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Annex II: Evaluation Procedure

NSA Monitoring

Procedure

Evaluation procedure for the NSA monitoring activity

Document Type: Procedure

Origin: ERA

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Document History

Version	*Date*	*Comments*
0.1	April 2017	New internal draft based on the comments from the MB workshop on NSA Monitoring
1.0	May 2017	Proposal for approval by the Managament Board
1.1	July 2017	Changes to accommodate the Management Board comments of 27 June 2017

Process Deployment	Core process > Monitoring > Monitoring Railway Activities
Owner	Head of the Safety Unit
Purpose	To establish all the audit activities to be carried out in NSA monitoring, from the planning until the issuing of the final report.
Scope	This document explains the NSA monitoring process used for the monitoring of the performance and decision making of national safety authorities (hereafter monitoring of NSAs).

Customers	National Safety Authorities, the society for which a capable NSA is an assurance for controlling the railway actors (RUs, IMs, ECMs,…) and European Commission.
Other Stakeholders	The monitoring of NSAs is performed "on behalf of the Commission" as stated in Article 33(1) of Regulation 2016/796
Input	All information related to National Safety Authority may be inputs to the process. For instance: › NSA Cross-Audits reports; › NSA annual report › ERA's studies and questionnaires; › NSA web sites / Other information/document proposed by NSA
Output	Either final Individual NSA monitoring report and spider diagram showing at a glance the results of the NSA Monitoring Matrix, or final individual NSA monitoring reports of performed compliance audits identifying lists of deficiencies.
Constraints	There is a risk for lack of resources The risk is to have not enough auditors to make the audits in the three years cycle. The Article 33(2) imposes to the Agency for promoting the inclusion in the audit team of qualified auditors from national safety authorities that are not subject to the actual audit. Asking for auditors from NSAs may mitigate the risk.
Legal Basis	Regulation (EU) 2016/796 - Art. 33 Directive (EU) 2016/798 Regulation (EC) 45/2001 on the protection of the individuals with regard to processing of personal data

General Process Risk

Identified Risk	*Risk Level*	*Mitigation Plan*
Lack of resources	Medium	Use of available resources will be planned by the Agency using the available project management platform. NSA monitoring does not follow a fixed deadline and can be planned in when it best suits the Agency and the Member State.
Lack of competencies	High	All the staff involved in the NSA Monitoring must be trained and qualified before they take part to an NSA Monitoring activity. Further requirements are defined in this procedure. There will be an NSA Monitoring Programme Team within the Safety Unit with the task to support on-going audits with templates, guidance and previous examples as well as help to solve upcoming issues. Return on experience: The NSA monitoring Programme Team will also ensure that auditors of the Agency and the NSA meet on a regular basis to discuss common issues. In connection with this the Team will collect lessons learned to provide next evaluations with the built-up experience from previous audits.
Inconsistencies in the evaluations performed by various audit teams	Medium	The structure of the audit team includes the role of the reviewer. The function of this audit team member, who is not involved in the interviews, is to compare different reports with the aim to ensure consistent attribution of level and ensure consistency in the content and structure of the reports. Moreover, auditors are invited to follow a training programme to ensure everybody has a common understanding of the NSA monitoring and therefore consistency in the audits performed.
Inconsistencies in the evaluation performed as two referentials can be used	High	Following the request of the Management Board of 27 June 2017, in addition to the NSA Monitoring Matrix Guide, a referential to perform compliance audit is developed. Before the NSA Monitoring 3 year audit cycle, the Member State chooses which audit referential should be used for its NSA. This means that 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. After the first 3 years of implementation of the NSA monitoring, the Agency will evaluate the performance of the NSA monitoring programme taking into consideration the return from experience of the performed audits.
Conflict of interests	Low	A specific declaration will be signed by the audit team members, including those belonging to NSAs. Members of the audit team evaluating one NSA cannot be staff members of this NSA.

Performance Indications	› Timely issuing of the NSA monitoring audits
	- Actual dates for carrying out the work correspond with the planned dates. The tool for measuring is MS Project.
	› Consistency between different NSA monitoring.
	- The same conditions in two different NSA have to result in the same level for that sub-element. This information is collected through analysis of sample reports carried out by the NSA monitoring programme team.
	The process owner is responsible for monitoring and analysing the performance indicators
Related Processes	› Monitoring railway activities › Competence management
Related Documents	› NSA Monitoring Matrix Guide GUI-MRA-001 › NSA Monitoring referential compliance audit
Enablers	NA

