is refused or if the single safety certificate contains restrictions or conditions of use, the NSA informs the applicant, giving reasons for the decision and notifies the procedure to request a review or an appeal against the decision.</p>
<b>Closing assessment</b>	Reg 2018/763, Annex II, 4.1.4 Reg 2018/762	<p>1. It records and justifies in writing all findings and judgements using OSS.</p> <p>2. Decisions on whether to accept or reject applications are based</p>



	Annex I	<p>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, when acting as the certification body, completes the administrative closure by ensuring that all documents and records are reviewed, organised and archived. To continually improve the process it identify historic information and lessons learnt for use by future assessments.</p> <p>3. The process used by the NSA refers to compliance with the requirements of Reg. 2018/761 in supervising an applicant after the award of a Safety Certificate.</p>
<p><b>Specific provisions for the renewal or an update of a single safety certificate</b></p>	<p>Reg 2018/763, Annex II, 7 – Renewal Reg 2018/763, Annex II, 8, update following a substantial change Reg. 402/2013 CSM Risk Assessment</p>	<p>1. In the case of a renewal application (received before the expiry date an existing certificate), the NSA acting as the safety certification body or in its role of addressing the national part of an application, checks details of changes to the evidence submitted in the previous application and considers 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.</p> <p>2. The NSA takes a proportionate approach to the reassessment, based on the level of changes proposed.</p> <p>3. The NSA starts the update process for a safety certificate, when the certification body, receives the notification by an RU of a substantial change proposed to the type and extent of operation or where there is an extension of the area of operation.</p> <p>4. The NSA, when acting as the certification body, checks that the change is clearly described and that the potential risks are assessed and it discusses with the RU the need for an update of the single safety certificate.</p> <p>5. The NSA, either acting as the safety certification body or as the party responsible for the national part, may make further enquiries with the applicant.</p> <p>6. The NSA, when acting as the safety certification body agrees or not whether the change is substantial. When the change is not substantial, it informs the applicant in writing, that in its view an update is not required, keeping a record of the decision and closing the application for an update.</p> <p>7. The NSA, acting as the certification body, checks the update application It checks details of changes to the evidence submitted in the previous application upon which the current certificate was issued; considers the results of past supervision activities; prioritises or targets the relevant SMS requirements and notified national rules to assess the update of the application.</p> <p>9. The NSA when acting as the certification body, after receiving an application for an update completes the assessment but does not extend the validity period of the single safety certificate.</p>



EU legal framework for Safety Authorisation 4th RP		
Topics	Legal requirements	Criteria
<b>General</b>	RSD 2016/798, Art 12 Commission Recommendation 2019/780	<ol style="list-style-type: none"> <li>1. The NSA has a structured and auditable process for the complete activity. The safety assessment process is iterative (See Appendix of Reg. 2018/763).</li> <li>2. The NSA has a process and establishes internal arrangements or procedures for managing the safety assessment process against the requirements of the relevant CSM.</li> <li>3. The NSA checks its own performance for the process in 1 above.</li> <li>4. The NSA process referred to in 1 above is periodically reviewed.</li> <li>5. The process in 1 above is appropriate to the risks, character and extent of the operations of individual applicants.</li> <li>6. The process in 1 above based on the overall capability of the applicant to operate safely as described in its SMS.</li> <li>7. Safety authorisations are issued using the recommended standard model for safety authorisation.</li> <li>8. The NSA ensures that staff involved in assessment have the required competences as described in Rec. 2019/780.</li> <li>9. The NSA is responsible for the planning implementation and monitoring of the assessment works it carries out.</li> <li>10. The NSA application Guide explains clearly the process of safety authorisation for an applicant including where necessary for cross border infrastructure.</li> <li>11. In the case of cross border infrastructure, the competent NSAs shall cooperate in order to issue the SA.</li> </ol>
<b>Pre-engagement, receipt of the application and initial screen</b>	RSD 2016/798, Art 12 Commission Recommendation 2019/780	<ol style="list-style-type: none"> <li>1. The process for the scrutiny of Safety authorisation applications is capable of being completed within the timescale set out in RSD 2016/798, Art 12.</li> <li>2. The NSA accepts pre-engagements when requested by the applicant and provides any requested clarification in the context of pre-engagement. <ul style="list-style-type: none"> <li>- it formally and promptly acknowledges the receipt of the application</li> <li>- it assigns competent resources to deliver the assessment process</li> <li>- it performs for its part an initial screen to check whether there is the basic information, sufficient evidence, sufficient internal cross-references, action plan to resolve non-compliance or residual concerns arising from supervision activities.</li> </ul> </li> <li>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 Reg. 2018/762, in particular its points 1, 5.1, 5.2</li> </ol>



