

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

Annex I: Policy

NSA Monitoring

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1. Background

Article 33 of the Regulation (EU) 2016/796¹ grants to the Agency the task of “*Monitoring of the performance and decision-making of national safety authorities*” (hereafter called “NSA Monitoring”).

Recital 21 of the same Regulation states that “*Performance, organisation and decision-making procedures in the field of railway safety and interoperability vary substantially among the national safety authorities and notified conformity assessment bodies, with a detrimental effect on the smooth operation of the single European railway area. In particular, small and medium-sized enterprises wishing to enter the railway market in another Member State can be negatively affected. Therefore, strengthened coordination with a view to greater harmonisation at Union level is essential. To that end, the Agency should monitor the performance and decision-making of the national safety authorities and the notified conformity assessment bodies through audits and inspections, where appropriate in cooperation with national accreditation bodies.*”

Therefore, the objective of the NSA monitoring is to support better coordination of all actors within the European railway area and in particular the harmonisation of performance, organisation and decision making of the NSA.

Those coordination and harmonisation aim at ensuring a smooth operation of the European railway system as well participating to an effective opening of the railway market. This includes safety as well as interoperability.

The Article 33(1) of the Regulation adds that the outcomes have to be used at least by the Agency and the European Commission but this does not prevent the NSAs themselves from benefiting by using the outcomes for improving and adapting their organisation as the performed audits identify ways for improvements.

The Agency believes also that the NSA monitoring should increase the trust between the NSAs and the Agency by offering the possibility of mature discussions based on clear, fair and transparent information on the ability of NSAs to perform their activities. The outcomes of the 1st audit cycle confirm this assumption.

2. Purpose

The purpose of the NSA monitoring is **to develop, implement and run a system of audits** (Article 33 (2) to of Regulation (EU) 2016/796) **and inspections** (Article 33(7) of Regulation (EU) 2016/796). The outcomes of those audits and inspections provide inputs for:

1. coordination between actors;
2. fostering mutual trust between NSAs and the Agency and
3. harmonisation of performance, organisation and decision making of the NSA.

In particular the Article 33 (2) specifies clearly that the audits must relate to:

- (a) the **capacity** of national safety authorities to execute tasks relating to railway **safety** and **interoperability**; and
- (b) 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.

¹ Regulation (EU) 2016/796 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Railways and repealing Regulation (EC) No 881/2004, published on 26 May 2016, hereafter Regulation 2016/796 or Agency Regulation.

3. Scope

The scope of the NSA monitoring encompasses all tasks allocated to NSAs listed under Articles 16 and 17 of Directive (EU) 2016/798 and, more broadly:

- directly in the Agency Regulation, the Interoperability Directive and the Safety Directive. For this purpose, the Agency will use the legislation applicable at the time of the audit;
- directly in the applicable CSMs, the legal acts addressing the ECM certification and any other legal act taken by virtue of the Interoperability Directive and the Safety Directive; and
- indirectly when the NSA is designated by its Member States in application of the legal acts described in both preceding bullets e.g. NSA designated as assessment body in application of Regulation (EU) 402/2013.

Additional tasks may be included after coordination between the NSA and the Agency (e.g. following a request of the European Commission).

Tasks allocated to NSAs by a Member State and that are not directly related to a requirement in the applicable EU legal framework, are outside the scope of the NSA monitoring.

All NSAs of the EU and EEA EFTA States and, upon agreement, NSA Switzerland and Channel Tunnel Intergovernmental Commission will undergo audit cycles.

In principle, each NSA is intended to be audited as minimum during each audit cycle. Within each cycle, scope, frequency and depth will be adapted depending on the results of its previous audits and set priorities.

4. Method

a) *Duration of audit cycle*

The duration of an audit cycle is 3 years.

b) *Referential to be used for performing the audits*

Two referentials are possible to monitor the performances and decision making of NSAs:

✓ **Referential Compliance (see Annex III bis)**

This referential aims at evaluating the performances and decision making of NSAs by checking whether the requirements set out in the applicable EU legal framework related to safety and interoperability are complied with and have been implemented effectively.

✓ **Referential Matrix (see Annex III)**

This referential aims at evaluating the performances and decision making of NSAs by checking whether the requirements set out in the applicable EU legal framework related to safety and interoperability are extended to the management system itself of the NSAs.

c) *Decision on the audit referential to be applied*

Prior to the start of each audit, NSAs shall indicate for which referential they opt to be audited with, Compliance or Matrix.

d) *Process of audits*

The NSA monitoring audits and auditors will follow the general following principles: integrity, fair presentation, due professional care, confidentiality, independence, evidence-based approach.

e) *Confidentiality*

Audit reports, third party documents and draft documents made by the Agency are kept confidential in principle without prejudice to Regulation (EC) 1049/2001. According to Article 33.3 of the Agency Regulation, as adapted under the EEA/ Agreement (cf. OJ. L, 2024/471, 22.2.2024), NSA monitoring reports are shared with the audited NSA, the concerned Member State and the Commission or, as regards the EFTA States, the EFTA Surveillance Authority².

Audited NSAs are invited to share among each other's audit results and action plans to foster mutual improvement and share possible good practices.

f) *Resources*

As laid down in the Article 33(2) of Regulation (EU) 2016/796, *“the Agency shall promote the inclusion in the audit team of qualified auditors from the national safety authorities that are not subject to the actual audit. For that purpose, the Agency shall establish a list of qualified auditors and provide them with training when needed.”*

The Agency established and maintains a list of auditors in the restricted access part of extranet.

The Agency strongly believes that this will reinforce trust, common understanding and collaboration between the NSAs and the Agency. Qualified auditors of NSAs will be included in the audit teams, as described in Annex IV.

To monitor all NSAs within 3 years, it can be anticipated that up to about 6,5 FTE per year will be needed, depending on the frequency and the depth of audits required as determined by the results of previous audits cycles.

The Annex IV defines elements of the competency framework to be used for qualification of auditors and lead auditor.

g) *Language policy*

The Agency will apply its general language policy.

Cost of translations and interpretations will be included in Agency budget.

5. Revision of audit cycles

At the end of each 3-year audit cycle of the NSA monitoring, the Agency with the NSAs and the European Commission will evaluate the performance of the NSA monitoring programme taking into consideration the return of experience to further improve the programme. For that purpose, the Agency will address a report to the Agency Management Board at the end of each audit cycle.

² Article 33(3) of Regulation 2016/796, as adapted under the EEA/ Agreement (cf. OJ. L, 2024/471, 22.2.2024) states: *“The Agency shall issue audit reports and send them to the national safety authority concerned, to the Member State concerned and to the Commission or, as regards the EFTA States, the EFTA Surveillance Authority. Each audit report shall include, in particular, a list of any deficiencies identified by the Agency as well as recommendations for improvement”*. (see point (15)(e) of Article 1 in the Decision of the EEA Joint Committee No 248/2021 (OJ. L, 2024/471, 22.2.2024))