1. Definitions and Abbreviations

ED: Executive Director

EC: European Commission

HoU: Head of Unit

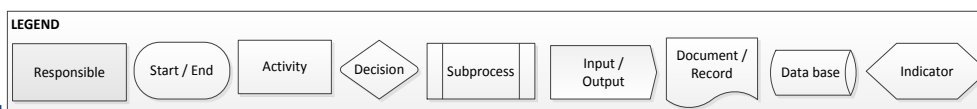**IM:** Infrastructure Manager

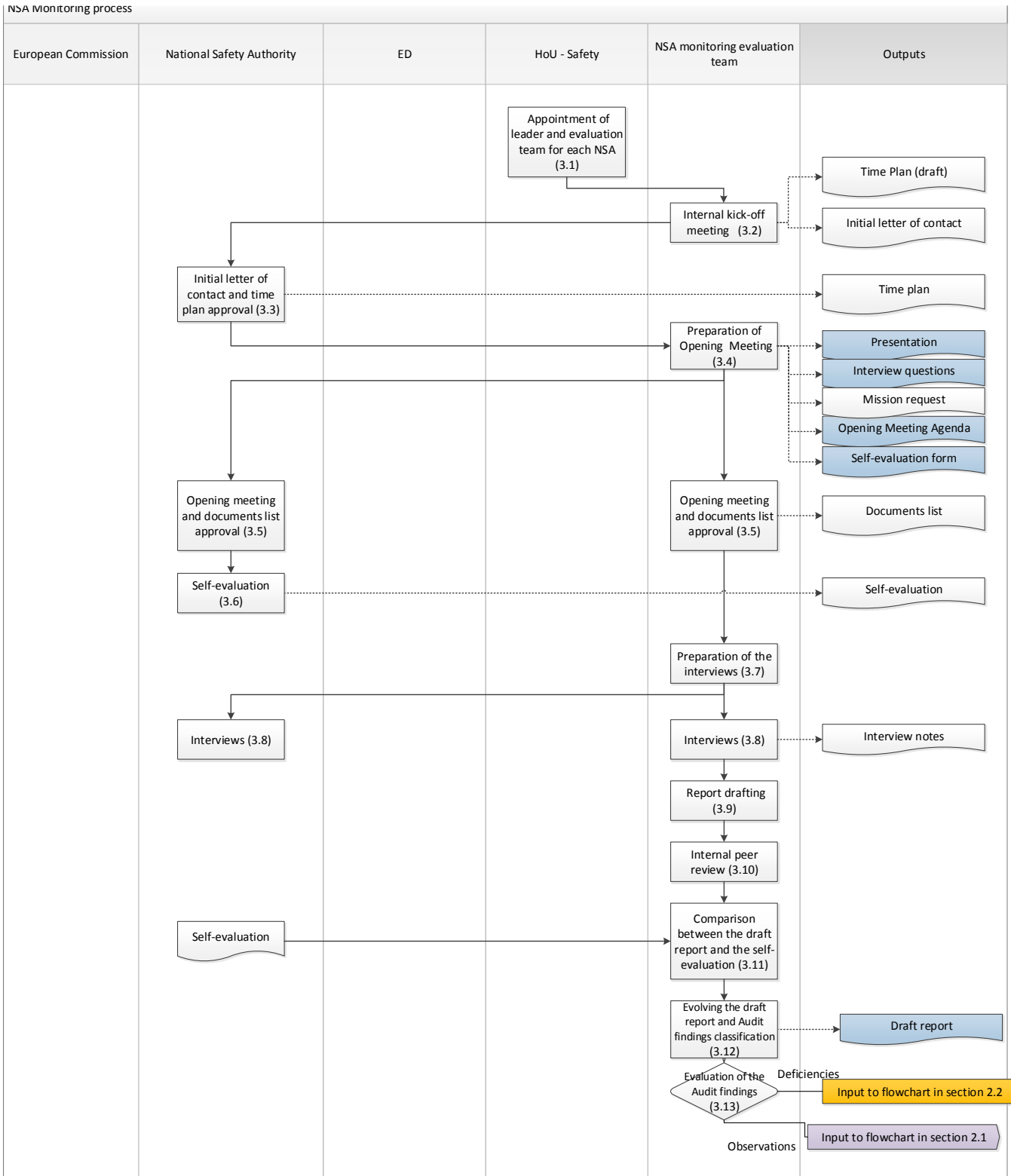**KOM:** Kick-off meeting (internal)