		<p>and 5.5.</p> <p>4. Following the initial screen, the NSA decides if there are any areas in which for its part, further information is needed. If yes, further information may be promptly asked to the extent they deem reasonably necessary to support the assessment.</p> <p>5. The NSA reviews a sufficient sample of the application for its own part, to check that its content is understandable. If it is clearly not, the NSA decides for its own part whether it needs to be returned with a request for an improved version.</p>
<p><b>Detailed assessment</b></p>	<p>RSD 2016/798, Art 12 Commission Recommendation 2019/780 Regulation (EU) 2019/773 (TSI OPE).</p>	<p>1. After the completion of the initial screen, the NSA proceeds with the detailed assessment of the application using the SMS requirements and relevant notified national rules.</p> <p>2. The NSA exercises its professional judgement, is impartial and proportionate, and provides documented reasons for conclusions reached.</p> <p>3. The NSA is authorised to undertake visits and inspections on the sites of the IM and audit. It may request supplementary information.</p> <p>4. The assessment determines whether the safety management system requirements, the TSI OPE and relevant notified national rules are met or whether further information shall be requested. The assessment is based on evidence that the SMS requirements and relevant notified national rules have been met from the outputs of the SMS processes using where appropriate sampling methods.</p> <p>5. Any type 4 issue shall be resolved to the satisfaction of the NSA and lead to an update of the relevant application file.</p> <p>6. Residual concerns (Type 3 issues) are deferred for consideration to supervision.</p> <p>7. The NSA is transparent in how it judges the severity of each identified issue. When identifying an issue, it shall be specific and help the applicant understand the level of detail expected in the response. To this end it shall take the steps described in Annex II, 4.7 of Rec. 2019/780.</p> <p>8. The timeframe for taking a decision on issuing the SA may be extended with the agreement of the applicant and only until the required information has been submitted in the case of type 1 issues, type 4 issues or multiple type 3 issues. The decision is taken with the certification body in coordination with the relevant NSA.</p> <p>9. The NSA assesses the applicant’s responses, explaining why a response is considered as not satisfactory (where relevant), identifying further information or demonstration required.</p> <p>10. The NSA as authorising body, in a case where the application could be rejected or it will take longer time than the allowed timeframe for assessment to reach a decision, may take</p>



		<p>contingency measures.</p> <p>11. The NSA completes the assessment when it is concluded that either the application meets all requirements or that further progress is unlikely in securing satisfactory responses to outstanding matters and in the latter case the NSA takes appropriate action to reject or restrict the application.</p>
<b>Decision-making</b>	Commission Recommendation 2019/780	<p>1. The NSA, based on the conclusions of the completed assessment issues a decision whether to issue SA or not. It may issue the SA even if there are some residual concerns, however, all type 4 issues shall be resolved during the assessment.</p> <p>2. The NSA, may decide to restrict the scope of the SA by identifying restrictions or conditions of use if these address type 4 issues. The SA is updated on request of the applicant after all residual concerns have been addressed.</p> <p>3. The NSA informs the applicant about its decision and the SA is issued as appropriate.</p> <p>In case the issue is refused or if the SA contains restrictions or conditions of use, the NSA informs the applicant, giving reasons for the decision and notifies the procedure to request a review or an appeal against the decision.</p>
<b>Closing assessment</b>	Commission Recommendation 2019/780 Reg 2018/762 Annex I	<p>1. 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>2. The NSA completes the administrative closure by ensuring that all documents and records are reviewed, organised and archived. To continually improve the process it identify historic information and lessons learnt for use by future assessments.</p> <p>3. The process used by the NSA refers to compliance with the requirements of Reg. 2018/761 in supervising an applicant after the award of an SA.</p>
<b>Specific provisions for the renewal or an update of a safety authorisation</b>	RSD 2016/798, Art.12 Commission Recommendation 2019/780 Reg. 402/2013 CSM Risk Assessment	<p>1. In the case of a renewal application (received before the expiry date of validity), the NSA checks details of changes to the evidence submitted in the previous application and considers 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.</p> <p>2. The NSA takes proportionate approach to the reassessment, based on the degree of changes proposed.</p> <p>3. The NSA receives the notification by an IM of a substantial change proposed to the infrastructure, the signaling, any energy supply used in connection with the infrastructure, signaling or energy supply in accordance with Art 12(2) of RSD 2016/798.</p> <p>4. The NSA checks that the change is clearly described and that the potential risks are assessed and it discusses with the IM and the NSA concerned with the intended area of operation the need for an</p>



