

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

ANNEX II

NSA Monitoring – Audit Procedure

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1. Appointment of audit teams

For each audit, an audit team is appointed pursuant to the Agency internal processes and consists of the following roles:

- › *Lead Auditor (Agency staff);*
- › *2 or more auditors (Agency staff and, when possible, NSA staff). Whenever possible, one or more auditors which participated to previous monitoring audits or similar activities of the same NSA, is/are integrated.*

Technical experts/observer may be included in the audit team, as relevant.

Detailed roles and responsibilities are described in Annex IV.

2. Initial contact with the NSAs

Each Lead Auditor contacts the concerned NSA to launch the audit, providing/requesting at least the following information:

- › *the request to the NSA to nominate a contact person,*
- › *the composition of the audit team, if already identified,*
- › *the request to the NSA to provide the Agency, within a proposed timeframe, the documents related to its organisation and to the audited areas,*
- › *the request to the NSA to provide the Agency, within a proposed timeframe, its choice in relation to which referential it opts for the audit (Matrix or Compliance),*
- › *the request to the NSA to complete and send back to the Agency, within a proposed timeframe, a "Self-Assessment form",*
- › *a proposal for the development of the audit, including provisional dates for the following phases.*

The Lead Auditor cooperates with the appointed NSA contact person to further refine and agree upon the practical organization of the following steps of the audit, striving to make the most efficient use of resources and avoid duplications.

3. Opening meeting

An opening meeting, which may be held at the NSA premises or remotely, is organized between the Agency audit team and the concerned NSA with the purpose to:

- › *establish mutual understanding and good cooperation in the course of the audit,*
- › *explain the audit methodology,*
- › *agree on the timeframe and the audit plan,*
- › *provide the possibility for the NSA to present an overview of their organization and the general set-up of their railway system,*
- › *clarify any doubt prior to the start of the interview phase.*

NSA Top Management shall attend the opening meeting and it is advisable that the NSA staff that will be audited attend the opening meeting, too.

The opening meeting may be organized separately or jointly with the on-site phase (see 4).

4. On-site phase

An on-site phase dedicated to the interviews follows the opening meeting, according to the audit plan agreed between the Agency Lead Auditor and the NSA contact person.

Interviews will be held preferably at the NSA premises. Hybrid interviews/meetings (e.g. a combination of onsite and remote activities) may represent an alternative to onsite depending on the circumstances (e.g.

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travel limitation, budget restrictions, etc.). This phase lasts approximately 4-5 days depending on the number of interviews within the different departments/services of the NSA, as detailed in the agreed audit plan. NSAs shall make available the relevant staff for the interviews.

If so agreed, the railway sector (e.g. Railway Undertakings and Infrastructure Managers) may be interviewed as well by the Agency audit team.

The auditors ask, when needed, the interviewees to provide evidence following the given answers.

During the on-site phase, the audit team provides regularly feedback to the audited NSA. In the last day of the on-site phase and based on all gathered inputs, audit documents, the self-assessment, evidence provided during the on-site interviews, the Agency audit team presents its preliminary findings of the audit to the concerned NSA.

5. Report drafting.

As soon as the on-site phase is concluded, the Agency audit team starts drafting the audit report.

The audit findings are classified either as “observations” or “deficiencies”.

An **observation** is a finding that does not prevent the concerned NSA from effectively performing its tasks in relation to railway safety and/or interoperability. Observations should be considered as issues which, if not dealt with appropriately, may in time and/or if circumstances change, adversely affect NSAs’ ability to perform its tasks in relation to railway safety and/or interoperability.

For observations, the Agency does not make any recommendation to remedy them and NSAs may produce an action plan to address them (see 7.2).

A **deficiency** is a finding or a combination of findings that prevents the concerned NSA from effectively performing its tasks in relation to railway safety and/or interoperability. Deficiencies should be considered as issues which are adversely affecting NSAs’ ability to perform its tasks in relation to railway safety and/or interoperability and which need to be dealt with as soon as practicably possible. Multiple observations, considered collectively, may raise the category to a deficiency.

For deficiencies, the Agency requests the NSAs to take appropriate actions to remedy the deficiencies and NSAs shall produce an action plan to address them (see 7.2).

To classify audit findings in observations and/or deficiencies, the audit team expresses its ‘expert judgement’ after having performed a risk evaluation on the effects of those findings and any interaction among them on the capability of the NSA to perform its tasks.