NSA: National Safety Authority
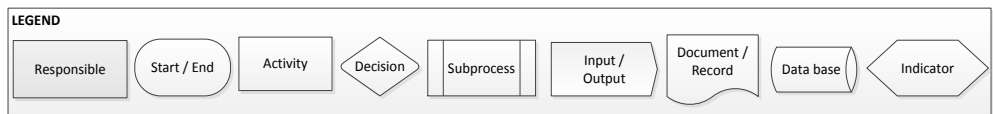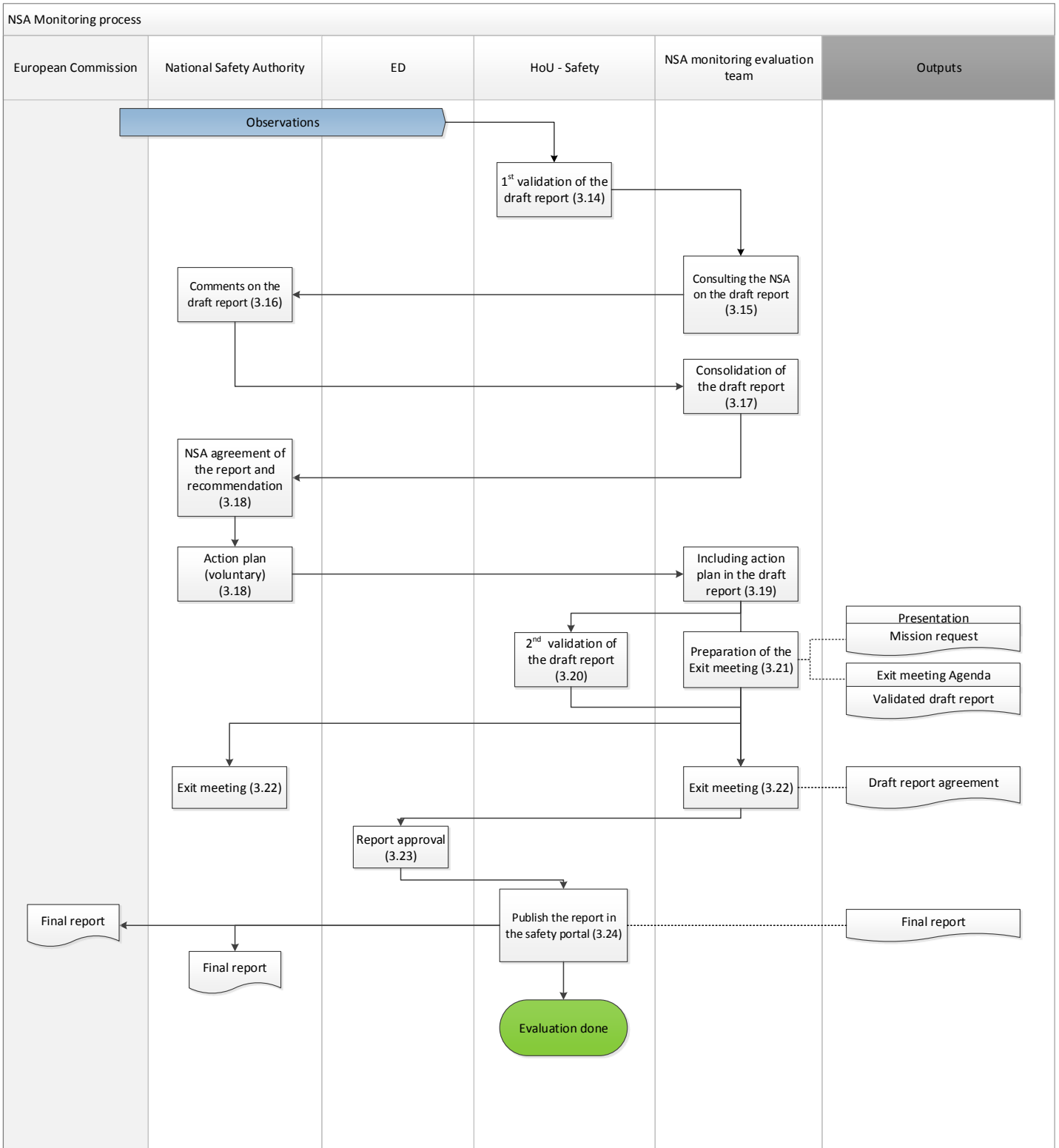
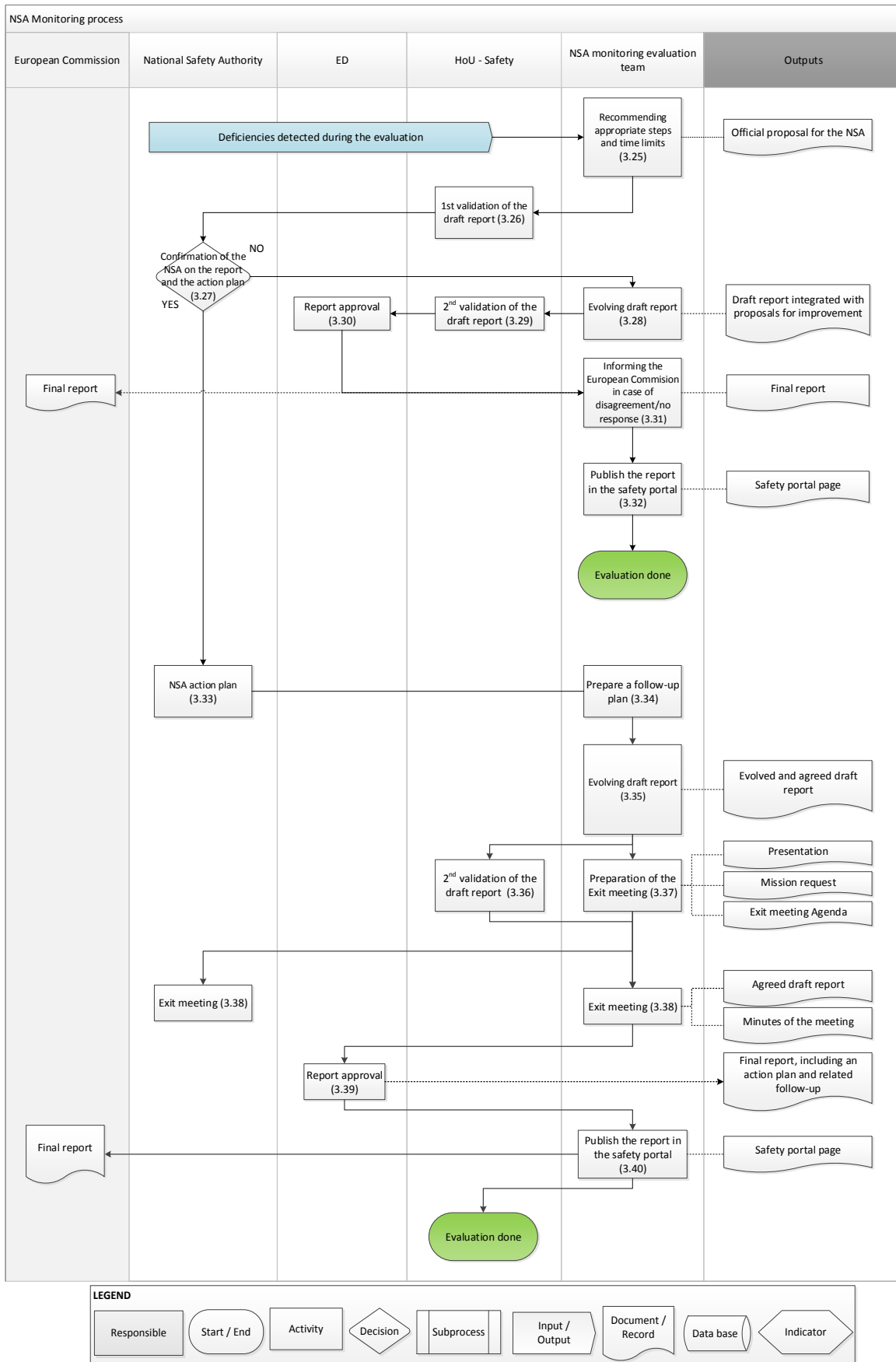**OM:** Opening meeting