		<p>update of the SA.</p> <p>5. The NSA may make further enquiries with the applicant.</p> <p>6. The NSA agrees or not whether the change is substantial. When the change is not substantial, it informs the applicant in writing, that in its view an update is not required, keeping a record of the decision and closing the application for an update.</p> <p>7. The NSA checks the update application It checks details of changes to the evidence submitted in the previous application upon which the current authorisation was issued; considers the results of past supervision activities; prioritises or targets the relevant SMS requirements and notified national rules to assess the update of the application.</p> <p>8. The NSA, after receiving an application for an update completes the assessment but does not extend the validity period of the single safety certificate.</p>
--	--	--

**EU legal framework for authorisation for the placing in service of fixed installations**

Topics	Legal requirements	Criteria
<b>General</b>	Directive (EU) 2016/798 Article 16 Directive (EU) 2016/797 Article 18(1)-(3)	1. The NSA issues authorisation for placing in service (APS) of fixed installations before those subsystems are allowed to be placed in service. 2. The NSA has the necessary organisational capacity (resources, competence, processes, procedures etc.) to perform the task to issue APS of fixed installations. 3. The NSA provides to the applicants, free of charge, an application guidance document that contains detailed guidance on how to obtain APS of fixed installations. The application guidance document includes at least: <ul style="list-style-type: none"> <li>- A description and explanation of the requirements for APS for fixed installations; and</li> <li>- A list of the required documents to be provided by the applicant to the NSA.</li> </ul>
<b>Processing the application</b>	Directive (EU) 2016/797 Article 18(1), 18(3)-(5), Regulation (EU) 402/2013 Article 2(3), 4, 5, 15, 16	1. The NSA processes the applications for APS of fixed installations in accordance with the application guidance document provided to the applicants. 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"> <li>- EC Declarations of verification (ECDofV) for the subsystems;</li> <li>- Technical compatibility of the subsystem with the system they are being integrated into on the basis of TSIs, national rules and registers;</li> <li>- Safe integration of the subsystems on the basis of TSIs,</li> </ul>





		<p>national rules and CSMs; and</p> <ul style="list-style-type: none"> <li>- For CCS subsystems including trackside ERTMS equipment the positive decision of the Agency.</li> </ul> <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.</p> <p>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.</p> <p>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.</p> <p>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.</p>
<b>Renewal/upgrading</b>	<p>Directive (EU) 2016/797 Article 18(1), 18(3), 18(6)</p> <p>Regulation (EU) 402/2013 Article 2(3), 4, 5, 15, 16</p>	<p>1. The NSA processes the file for renewal or upgrading of fixed installations in accordance with the application guidance document provided to the applicants.</p> <p>2. The NSA informs the applicant within one month of the receipt of the file that it is complete or asks for relevant supplementary information.</p> <p>3. In case of ERTMS trackside equipment, the NSA cooperates with the Agency when examining the file.</p> <p>4. The criteria applied by the NSA to evaluate if a new authorisation is required, or not, is on the basis of if:</p> <ul style="list-style-type: none"> <li>- The overall safety level may be adversely affected;</li> <li>- It is required by the national implementation plan; and</li> <li>- Changes are made to the values of the parameters on the basis the APS was issued.</li> </ul> <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>
<b>Decision making</b>	<p>Directive (EU) 2016/797 Article 18(1), 18(7)</p> <p>Directive (EU) 2016/798 Article 18(4)</p> <p>Regulation 2016/796 Article 37(3)</p>	<p>1. The decision-making criteria described to the applicant in the application guidance document are applied by the NSA.</p> <p>2. The issued decision is duly substantiated by the NSA.</p> <p>3. The NSA conducts an active exchange of views and experience with other NSAs in order to harmonise their decision-making criteria.</p> <p>4. The NSA checks that ERADIS has been updated as appropriate before delivering the APS for fixed installations.</p>
<b>Review and appeal</b>	<p>Directive (EU) 2016/797 Article</p>	<p>1. The decisions for APS of fixed subsystems are subject to judicial review.</p>



	18(7) Directive (EU) 2016/798 Article 18(3)	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.
<b>Link between supervision and APS of fixed installations</b>	Directive (EU) 2016/798 Article 17(1), 17(7), 17(8) Regulation (EU) 2018/761 Annex I point 2(a)	1. The NSA does supervise that the fixed installation subsystems are in compliance with the essential requirements. 2. The NSA ensures that there is a link between APS of fixed installations and supervision in order to transfer relevant information.

