

**Guidance for safety
certification and
supervision**



Supervision guide

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1. Introduction

1.1. Purpose of the guide

The National Safety Authorities (NSAs) of Europe vary in size and complexity. This guidance sets out how NSAs can supervise primarily their infrastructure managers and railway undertakings but also entities in charge of maintenance, where appropriate, in a consistent manner proportionate to their size. The guide aims to provide NSAs and other interested parties with an explanation of the role that supervision plays within the European railway system and how it is related to safety assessment.

Note; for the purpose of the Supervision of the Transport of Dangerous Goods by Rail an NSA may have a direct role as the competent authority or may have a co-ordinating role liaising as necessary with any other competent authority.

1.2. What is supervision?

Supervision means the arrangements put in place by the NSA to oversee the effectiveness of the safety management system after it has granted a safety certificate or a safety authorisation and that all the necessary requirements are complied with on a continuous basis.

This supervision covers the actions of an NSA to ensure that an organisation which has been granted a single safety certificate or safety authorisation maintains its safety management system so that it controls risk effectively during the life of that safety certificate as well as a number of other specific tasks set out in Commission Delegated Regulation (EU) 2018/761 (hereafter 'the common safety method on supervision'). In order to carry out supervision the NSA should ensure that it has competent people who are selected and whose competence is maintained through a competence management system.

The common safety method (CSM) on supervision carries into effect the requirements of Directive (EU) 2016/798, as to the need for NSAs to supervise the railway undertakings and infrastructure managers within their jurisdiction once a single safety certificate or safety authorisation has been granted.

Article 17 of Directive 2016/798 requires that NSAs oversee continued compliance with the legal obligation imposed by Article 9 of the same Directive for railway undertakings and infrastructure managers to use a safety management system (SMS). In carrying out this function, the NSAs must ensure that its supervision activities include:

- ▶ The monitoring of the effectiveness of the application by the railway undertakings or infrastructure managers of the SMS in part or as a whole;

- ▶ The monitoring of the correct application of relevant common safety methods (CSMs) by the railway undertakings or infrastructure managers through their SMS, including the case where the railway undertaking or the infrastructure manager is an entity in charge of maintenance (ECM) of its own vehicles that is not certified in accordance with ECM Regulation;
- ▶ The monitoring that, in its territory, interoperability constituents are in compliance with the essential requirements as required by Article 8 of Directive (EU) 2016/797, through the railway undertaking's or infrastructure manager's SMS.

Following the outcomes of their supervision, the NSAs may take proportionate enforcement actions (e.g. temporary safety measures) to ensure legal compliance, identify any opportunities for improvement of its national law for better effectiveness and inform the stakeholders about the changes made to the safety regulatory framework as well as any emerging risks or increase of risks in their Member States.

Supervision would normally be carried out in the language of the Member State in which the Supervision takes place unless there is agreement between the relevant NSA for the area of operation and the organisation being supervised that another language be used.

1.3. Who is this guide for?

This guide is primarily for NSAs to assist them in meeting the requirements of the common safety method on supervision following the granting of a single safety certificate or safety authorization. The guide is also available for those being supervised to see what they can expect during the course of their relationship with an NSA which will help them to plan and organise accordingly.

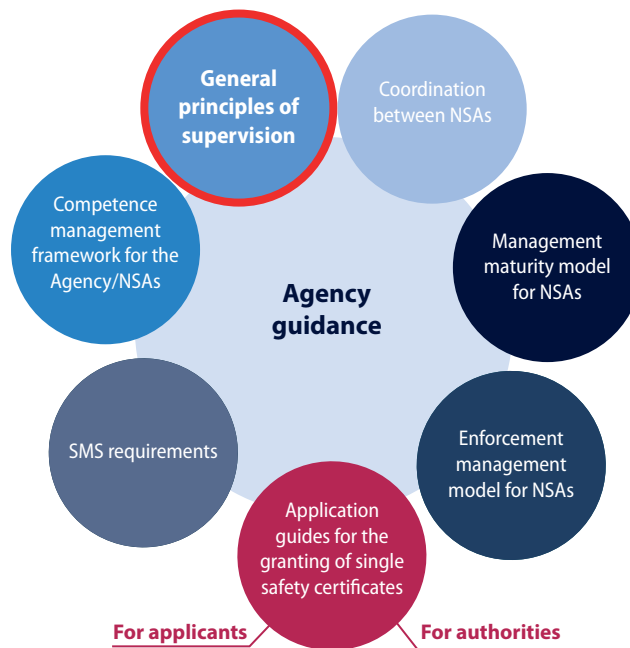
1.4. Scope

It provides detailed practical information to support the understanding of the requirements regarding supervision stipulated in the EU legal framework.

1.5. Guidance structure

This document is part of the Agency compendium of guidance supporting the railway undertakings, infrastructure managers, national safety authorities and the Agency, in fulfilling their roles and undertaking their tasks in accordance with Directive (EU) 2016/798.

Figure 1: Compendium of Agency guidance



1.6. Who gets supervised?

From the legal context set out above it can be seen that the NSAs must supervise those entities which have a single safety certificate or a safety authorisation, respectively the railway undertaking or the infrastructure manager. They do this for the purpose of checking that those entities are delivering on the commitment in their applications for a single safety certificate or safety authorisation to maintain a SMS which controls risk.