RU: Railway Undertaking

2. Flow Charts

The numbers in this flowchart match the number of the sub-chapters in chapter 3.

2.1. Flowchart in case of observations

NSA Monitoring process

European Commission	National Safety Authority	ED	HoU - Safety	NSA monitoring evaluation team	Outputs

Observations

1st validation of the draft report (3.14)

Consulting the NSA on the draft report (3.15)

Comments on the draft report (3.16)

Consolidation of the draft report (3.17)

NSA agreement of the report and recommendation (3.18)

Action plan (voluntary) (3.18)

Including action plan in the draft report (3.19)

2nd validation of the draft report (3.20)

Preparation of the Exit meeting (3.21)

- Presentation
- Mission request
- Exit meeting Agenda
- Validated draft report

Exit meeting (3.22)

Exit meeting (3.22)

Draft report agreement

Report approval (3.23)

Final report

Publish the report in the safety portal (3.24)

Final report

Final report

Evaluation done

LEGEND

Responsible	Start / End	Activity	Decision	Subprocess	Input / Output	Document / Record	Data base	Indicator

2.2. Flowchart in case of deficiencies

NSA Monitoring process

European Commission	National Safety Authority	ED	HoU - Safety	NSA monitoring evaluation team	Outputs

Deficiencies detected during the evaluation

Recommending appropriate steps and time limits (3.25)

Official proposal for the NSA

1st validation of the draft report (3.26)

Confirmation of the NSA on the report and the action plan (3.27) — NO / YES

Report approval (3.30)

2nd validation of the draft report (3.29)

Evolving draft report (3.28)

Draft report integrated with proposals for improvement

Final report

Informing the European Commision in case of disagreement/no response (3.31)

Final report

Publish the report in the safety portal (3.32)

Safety portal page

Evaluation done

NSA action plan (3.33)

Prepare a follow-up plan (3.34)

Evolving draft report (3.35)

Evolved and agreed draft report

2nd validation of the draft report (3.36)

Preparation of the Exit meeting (3.37)

Presentation

Mission request

Exit meeting Agenda

Exit meeting (3.38)

Exit meeting (3.38)

Agreed draft report

Minutes of the meeting

Report approval (3.39)

Final report, including an action plan and related follow-up

Final report

Publish the report in the safety portal (3.40)

Safety portal page

Evaluation done

LEGEND

Responsible | Start / End | Activity | Decision | Subprocess | Input / Output | Document / Record | Data base | Indicator

3.   Description

The length of the process might be impacted by a potential disagreement between the NSA and the ERA on the final report, the estimation of the resources needed to conduct the audit is about 60 man/days. The different process steps are outlined in the following sub-chapters.

Activities
Phase 1 – Planning and deployment of the monitoring activity
Appointment of leader and evaluation team for each NSA (3.1)
Internal kick-off meeting (3.2)
Initial letter of contact and time plan approval (3.3)
Preparation of opening meeting (3.4)
Opening meeting and documents list approval (3.5)
Self-evaluation (3.6)
Preparation of the interviews (3.7)
Interviews (3.8)
Report drafting (3.9)
Internal peer review (3.10)
Comparison between the draft report and the self-evaluation (3.11)
Evolving the draft report and audit findings classification (3.12)
Evaluation of the audit findings (3.13)
Phase 2 – Reporting
Phase 2.1 – Reporting in case of observations
1st validation of the draft report (3.14)
Consulting the NSA on the draft report (3.15)
Comments on the draft report (3.16)
Consolidation of the draft report (3.17)
NSA agreement of the report and recommendation (3.18)
Action plan (voluntary) (3.18)
Including action plan in the report (3.19)
2nd validation of the draft report (3.20)
Preparation of the Exit meeting (3.21)
Exit meeting (3.22)
Report approval (3.23)
Publish the final report in the safety portal (3.24)
Phase 2.2 – Reporting in case of deficiencies
Recommending appropriate steps and time limits (3.25)
1st validation of the draft report (3.26)
Consulting the NSA on the report and the action plan (3.27)
IF NO →
Evolving draft report (3.28)
2nd validation of the draft report (3.29)
Report approval (3.30)