EU legal framework for vehicle authorisation for placing on the market and vehicle type authorisation		
Topics	Legal requirements	Criteria
<b>General</b>	Directive (EU) 2016/798 Article 16 Directive (EU) 2016/797 Article 21(1), 21(4); 21(5), 21(8); 21(14), 21(15), 21(16), 24(1), 24(2), 25 Regulation (EU) 2018/545 Article 4, 7, 12, 35(3)	<ol style="list-style-type: none"> <li>1. The NSA has the necessary organisational capacity to perform the tasks to issue vehicle authorisation for placing on the market, vehicle type authorisation, issue the assessment file to the authorising entity and to provide pre-engagement.</li> <li>2. The NSAs has internal arrangements for managing the issuing of vehicle type authorisations, vehicle authorisation for placing on the market, issue the assessment file to the authorising entity and to provide pre-engagement.</li> <li>3. The NSA has put in place a cooperation agreement with the Agency and when applicable also a multilateral agreement. The internal arrangements of the NSA take into account those agreements.</li> <li>4. The NSA has published and keeps up to date a guideline describing their language policy, communication provisions and when applicable the process for temporary authorisations. The guideline is made available free of charge.</li> <li>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.</li> </ol>
<b>Pre-engagement</b>	Regulation (EU) 2018/545 Article 4(4), 7(3), 22-24	<ol style="list-style-type: none"> <li>1. The NSA provides pre-engagement upon request from the applicant.</li> <li>2. The NSA reviews the pre-engagement application and issues an opinion on the approach proposed by the applicant.</li> </ol>
<b>Changes to an already authorised vehicle</b> <b>Changes to an already authorised vehicle type</b>	Directive (EU) 2016/797 Article 21(12) Regulation (EU) 2018/545 Article 16(4)	<ol style="list-style-type: none"> <li>1. After the NSA, as authorising entity, has been notified of a change it issues, when applicable and within 4 months, a reasoned decision in case of a wrong categorisation of a change or insufficiently substantiated information.</li> </ol>
<b>Processing the application</b>	Directive (EU) 2016/797 Article 21(2) - (5), 21(8), 21(13), 24(1), 24(2), 25 Regulation (EU) 2018/545 Article 32 ; 34 – 42,	<ol style="list-style-type: none"> <li>1. Within one month from the receipt of the application the NSA 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.</li> <li>2. The NSA, when applicable, plans, organises and agrees with other involved NSAs on the necessary arrangements to take into account the classification of national rules.</li> <li>3. The NSA performs its assessment in accordance with Article 39</li> </ol>



	43(3)-(6), 45, Annex I-III	<p>or 40 of Regulation (EU) 2018/545 and issues an assessment file for its scope of the assessment.</p> <p>4. The NSA takes into account information resulting from return of experience in the course of its assessment.</p> <p>5. Issues are recorded and categorised by the NSA 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.</p> <p>6. The NSA as authorising entity checks in an independent manner that the process has been carried out correctly and covers the required aspects.</p>
<b>Decision making and final documentation</b>	<p>Directive (EU) 2016/797 Article 21(4), 21(8), 21(10), 21(11), 24(7), 25(1)</p> <p>Regulation (EU) 2018/545 Article 4(1), 4(5), 4(7), 7(1), 7(2), 45(5), 46 - 50</p>	<p>1. The NSA as authorising entity provides documented reasons for its decision.</p> <p>2. The decision issued by the NSA as authorising entity contains the required information and does 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> <p>3. The NSA as authorising entity checks the consistency of the data provided by the applicant, completes the ERATV entry and makes it available to the public.</p> <p>4. The NSA as authorising entity ensures that ERADIS has been updated as appropriate before delivering a vehicle type authorisation and/or vehicle authorisation for placing on the market.</p>
<b>Review and appeal</b>	<p>Directive (EU) 2016/797 Article 21(7), 21(11)</p> <p>Regulation (EU) 2018/545 Article 46(8), 48(j), 49(k), 51</p>	<p>1. The NSA as authorising entity has an impartial review process in place.</p> <p>2. The timeframe for the review process is 2 months from the receipt of a request for review.</p> <p>3. Vehicle type authorisation and/or vehicle authorisation for placing on the market decisions taken by the NSA are subject to judicial review.</p> <p>4. Decisions to revoke or amend a vehicle type authorisation and/or revoke a vehicle authorisation for placing on the market that are taken by the NSA are subject to judicial review.</p>
<b>Link between supervision and vehicle authorisation for placing on the market and vehicle type authorisation Suspension, revocation and amendment of</b>	<p>Directive (EU) 2016/798 Article 17(1) 17(8)</p> <p>Directive (EU) 2016/797 Article 26</p> <p>Regulation (EU) 2018/545 Article 7(4), 53, 54</p>	<p>1. The NSA ensures that 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 relevant information.</p> <p>2. The NSA as authorising entity ensures that when it takes a decision to revoke, suspend or amend a vehicle type authorisation it updates ERATV and ensures that ERADIS is updated accordingly.</p> <p>3. The NSA ensures that it informs the Agency, the concerned RUs and NSAs when:</p> <ul style="list-style-type: none"> <li>- It becomes aware that a vehicle/vehicle type when used as intended does not meet an applicable essential requirement</li> </ul>



