



Making the railway system
work better for society.

Annex I: Policy

NSA Monitoring

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1. Background

The requirements addressing the NSA monitoring are described in the Article 33 of Regulation (EU) 2016/796 and an explanation is provided in the recital 21 of the same Regulation.

The 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 monitoring of NSAs).

The 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.

Consequently the outcomes of this NSA monitoring have to be used as input for future coordination and harmonisation.

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 also 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.

2. Purpose

The purpose of the NSA monitoring is **to develop, implement and run a system of audits** (Article 33 (2) to (6) of Regulation 216/796) **and inspections** (Article 33 (7) of Regulation 2016/796).

The outcomes of those audits and inspections provide inputs for:

1. future coordination between actors; and
2. harmonisation of performance, organisation and decision making of the NSA.

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

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.

- (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.

3. Scope

The system of audits that the Agency proposes to develop, implement and run addresses:

1. All the NSAs of the EU and, upon agreement, NSAs Norway and Switzerland in a cycle of 3 years.
2. Potentially all the tasks allocated to NSAs:
 - 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 402/2013.

The Article 33 does not introduce any limitations to the tasks to be considered. However, tasks allocated to NSAs by a Member State decision that is not related to a requirement in the applicable EU legal framework, are not within the scope of the NSA monitoring. For instance when an NSA acts as notification body on behalf of its Member State.

For the Pilot Phase and the first 3-year audit cycle, the scope of the NSA monitoring will be limited to the NSA tasks listed under Article 16 of the Railway Safety Directive 2004/49, and Articles 16 and 17 of Directive 2016/798.

Additional tasks may be included upon agreement between the NSA and the Agency .

At the end of the first NSA monitoring cycle, the opportunity to extend the scope of the NSA monitoring to all the tasks allocated to NSAs will be evaluated and reported in the report mentioned in 'section 5 Revision for the second 3-years cycle (2022-2024) of this document.

3. The Agency Management Board did not reach consensus on the form of the audits previously proposed by the Agency and as a result the Agency has developed two referentials to perform the NSA monitoring:

Before the NSA monitoring audit cycle, the Member State chooses which one of the two referential is to be applied.

Depending on the referential used to perform the audit, the output (report), will be different, the Monitoring Matrix Guide focusing on the learning while the compliance audit model focuses on the compliance / non compliance (deficiencies) of the requirements.

3.1. The **NSA Monitoring referential to perform compliance audits.**

This referential is a tool designed to check whether the NSA performance and decision-making of national safety authorities are in line with the applicable EU legal framework related to safety and interoperability.

The requirements are only those formally stated in the applicable EU legal framework. The referential is more than a transposition check, it is intended to establish whether in practice the EU legal framework has been implemented effectively.

The output of such audits will be a clear record on deficiencies and observations, based on the evidence provided during the audit.

3.2. The **NSA Monitoring Matrix** (maturity survey)

This referential aims at evaluating the capacity of the NSAs to execute their tasks and the effectiveness of the activities of supervision of SMS. The audits are not limited to checking the conformity to requirements specified only in applicable legal texts but are extended to the management system itself of the NSAs.

To be capable to perform its tasks or to effectively perform its tasks, the Agency considers that an organisation is deemed to have:

- Production processes. For instance supervision or vehicle authorisation processes for NSAs
- Support processes. For instance processes of management of resources including competence of staff.
- Organisational processes aiming at organising and linking the processes defined in both preceding bullets
- All the preceding processes must be interrelated in a management system.

Therefore the Agency proposes to audit all those aspects.

The advantages of the NSA Monitoring Matrix method are:

- It provides a global and complete view as it covers the whole management system of the NSAs and the requirements specified in the applicable legal acts such as the CSM on supervision.
- It is quickly applicable as it has been experienced successfully by the Agency.
- It provides rich information about the maturity of the assessed organisation to perform and control its tasks, to identify gaps and implement improvements.
- It supports the learning of the NSA rather than focusing only on a binary approach compliance / non compliance.

The main disadvantages are:

- It implies a strong analysis for defining the deficiencies as they may result from the combinations of multiple detected weaknesses/low maturity.
- It is less effective in providing a clear statement of non-compliance with the EU legal framework.

4. Method for the first 3-years cycle (2019-2021)

a) Decision on the audit referential to be applied

Prior to the start of the three year audit cycle, Member States should indicate for which referential they opt, compliance audit or maturity survey using the Maturity Matrix. This is necessary to ensure proper planning of the audit cycle. The choice should be made by the Member State because the results of the NSA monitoring activity may led to infringement actions launched by the European Commission against the Member State.

b) 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.

The Agency has already experienced those principles within the NSA cross-audit scheme, the matrix evaluation scheme and the assessments performed in the framework of the mandate related to the priority countries.

c) Confidentiality

Audit reports, third party documents and draft documents made by the Agency are kept confidential in principle without prejudice to Regulation 1049/2001. According to Article 33.3 of the Agency Regulation, NSA monitoring reports are shared with the audited NSA, the concerned Member State and the Commission.

d) Resources

As laid down in the Article 33(2) of 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”*.

The Agency strongly believes that this will reinforce trust, common understanding and collaboration between the NSAs and the Agency.

The audit teams will be composed of a qualified team leader and qualified auditors including at least one NSA qualified auditor.

As the NSA monitoring is a task under the responsibility of the Agency, the team leader will be an Agency staff member.

Nevertheless, as the NSAs are not obliged to nominate any of their staff members to participate as qualified auditors, the Agency may compose audit teams including only Agency staff in case of insufficient availability of NSA qualified auditors.

Team leader and auditors will be qualified under a process under the responsibility of the Agency and similar to the experience in NSA cross-audit.

To monitor all NSAs within 3 years, it can be anticipated that about 3 FTE per year are needed (including about 0,85 FTE for NSA auditors).

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

e) Language policy

The Agency will apply its general language policy.

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

5. Revision for the second 3-years cycle (2022-2024)

At the end of the first 3 year of implementation 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 in September 2021.