Informing the European commission in case of disagreement/no response (3.31)
Publish the report in the safety portal (3.32)
IF YES →
NSA action plan (3.33)
Prepare a follow-up plan (3.34)
Evolving draft report (3.35)
2nd validation of the draft report (3.36)
Preparation of the Exit meeting (3.37)
Exit meeting (3.38)
Report approval (3.39)
Publish the report in the safety portal (3.40)

3.1.   Appointment of leader and and evaluation team for each NSA

The audit team is appointed by the HoU on a proposal of the NSA monitoring Programme Team leader and consists at least of the following roles:

> › Lead auditor (Agency staff), who has the responsibility of running the activity according to this procedure, ensuring the highest quality possible with the assigned resources;
> › 2 Auditors (Agency and NSA staff), who provides evaluations to the lead auditor; at least one of the auditors should be NSA staff when possible (but not from the NSA being audited);
> › Reviewer (Agency staff), who has the role to ensure consistency between the audit report and other audit reports already issued for other NSAs.

The first three persons are fully involved in the evaluation, the reviewer participates only during the review.

The team should be appointed according to the following requirements:

> › Lead auditor: Qualified for the NSA monitoring at least one experience as auditor;
> › Auditors: Qualified for the NSA monitoring;
> › Reviewer: Qualified for the NSA monitoring, at least one experience as auditor.

3.2.   Internal kick-off meeting

The lead auditor will organise an internal Kick-off meeting with the appointed team where a first draft of the Time plan for the audit will be produced.

The Time plan shall include:

> › a planning of the meetings;
> › the name of the NSA monitoring evaluation team members and their contact information;
> › the name of the persons to be interviewed and their contact information;
> › the name of the NSA contact person in charge of managing the interface between the NSA and the Agency; the role includes: full support for the organisation of meetings, video conferences, etc.

The Lead auditor:
> › attributes also the tasks to the team members and the different milestones;
> › prepares an official letter to inform the NSA on the monitoring activity. This letter should include:
>> o The composition of the audit team;
>> o The draft time plan of the audit;

o   The request to nominate the NSA contact person and to complete the draft time plan with the name of the persons to be interviewed and their contact information.

The Lead auditor will cooperate with the appointed contact person to discuss the practical organisation of the meetings before the Time plan is finalised.

In the Kick-off meeting, a list of documents to be used during the exercise shall also be drafted. This is a list of all documents that the Agency has access regarding the NSA.

The Lead auditor proceeds to the sending of the initial letter to contact the NSA (registered email).

3.3.   Initial letter of contact and time plan approval

To be adopted, the Time plan must be approved by the NSA. This is done via email before the Opening meeting. The NSA can propose to modify the plan according to its internal needs, these changes should not impact on the overall organisation of the audit.

3.4.   Preparation of Opening meeting

The preparation of the Opening Meeting (OM) includes the preparation of:

›   Draft agenda;
›   Presentations;
›   List of general interview questions;
›   Self-evaluation form ;
›   Mission arrangements.

The list of general interview questions and the self-evaluation form are templates available to the audit team, stored in the Safety portal[1]. A communication including the draft agenda, presentations and other relevant information about the Opening Meeting is sent to the NSA contact person in advance.

The NSA is normally asked to prepare short presentations about its internal organisation, activities, etc. in relation with the planned audit.

3.5.   Opening meeting and documents list approval

In the Opening meeting, the Agency explains how the NSA monitoring evaluation will be done and how the NSA should carry out their self-evaluation.

The NSA representatives present an overview of their organisations and the general set-up of their railway system.

When the NSA agrees to interview members/representatives from the railway sector, those should also participate in the OM in order to get a better understanding of the process and how their input will be used to set the levels.

In case classified documents (e.g. the NSA cross-audit reports) are used during the audit, the Agency will have to obtain, during the OM, an explicit permission to use them.

In addition, the NSA representatives may provide information/evidence in connection with the interviews, for example reports, studies, process descriptions, legislation etc. The use of these added documents must be agreed with all parties that they concern. The NSA and the Agency can refuse the use of specific documents but have to justify the reasons.

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[1] The Safety Portal access is limited to Agency staff. Access to audit documentation is limited to staff needing to have access to these.

The OM can also be used to clarify any issues.

In any case the results of the meeting must be reported in the relevant minutes of the meeting.

3.6. Self-evaluation

The Agency requests from the NSA to carry out a self-evaluation before the audit and send it to the Agency. The self-evaluation shall be done using the specific template.

The reasons for undertaking a self-evaluation are multiple:

› The NSA will get familiar with the maturity model or the referential compliance audit used by the Agency for the NSA Monitoring activity; this will increase the effectiveness and the efficiency of the process;
› It will facilitate the discussions on the levels during the consultation on the final report;
› It will support the development of self-awareness within the NSA;
› It will help the Agency in understanding the maturity level of the NSA.

To drive the self-evaluation and justify the level, the NSA should use the list of general questions provided by the Agency during the Opening Meeting and the evaluation criteria defined in the NSA Monitoring Matrix guide.