<b>an issued authorisation</b>		- Revokes a vehicle authorisation for placing on the market. 4. The NSA shares information resulting from return of experience with the Agency and all other NSAs.
--------------------------------	--	---

EU legal framework for NSA supervision		
Topics	Legal requirements	Criteria
<b>Structured and auditable process</b>	Dir. 2016/798 Art.16 (2) (i) & (j) & art. 17 Reg. 2018/761, art.3, Annex I, 1. Reg. 2018/761, Annex I, 4.d	<ol style="list-style-type: none"> <li>1. The supervision process is iterative and takes into account the need to continually improve.</li> <li>2. The results of supervision activities are documented.</li> <li>3. The NSA supervision activities pursuant to the relevant CSMs cover all relevant stakeholders and matters such as ECM (where appropriate), training centers, rules for train drivers, trackside, control-command and signalling, energy and infrastructure subsystems ensuring that they are in compliance with the essential requirements.</li> </ol>
<b>Supervision Strategy and Plan</b>	Dir. 2016/798 Art.16 (2) (i) & (j) & art. 17 Dir. 2016/798 Art.26 (2) & (3) Reg. 2018/761, art.4 Reg. 2018/761, Annex I, 2	<ol style="list-style-type: none"> <li>1. There is a Supervision Strategy and Plan which follows the structure of the Annex to the CSM.</li> <li>3. The Strategy and Plan explains how the NSA identifies and targets its activities at the areas of greatest risks taking into consideration various sources including results of past supervision activities and NIB reports and safety recommendations.</li> <li>4. The plan(s) include(s) resources to give effect to the plan(s) and selects the most appropriate technics for the supervision activities.</li> <li>5. The techniques which can be used by the NSAs such as audits and inspections) are described and NSAs explain how they select the most appropriate when planning their supervision activities.</li> </ol>
<b>Communicating the plan</b>	Dir. 2016/798 Art.16 (2) (i) & (j) & art. 17 Reg. 2018/761, Annex I, 3	<ol style="list-style-type: none"> <li>1. The NSA communicates the overall objectives of the supervision strategy and overall explanation of the plan and how it will be undertaken to relevant railway undertakings or infrastructure managers and, where appropriate, more widely to other stakeholders.</li> </ol>
<b>Delivering the supervision activities</b>	Dir. 2016/798 Art.16 (2) (i) & (j) & art. 17 Reg. 2018/761, Annex I, 4. Dir.2016/798, art.18.2 Dir 2007/59, art. 29.1	<ol style="list-style-type: none"> <li>1. The NSA gives effect to the plan.</li> <li>2. The NSA checks the effectiveness of the SMS as a whole.</li> <li>3. The NSA checks the effectiveness of individual or partial elements of the SMS.</li> <li>4. The NSA is free to carry out all inspections, audits and investigations that are needed for the accomplishment of their tasks and is granted access to all relevant documents and to premises, installations and equipment of the stakeholders as needed.</li> </ol>
<b>Outcomes of the supervision activities</b>	Dir. 2016/798 Art.16 (2) (i) & (j) & art. 17 Reg. 2018/761, Annex I, 5 Dir.2016/798,	<ol style="list-style-type: none"> <li>1. The NSA shares the results of its supervision activities with the supervised entities (including non-compliances and good practices).</li> <li>2. The NSA gives reasons for its decisions.</li> <li>3. The NSA has an overview of the safety performance of the individual railway undertakings or infrastructure managers</li> </ol>