Among other, the risk evaluation includes the applicable legal requirements when they exist, be time oriented, consider the necessary efforts to achieve a correct level and relate on the effect on the national safety level (short-term, mid-term, long-term).

The risk evaluation is part of the audit report.

Possible good practices and/or strengths identified during the audit will be shared in the report to the audited NSA.

For audits carried out according to the Matrix referential, levels are assigned for each audited area.

6. Internal review

Once the audit team has finalised the draft report and before communicating it to the concerned NSA, the report undergoes an internal review (internal Review Committee or other appropriate means), in order to ensure consistency among the different audits undertaken.

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7. Communication of draft audit reports to NSAs and development of NSA action plan

7.1 Communication of the draft report to the concerned NSA

The Agency Lead Auditor sends the draft audit report to the NSA contact person who, in turn, dispatches the draft report to the NSA staff involved in the audit to collect comments and opinions.

For findings classified as observation, the report shall not include any recommendation by the Agency to the NSA to address them: the Agency trusts the NSA to take the necessary corrective and preventive actions on its own to address the findings of the audit.

For findings classified as deficiencies, in line with the provision of art 33(4) of AR, the report shall include recommendations by the Agency to the NSA, to take appropriate steps to remedy the deficiencies within a mutually agreed time limit.

The concerned NSA is asked to provide any comment to the draft report within a reasonable timeframe.

The NSA shall justify its comments when they oppose to/modify the evaluation made by the audit team.

It is generally not possible to provide further evidence after the interviews.

7.2 Consolidation of the draft report (including diverging opinions) and preparation of the NSA action plan

The audit team shall reply to the comments raised by the NSA and shall provide justifications when they are rejected.

For findings classified as deficiencies, NSA shall prepare a plan with actions it intends to undertake to answer to the Agency recommendations and to address the identified deficiencies. The plan may include also actions to address observations.

The action plan shall contain, for each deficiency (and each observation, if relevant):

- › *the detailed steps that the NSA intends to implement,*
- › *a timeline for their implementation, including the body/ies responsible,*
- › *a commitment to inform the Agency in due time.*

In line with the provisions of art. 33(5) of Agency Regulation, should the NSA:

- › *disagree with the Agency recommendation, or*
- › *not take any appropriate steps, or*
- › *not reply to the Agency recommendations within 3 months*

the Agency informs the Commission¹ accordingly.

The Agency informs the Commission¹ also in those cases in which the steps envisaged by the NSA to remedy a deficiency are not within the remit of the NSA itself (e.g. actions needed at MS level).

The Agency seeks consensus with the audited NSA on the content of the report. In case consensus is not reached, the audit report reflects and documents the diverging opinions between the audit team and the audited NSA. The Agency audit team has the possibility to add comments on diverging opinions.

¹ 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) .

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7.3 Inclusion of the NSA action plan in the draft audit report

The Agency audit team does not approve the NSA action plan, but it:

- › *checks that all its recommendations are addressed by the NSA action plan, and*
- › *agrees with the NSA on the timeline for the implementation of the actions.*

The NSA action plan is included as annex to the audit report.

8. Exit meeting

An exit meeting, which may be held at the NSA premises or remotely, is organized between the Agency audit team and the concerned NSA with the purpose to:

- › *discuss and consolidate the NSA action plan, if any, and*
- › *formally agree on the content of the final audit report.*

It is advisable that the whole NSA Top Management and audited staff attend the exit meeting.

The exit meeting is also an opportunity for the NSA to provide feedback to the Agency on the whole audit process and/or to share any thoughts on possible next steps.

9. Delivering the audit report

After the exit meeting is over, the audit report is finalised by the audit team, in cooperation with the audited NSA, and it undergoes the Agency hierarchical approval, with the final authorization signature of the Executive Director.

The signed audit report is delivered to:

- › *the concerned NSA*
- › *the European Commission or the EFTA Surveillance Authority¹*
- › *the Member State in which the NSA is established (via the respective Permanent Representation to the European Union)*

10. Follow up of the NSA action plan

An NSA action plan developed to address deficiencies may trigger a follow-up by the Agency to monitor the actual implementation of the actions envisaged in the plan. The Agency Lead Auditor and the NSA contact person agree upon the practical arrangements to perform this task after the completion of the audit.