The representatives should carry out the self-evaluation following the specific form. The people involved in the self-evaluation should be the same that will later take part to the interviews.

The self-evaluation will not be used as evidence in on-site interviews. The audit team makes an evaluation exclusively based on the evidence (facts) gathered in the document review and during the interviews.

3.7. Preparation of the interviews

The necessary evidence for the audit are gathered from document review and during interviews.

The interviews are based on the generic list of questions prepared for the opening meeting, nevertheless, the questions can be tailored for each audited NSA.

The questions could also be adapted to the audited NSA, taking into account the result of the document review including the self evaluation.

The document review is an activity where the audit team studies all the relevant documents mentioned in the document list and starts to draw some preliminary findings.

The template with the generic list of questions is stored in the Safety portal.

The auditors should pay attention to the limited time available for the interviews; therefore, they should not ask too many questions on topics sufficiently covered by available documentation. As already mentioned, the OM can be used to clarify small issues.

3.8. Interviews

Interviews are carried out on-site within the different departments/services of the NSA.

If agreed with the NSA, the railway sector (e.g. RUs and IMs) can be interviewed as well.

Normally, the NSA is interviewed three days in total, the interviews with the sector representatives should, in principle, not last longer than half a day.

All interviews should be carried out by the three auditors in co-operation.

The auditors can ask the interviewee to provide evidence following the given answers.

3.9.   Report drafting

As soon as possible, after the interviews, the auditors clarify and analyse their notes (from both the document review and interviews), assign and justify a level for each sub-element (when the Monitoring Matrix Guide is used), or assess whether the requirement is complied with or not when the referential compliance audit is used).

The levels should be assigned comparing the documents and the results of the interviews against the evaluation criteria that are described, for each sub-element, in the NSA Monitoring matrix guide.

When the Monitoring Matrix Guide is used:

- The report should also include recommendation (where relevant) of what the NSA needs to do in order to move to a higher level.
- When the audit team identifies that an activity of a NSA could be considered has a best practice to be shared with other NSA, it would be useful to mention it in the report.

When the referential compliance audit is used, the report should include recommendation on how to redress the non compliance leding to deficiency.

The evaluation shall follow the relevant template provided for audit reports available in the Safety portal.

3.10.   Internal peer review

Once the auditors agree on the content of the draft report, this is sent to the reviewer.

In addition, it is possible (optional) to arrange meetings with other on-going audit teams in which specific similar evaluation cases are discussed.

These activities will contribute to ensure consistency among different audits.

3.11.   Comparison between the draft report and the self-evaluation

The auditors compare their assigned levels or the compliance and non-compliances identified with the NSA self evaluation.

The purpose of this comparison is to support the auditors in:

- › Understanding the overall maturity of the NSA, e.g. by measuring the level of self-awareness of the NSA;
- › Preparing the Exit meeting as it will point out where they and the NSA have different views on the levels or on the compliance and non compliances identified.

3.12.   Evolving the draft report and audit findings classification

The result of the activities described in section 3.10 and 3.11 shall be included in the draft report.

Audit findings can be classified as observations or 'deficiencies'.

A deficiency or multiple observations that, considered collectively, may raise the category to a deficiency, have the consequence that if they were not corrected they would prevent the NSA concerned from effectively performing some or all of its tasks in relation to railway safety and interoperability.

To classify audit findings between observations and deficencies, the audit team proceeds to a risk evaluation on the effects of those audit findings and any interaction between them on the capability of the NSA to perform its activities or on the effectiveness of its supervision.

Among other, this risk evaluation has to include 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, middle-term, long term).

The risk evaluation has to be clear, complete and understandable. The risk evaluation is part of the report.

Based on this risk evaluation, the audit team express its 'expert judgement' on the classificationof audit findings between observations and deficiencies.

For the classification, there are four means to ensure proper judgement, coherence with other audits and proportionality:

- The internal review;
- The consultation of the audited NSA;
- The validation of the report by the Head of the Safety Unit;
- The approval of the report by the Executive Director.

Examples (simplified) to apply the NSA Monitoring Matrix Guide

Those examples aim at showing how the audit team may express its judgement but must not be considered as rules for application.

1) In maturity assessment, one NSA gets a level 1 for the sub-element 4.3 - Promoting the safety regulatory framework.
   As:
   - this promotion is an obligation from the Safety Directive (2016/796 as well as 2004/49); and
   - the safety level may suffer from unawareness of the RUs and IMs about their obligations;
   Then the audit finding may be considered as deficiency.
   But if there is an organisation such as 'RSSB' in UK or 'VPI' in Germany providing a lot of appropriate support to the railway actors, then it is less important for the NSA to make promotion by itself, there will be less effect on safety as awareness is maintained and then the audit finding could be considered as observation.

2) In maturity assessment, one NSA gets a level 2 for the sub-element 3.1 - Resource management in particular regarding the competencies of staff. This may have direct implication on the capability of performing the activities in case the allocated staff has not the adequate competencies. At first the audit finding may be classified as deficency because the risk is great that the NSA has no control on the railway system. But if the NSA receives a level 3 for the sub elements 1.1 goal setting, 5.1 Monitoring and 5.2 Review and has identified its weakness for the sub-element 3.1, the audit team may consider that the NSA management system is effective and then trust the NSA on making improvements in short delays. Therefore the audit team may judge the audit finding as an observation.