	art.18.1	<p>operating in its Member State.</p> <p>4. The NSA publishes and communicates to relevant stakeholders its views on the overall safety performance in the Member State and its views on the effectiveness of the safety regulatory framework.</p> <p>5. The NSA uses and when relevant, shares information on the performance of the safety management system gathered during the supervision for SSC and SA processes including with the Agency.</p> <p>6. The NSA, where appropriate, takes any enforcement actions in a proportionate way.</p>
<b>Reviewing supervision activities</b>	Dir. 2016/798 Art.16 (2) (i) & (j) & art. 17 Reg. 2018/761, Annex I, 5 and 6	1. On the basis of supervision activities and the safety performance both at individual level and at Member State level, the NSA reviews at regular intervals the supervision strategy and plan and may contribute to the MS to overcome any deficiencies in the safety regulatory framework. The NSA takes into account information from Supervision when reviewing its Supervision Strategy and Plan.
<b>Competence</b>	Dir. 2016/798 Art.16(1) Reg. 2018/761, art. 6	<p>1. The NSA ensures that it has competent staff to carry out Supervision Activities as required in Reg. 2018/761, art. 6.</p> <p>2. The NSA has a system in place to ensure that staff carrying out Supervision are competent.</p>
<b>Decision Making</b>	Dir. 2016/798 Art.16 (2) (i) & (j) & art. 17 and art.18 Dir. 2016/798, art. 17. Dir. 2016/798 art 18, points 3 and 4 Reg. 2018/761, art. 7	<p>1. The NSA establishes and publishes decision-making criteria on how it evaluates the correct application of a SMS by a railway undertaking or an infrastructure manager and the effectiveness of the SMS in controlling safety risks associated with the activities of the railway undertaking or infrastructure manager. These include information on how the NSA deals with non-compliance.</p> <p>2. The NSA has decision making criteria in place for how it enforces compliance with the safety regulatory framework where appropriate.</p> <p>3. The NSA has a complaints procedure for supervised entities.</p>
<b>Coordination and Cooperation</b>	Dir. 2016/798 Art.16 (2) (i) & (j) & art. 17 Reg. 2018/761, art.8	<p>1. For supervision of IM with cross-border infrastructure, the NSA coordinates the approach to supervision with relevant cross-border NSA(s) in accordance with Article 17(7) and (9) of Directive (EU) 2016/798.</p> <p>2. The NSA develops and implements arrangements based on the framework for coordinated and joint supervision set out in Annex II.</p> <p>3. The NSA develops cooperation arrangements with NIBs, certification bodies for ECM and other competence authorities or bodies.</p>
<b>Reporting to the Agency</b>	Dir.2016/798, art.19 Reg. 2016/796, art. 30.3	<p>1. The NSA reports the result of the Supervision of Railway Undertakings and Infrastructure Managers in its Annual Report submitted to the Agency.</p> <p>2. It also includes the experience of RU/IM on CSM</p>



	Reg. 2018/545 art. 7.4 Reg. 2016/796, art.17.5 and 6	implementation. 3. The NSA reports to the Agency in case of detected risk during supervision activities or return of experience relevant for the Agency tasks as authorising entity.
--	---	---



EU legal framework for promoting the safety regulatory framework		
Topics	Legal requirements	Criteria
<b>Promotion of the safety regulatory framework</b>	Dir. 2016/798 Art. 16 (2) (i) RSD Art. 18 (1)	<ol style="list-style-type: none"> <li>1. 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.</li> <li>2. In its processes, the NSA consults as appropriate all actors and interested parties, including IMs, RUs, manufacturers and maintenance providers, users and staff representatives.</li> </ol>
<b>Contribution</b>	Regulation (EU) 2018/761 Annex, 5 (d) and 6 (c)	<ol style="list-style-type: none"> <li>1. The NSA publishes and communicates to relevant stakeholders its views on the effectiveness of the safety regulatory framework.</li> <li>2. The NSA contributes when necessary with its views and any proposals to its Member State to overcome any deficiencies in the safety regulatory framework.</li> </ol>
<b>Coordination and cooperation</b>	Regulation (EU) 2018/761 Article 8	<ol style="list-style-type: none"> <li>1. The NSA develops 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.</li> </ol>



EU legal framework for NSA tasks on recognition by the NSA of AsBos or NSA acting as AsBo		
Topics	Legal requirements	Criteria
<b>Recognition</b>	Regulation (EU) 402/2013 - Articles 7, 8, 9, 13(3) and 14(1) Annex II	<ol style="list-style-type: none"> <li>1. Criteria defined in Annex II (e.g. organisation, methodology) are used in a systematic way.</li> <li>2. Recognition is equivalent to accreditation and follows the principles of Regulation 765/2008 and the ISO/IEC 17011 standard.</li> <li>3. Accreditation or recognition is accepted when done in accordance with article 7.</li> <li>4. The administrative procedure to follow in order to get the assessment body recognised is well established.</li> <li>5. The recognition body provides the relevant information on recognised Assessment Bodies to the Agency.</li> </ol>
<b>Information - Report</b>	Regulation (EU) 402/2013 - Article 18(2) and 18(6)	<ol style="list-style-type: none"> <li>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.</li> <li>2. The NSA includes in its annual report a section on its experience with the recognition of assessment bodies.</li> </ol>
<b>Only where NSA acts directly as Assessment Body</b>	Regulation (EU) 402/2013 - Article 6(2), 6(4), 15(1) and 9(2), second sentence – Annex III	<ol style="list-style-type: none"> <li>1. NSA fulfils the requirements of Annex II and Articles 6(2) and 15(1) of Regulation (EU) 402/2013.</li> <li>2. The assessment body functions of the NSA are demonstrably independent of the other functions of the national safety authority.</li> <li>3. The NSA documents the evidence of its independent assessment in compliance with Annex III of Regulation 402/2013.</li> </ol>
<b>Supervision/ Surveillance</b>	Regulation (EU) 402/2013 - Article 11	<ol style="list-style-type: none"> <li>1. Establish a surveillance plan of the assessment bodies that it recognised.</li> </ol>
<b>Use of ERA recommendations for use</b>	Recommendations for use [RFUs] applicable to AsBos (Not legally binding Guidance material)	<ol style="list-style-type: none"> <li>1. For the recognition role, the NSA uses as inputs the ERA RFUs for the recognition and surveillance of AsBos it recognised.</li> <li>2. NSA acts as AsBo: the NSA actively takes part to the AsBo Cooperation Group organised by ERA.</li> <li>3. NSA acts as AsBo: the NSA implements the recommendations for use of the AsBo Cooperation Group.</li> </ol>

EU legal framework for NSA tasks on Train Driver Directive (TDD)		
Topics	Legal requirements	Criteria
<b>Issuance of licence</b>	Dir. 2007/59/EC Art.14	<ol style="list-style-type: none"> <li>1. A procedure to issue licences is set up.</li> <li>2. The procedure is communicated and transparent to all relevant stakeholders.</li> <li>3. The procedure is continuously improved.</li> <li>4. If more stringent requirements are applied, it does not impact the recognition of licences issued in other Member State.</li> </ol>
<b>Sanctions</b>	Dir. 2007/59/EC Art. 5, 21, 29 & 30	<ol style="list-style-type: none"> <li>1. Anti-fraud measures are adopted and applied.</li> <li>2. A procedure of suspension and withdrawal is developed and applied.</li> <li>3. A procedure to review the decision of the NSA (appeal procedure) related to the issuance of a licence exists.</li> <li>4. Penalties rules in case of infringement to the licensing scheme are established and used appropriately.</li> </ol>
<b>Recognition/accreditation</b>	Dir. 2007/59/EC Art. 20	<p>In case where the national legislation provides that the NSA is the competent authority:</p> <ol style="list-style-type: none"> <li>1. Criteria for recognition are developed following the commission decision 2011/765/EU;</li> <li>2. Procedure of recognition is established following the Commission recommendation 2011/766/EU;</li> <li>3. The list of recognised persons or bodies is published and accessible.</li> </ol>
<b>Training/examination</b>	Dir. 2007/59/EC Art. 24 & Annex IV	<ol style="list-style-type: none"> <li>1. EU requirements are fully integrated in the training scheme and applied.</li> </ol>
<b>Quality system</b>	Dir. 2007/59/EC Art. 26	<ol style="list-style-type: none"> <li>1. Quality system set up, monitoring plan developed and both are regularly reviewed (all activities associated with training, the assessment of skills and the updating of licences and certificates are subject of continuous monitoring).</li> <li>2. The quality system takes into account the findings and recommendations received following independent assessments according Art 27.</li> </ol>
<b>Supervision</b>	Dir. 2007/59/EC Art. 19 & 29	<ol style="list-style-type: none"> <li>1. Measure are set up, applied and continuously improved to monitor the drivers' certification process.</li> <li>2. Inspection plan is established in relation to drivers' documentation, which may include on-board controls. In case of delegation of tasks the NSA insures compliance with provisions of Art 19 2. – 6.</li> </ol>
<b>Register</b>	Dir. 2007/59/EC Art. 22	<ol style="list-style-type: none"> <li>1. Register exists, contains the relevant information and is rightfully updated.</li> </ol>



		<p>2. Knowledge about Internal Market Information system and use it appropriately.</p> <p>3. Information is provided to the train driver when they so request it.</p>
--	--	---