3.13.   Evaluation of the audit finding

Depending on the classification of audit findings (see section 3.12) the next step of the process is:

› Observations, please go to section 3.14;
› Deficiencies, please go to section 3.25.

In case ofobservations, the Agency trusts the NSA to make the necessary corrective and preventive action on its own. Therefore no more actions is necessary but closing the audit.

In case ofdeficiency, the Agency shall apply the provisions of art 33(4) of Regulation 2016/796: "…*the Agency shall recommend to the national safety authority that it take appropriate steps within a mutually agreed time limit, taking into account the seriousness of the deficiency*."

3.14. 1st validation of the draft report

This step consists of a first validation of the draft report by the Head of Safety Unit before sending the document for consultation to the NSA.

3.15. Consulting the NSA on the draft report

The draft report is sent to the NSA for consultation so that they can confirm the correct description of the findings and the appropriateness of the recommendations.

The document sent for consultation shall include the results of the audit related to all the departments of the NSA. The audit team shall justify each attributed level, which can be modified after discussion with NSA if there is evidence to support the change.

There must be a clear link between findings and recommendations provided by the Agency.

The document has to be sent to the contact person (NSA staff) who will be responsible to dispatch the draft report to the NSA staff involved to collect comments and opinions.

In any case the audit team is responsible for granting full traceability of the comments.

3.16. Comments on the draft report

The comments shall be addressed by the NSA using track changes or a comment sheet.

If this solution is not applicable (e.g. different software used by the NSA) other options can be agreed between the audit team and the NSA.

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

It is normally not possible to provide further evidence after the interviews, so new evidence should not be used to support comments.

3.17. Consolidation of the draft report

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

The outcome of the consultation with the NSA should be a definitive draft report even if it is still possible to discuss minor (justified) changes during the Exit meeting.

The diverging opinions between the audit team and the audited NSA will be clearly identified and documented in the report. Both opinions must clearly appears.

3.18. NSA agreement on the draft report / Preparation of the action plan

The NSA analyses the new revision of the report and possibly agrees on the content of the report, including the recommendations provided by the Agency. The NSA might provide the Agency with an action plan. This last step is not mandatory in case of minor deficiencies.

3.19. Including the action plan in the draft report

If the NSA provides the Agency with an action plan, this should be included, as annex, in the report. The Agency does not approve the action plan, the document is attached as record of the NSA Monitoring activity.

The action plan should include:

> › Type of intervention, specifying which basic elements and sub-elements are going to be improved;
> › Deadline and body responsible for its implementation;
> › Commitment to inform the Agency about its results.

The action plan does not trigger the creation, from the agency side, of a follow-up plan. Normally, the actual implementation of the action plan will be verified in the next audit cycle.

3.20.   2nd validation of the draft report

Before reaching a formal final agreement in the exit meeting, the draft report needs to be validated by the HoU – Safety.

3.21.   Preparation of the Exit meeting

The preparation of the Exit meeting includes:

> › Presentation;
> › Mission arrangements;
> › Agenda;
> › Draft report.

There are examples of agenda, presentations, etc. from NSA monitoring in the Safety portal.

A letter including the above documents is sent to the NSA contact person in advance. Normally, the Exit meeting is held in the premises of the NSA.

3.22.   Exit meeting

The Exit meeting gathers the three auditors (normally the reviewer is not participating) and the NSA representatives that were interviewed. The main purpose of the meeting is to agree formally all the levels from the report, but it is also important that the NSA is given the opportunity to share some thoughts on possible next steps, for example an action plan for improvement measures and how to best disseminate their best practices to other NSAs.

The Executive Director of the NSA should participate in the Exit meeting even if s/he was not interviewed.

During the Exit meeting each attributed level is agreed as consequence of the consultation process. Changing levels is still possible but it must be documented in the minutes and supported by evidence collected during the audit.

3.22.1.   Draft report agreement

The final report is the output of the Exit meeting. It is possible to include an action plan, if the NSA declares one.

The action plan should include:

> › Type of intervention, specifying which basic elements and sub-elements are going to be improved;
> › Deadline and body responsible for its implementation;
> › Commitment to inform the Agency about its results.

3.23.   Report approval

Once the draft report has been formally agreed by the NSA during the Exit meeting, it goes through a quality check by the Safety unit before being approved by the ED, which gives the report an official and final status.

3.24.   Publish the final report in the safety portal

After the approval of the ED, the Lead auditor uploads the report on the safety portal, sending a copy to the European commission.

The NSA can access the safety portal and have access to the report.

This activity closes the evaluation in case of observations.

3.25. Recommending appropriate steps and time limits

➔ *From section 3.13*

In case of deficiencies, the Agency will recommend to the NSAs that it takes appropriate steps within a mutually agreed time limit.

In practice, the Agency will complete the 1st draft report in step 3.12 with the recommendations and by inviting the NSA to submit an action plan answering to these recommendations.

The action plan shall include:

> › The steps that the NSA intends to implement;
> › A timeline for their implementation;
> › A commitment to inform the Agency in due time.

3.26. 1st validation of the draft report

This step consists of a first validation of the draft report by the head of the Safety Unit before sending the document for consultation to the NSA.