EU legal framework for NSA tasks relating to Entity in Charge of Maintenance (ECM)		
Topics	Legal requirements	Criteria
<b>NSA designated as ECM certification body</b>	Sectorial accreditation/recognition scheme ERA 1172/002 V3.1 Directive 2016/798 Article 14 Annex I Regulation 2019/779 Sectorial certification scheme ERA 1172/003 V1.1	<p>1. NSA shall 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).</p> <p>2. The NSA (acting as a 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).</p> <p>3. The NSA (acting as certification body) shall identify each decision on certification, i.e. award, renewal, amendment, suspension or revocation of certificates, in conformity with the European Identification Number (EIN) via ERADIS.</p>
<b>Assessment team</b>	Sectorial accreditation/recognition scheme ERA 1172/002 V3.1	<p>1. Specific requirements for the assessment team of the certification body (NSA) performing the certification of Entities in Charge of Maintenance and/or outsourced maintenance functions:</p> <p>a/ Knowledge of the European railway sector</p> <p>b/ Knowledge and skills addressing the maintenance of railway vehicle</p> <p>c/ Knowledge and skills addressing assessment principles, practices and techniques and knowledge of the specific standards related to them.</p> <p>d/ Language skills in accordance with the country of ECMs.</p>
<b>Certification committee</b>	Sectorial accreditation/recognition scheme ERA 1172/002 V3.1	<p>1. Specific requirements of certification committee of the certification body (NSA) performing the certification of Entities in charge of maintenance and/or outsourced Maintenance Functions):</p> <p>a/ Knowledge of the European railway sector</p> <p>b/ Knowledge and skills addressing the maintenance of railway vehicles</p> <p>c/ Knowledge and skills addressing assessment principles, practices and techniques and knowledge of specific standards</p> <p>d/ Language skills in accordance with the country of ECMs</p> <p>2. The composition of the certification committee shall be different from the assessment team for the certification.</p>
<b>Activity Report</b>	Regulation (EU)	1. The NSA (acting as a certification body) shall deliver an



	2019/779, art. 6 (7)	activity report in an electronic form every 3 years to the Agency.
<b>Surveillance</b>	Regulation (EU)2019/779, art 7(4) and 8(1), Annex II	1. The NSA (acting as a certification body) shall verify the fulfilment of the requirements set out in Regulation (EU)2019/779, Annex II. To that end, it shall conduct site visits at least once every 12 months counting from the date of issuing the certificate.
<b>Requirements to be used by the NSA acting as recognition body</b>	Regulation (EU) 2019/779 art. 6(1) Sectorial accreditation/recognition scheme ERA 1172/002 V3.1 Annex I Regulation 2019/779	1. To recognise ECM certification bodies, the NSA has to apply the sectorial scheme for accreditation-ERA-1172-002 V3-1. 2. The NSA shall inform the Agency via ERADIS of the names of the recognised ECM certification bodies.

<b>EU legal framework for NSA tasks when appointed as Notifying Authority for the assessment, notification and monitoring of CABs (NoBos)</b>		
<b>Topics</b>	<b>Legal requirements</b>	<b>Criteria</b>
<b>Responsibility</b>	Articles 27 (3, 4 & 5), 37(1) & 39 of Directive 2016/797	<ol style="list-style-type: none"> <li>1. The NSA shall take full responsibility for the assessment and monitoring carried out by a national accreditation body.</li> <li>2. The NSA shall have 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.</li> <li>3. When a notified body no longer meets the IOD requirements in Articles 30 to 32, the NSA shall restrict, suspend or withdraw notification as appropriate.</li> </ol>
<b>Independence and impartiality</b>	Article 28 (a, b & d) of Directive 2016/797	<ol style="list-style-type: none"> <li>1. The NSA shall avoid conflicts of interest with CABs.</li> <li>2. The NSA shall be organised and operated to safeguard objectivity and impartiality of its activities.</li> <li>3. The NSA shall not offer or provide activities that are performed by CABs or consultancy services on a commercial or competitive basis.</li> </ol>
<b>Resources</b>	Articles 28 (c & f), 30 to 34, 27 (3 & 5) of Directive 2016/797 ERA Assessment Scheme (Technical Doc. 000MRA1044) ISO 17065:2012	<ol style="list-style-type: none"> <li>1. The NSA shall be organised in such a way that decisions relating to notification of a CAB is taken by competent persons different from those who carried out the assessment.</li> <li>2. The NSA shall have at its disposal a sufficient number of competent personnel for the proper performance of its tasks.</li> <li>3. In case of RECOGNITION by the NSA, the NSA shall ensure their resources are competent in the assessment of IOD requirements (Art. 30-34), ERA AS (optional) and ISO 17065 (optional).</li> <li>4. In case NSA notifies based on ACCREDITATION, the NSA resources shall be competent in ISO 17065 and ERA AS to take full responsibility for the tasks performed by the accreditation body.</li> </ol>
<b>Confidentiality</b>	Article 28 (e) of Directive 2016/797	<ol style="list-style-type: none"> <li>1. The NSA shall safeguard the confidentiality of the information it obtains.</li> </ol>
<b>Information</b>	Articles 27(1 & 2), 29 and 37(2) of Directive 2016/797	<ol style="list-style-type: none"> <li>1. The NSA shall inform the Commission of their procedures for the assessment, notification and monitoring of CABs, and of any changes to those procedures.</li> <li>2. The NSA shall notify CABs to the Commission and other MSs via <a href="#">NANDO</a>.</li> </ol>