3.27. Consulting the NSA on the report including the recommendations

The draft report is sent to the NSA for consultation so that they can confirm the correct description of the findings.

The document sent for consultation shall include the results of the audit related to all the departments of the NSA.

The audit team shall justify each attributed level and recommendations, which can be modified after discussion with NSA if there is evidence to support the change.

The document has to be sent to the contact person (NSA staff) who will be responsible to dispatch the draft report to the NSA staff involved to collect comments and opinions.

In any case the audit team is responsible for granting full traceability of the comments.

The comments shall be addressed by the NSA using track changes or a comment sheet. If this solution is not applicable (e.g. different software used by the NSA) other options can be agreed between the audit team and the NSA.

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

It is normally not possible to provide further evidence after the interviews, so new evidence should not be used to support comments.

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

The diverging opinions between the audit team and the audited NSA will be clearly identified and documented in the report. Both opinions must clearly appears.

For addressing the recommendations, the NSA shall provide also a draft action plan for which the time limits must be agreed with the Agency.

The outcome of the consultation with the NSA should be a definitive draft report even if it is still possible to discuss minor (justified) changes during the Exit meeting.

Next steps:

➔ *If the NSA disagrees (or does not answer within 3 months) on the recommendations ➔ next step 3.28;*

➔ *If the NSA agrees on the recommendations ➔ next step3.33 .*

3.28.   Include the official proposal in the draft report

If the NSA does not answer within three months to the consultation or rejects the Agency's recommendations or does not propose any action plan, the evaluation team will anyway maintain the recommendations in the 2nd draft report.

It is important to include in the report (as annex) all the reasons used by the NSA as justification to the disagreement with the Agency's report. This is to ensure full traceability of the activity.

Recommendations provided by the Agency are, in any case, part of the report.

3.29.   2nd validation of the draft report

The 2nd draft report shall now be validated by the HoU safety before being approved by the ED.

3.30.   Report approval

Before informing the European commission the report shall be discussed with the ED, which, eventually approves it.

3.31.   Informing the Commission in case of disagreement/no response

The Agency shall inform the European commission on the current status of the NSA and on the status of the audit. This action is done by sending the report.

3.32.   Publish the report in the safety portal

As for the normal evaluation activities, the final report shall be uploaded by the lead auditor in the safety portal.

3.33.   NSA action plan

➔ *From section 3.27*

If the NSA agrees with the content of the report drafted (and amended, if necessary) by the Agency, it will formalise an action plan.

This will include, at least:

› Type of intervention, specifying which basic elements and sub-elements are going to be improved;
› Deadline and body responsible for its implementation;
› Commitment to inform the Agency about its results.

The lead auditor will discuss with the NSA to agree on the time limits of the action plan and will check that all the recommendations are addressed by the action plan itself.

3.34.   Prepare a follow-up plan

When an agreement is reached on the action plan between the Agency and the NSA, the lead auditor will also prepare a follow-up plan that will be managed as an independent project, in the scope of the PPS procedure.

3.35.   Evolving draft report

The evaluation team will incorporate the action plan, the agreement in the draft report.

3.36.   2nd validation of the draft report

Before getting a formal agreement on the final report in the exit meeting, the report shall be validated by the HoU Safety.

3.37. Preparation of the Exit meeting

The preparation of the Exit meeting includes:

›   Presentation;
›   Mission arrangements;
›   Agenda;
›   Draft final report.

There are examples of agenda, presentations, etc. from NSA monitoring in the Safety portal.

A letter including the above documents is sent to the NSA contact person in advance. Normally, the Exit meeting is held in the premises of the NSA.

3.38. Exit meeting

The Exit meeting gathers the three auditors (normally the reviewer is not participating) and the NSA representatives that were interviewed. The main purpose of the meeting is to agree all the levels from the report, but it is equally important that the NSA is given the opportunity to start thinking about possible solutions to their problems.

The Executive Director of the NSA should participate in the Exit meeting even if he/she was not interviewed.

During the Exit meeting each attributed level is agreed as consequence of the consultation process. Changing levels is still possible but it must be documented in the minutes and supported by evidence.

The final report, integrated by an action plan with agreed time limits, is the output of the Exit meeting.

3.39. Report approval

The draft final report, formally agreed with the NSA during the exit meeting, shall be approved by the ED before publication.

3.40. Publish the report in the safety portal

After the approval by the ED, the final report shall be uploaded by the Lead auditor in the safety portal, sending a copy to the European commission.

The NSA can access the safety portal and have access to the report.

This activity closes the evaluation in case of deficiencies.

4.   Templates / Forms

›   NSA monitoring Time plan;
›   Self-evaluation form;
›   General interview questions;
›   Report.

5. Records and Others Outputs (Mandatory for process documents and procedures)

Record Name	Storage Responsible	Storage Location	Minimum Retention Time
Time plan	HoU - Safety	Safety Portal	5 years

Opening meeting email
 	
    › Agenda
    › Presentation
    › General questions
    › Self-evaluation form
	HoU - Safety	Safety Portal	5 years

Documents list	HoU - Safety	Safety Portal	5 years
Self-evaluation	HoU - Safety	Safety Portal	5 years

Exit meeting email
 	
    › Agenda
    › Presentation
	HoU - Safety	Safety Portal	5 years

Final report	HoU - Safety	Safety Portal	5 years