2. Definitions

The following definitions are used in this guide:

Relevant stakeholders

Relevant stakeholders means anyone with a role in or affected by railway operations who has an interest in the safety outputs e.g. industry bodies, passenger organisations or local authorities.

Unnecessary inconvenience

This simply means that if you are going to a railway undertaking to carry out some supervision then the work is coordinated in such a way that the railway undertaking doesn't have two different sets of supervision requiring the interviewing of the same people at the same time or that it does not have several supervision visits within the same timescale from different people from the same department. This is about planning the necessary interventions in the most efficient way possible so that the work gets done in a sensible timeframe without causing major disruption to the organization being supervised.

Management arrangements

Management arrangements refer to the processes and procedures of the SMS put in place by the railway undertaking or infrastructure manager to manage safety and to achieve its safety objectives, while complying with its legal obligations and other requirements relevant for safety.

Major non-compliance

A major non-compliance is an issue identified by an NSA where the deviation from the expected position is such that remedial action must be taken under the direction of that NSA or in the case of matters referred to the Safety Certification Body (SCB), consideration given to the withdrawal or restriction of the Single Safety Certificate or Safety Authorisation.

Any other area of concern

Any other area of concern refers to a situation where the NSA during supervision has identified a deviation from the expected position but this is not serious enough for direct action to be taken but is serious enough for the NSA to record their findings and notify the organisation being supervised of the need to improve the position. The information in both categories identified by the NSA should be forwarded to the safety certification body in an appropriate timeframe after an application for a single safety certificate has been made so that any issues around non-compliances can be considered by this body.

3. Risk based supervision

It is possible to identify some key areas of importance for risk based supervision to work effectively. These are:

- ▶ The NSA must have a global understanding of the risks within the national railway system and which of these are the most significant;
- ▶ The NSA must have a good understanding of the management capability of Railway Undertakings and Infrastructure Managers (and related actors), to control the risk;
- ▶ The NSA must have staff competent in making judgements across the bullet points above and flexible enough to adjust their approach if they see risks rising or falling (see Agency guide on the competence management framework);
- ▶ NSAs should draw information from as wide a range of sources (both from within and outside the railway industry), as possible to aid their risk based supervision decision making;
- ▶ NSAs must be able to justify the decisions they make in relation to what they supervise and what they don't;
- ▶ NSAs must be able to accommodate other drivers for supervision within the Member State, such as political imperatives or societal concern which may not be risk based;
- ▶ Supervision must be linked to single safety certificate and safety authorisation assessment in such a manner that those operators or activities within operations which are considered of greater risk receive more supervision immediately following the award of the single safety certificate or safety authorisation;
- ▶ The supervision undertaken must allow the NSA to satisfy themselves that the railway undertaking's or infrastructure manager's SMS is capable of controlling the risks that they face.

In implementing the above principles, NSAs should have some means (quantitative, semi-quantitative or qualitative) of understanding the global risk within the Member State. This is critical for developing the supervision strategy. Without a clear idea of the risks faced it is impossible to make proportionate and targeted decisions about what to supervise and how best to do this. Lack of understanding of the risks within the system also means that in conversations between the state and the NSA there is a missed opportunity to reflect adequately on what safety improvements can be managed within available funding. The NSAs ability to clarify for the Member State where safety improvements should be targeted can be a useful input for Member States in creating the opportunities for safety improvements. The global understanding of safety risk within the system is effectively the starting point for a business case for safety improvement to reduce that risk.

It is also worth noting at this point that the NSA's understanding of the global risk within the Member State should not be too dissimilar to that of any national infrastructure manager. One would expect for example a similar view of the level of overall risk from level crossings in the Member State between the infrastructure manager and the NSA. If the view between the infrastructure manager and the NSA is very different, this might be an indication of failures within the system to manage risk.

In terms of the means of arriving at a global view of risk in the Member State, it would be helpful at a European level if there was convergence towards a standard method of achieving this. At this stage however, even amongst those countries which are using similar approaches there are detailed differences which make a European level comparison difficult. Current approaches vary from the extremely sophisticated to the very simple and this maybe a reflection of the maturity of the Member State railway system in use of the European approach, their sizes as well as different cultural biases.

Assessing the capability of the different actors within the railway system to manage risks requires an ability on the part of the NSA to use supervision to determine how effective the safety management systems are of the organisations they supervise. For most NSAs this comes down in practice to employing trained and competent inspectors who are capable of making these judgements.

NSAs must be able to use information from as many sources as possible in order to be able to cross-check information and avoid relying on one data set to determine supervision priorities. NSAs are also encouraged to use information on risk management from outside the railway industry where appropriate in order to verify findings and drive improvement in risk management processes. There will be data sets or sources of information of particular relevance such as accident or incident data, company daily logs and outputs of risk models within the Member State which can be used if these are available. However, other information from complaints, or issues arising from public perception or academic study should also be considered as useful information on which to develop a risk based supervision strategy and plan.

In accordance with Article 7 of CSMs on supervision, NSAs should have a set of criteria for who will be supervised and why. This set of criteria is related to the achievement of the strategy. The purpose of this is to make sure that there is a consistent approach taken across the supervision activities and that the various actors within the system are clear as to why particular activities are being assessed and what the success measures against which they are being judged are.

The TSI OPE also requires that NSAs as part of their supervision strategy and plan monitor effective compliance, (because the TSI OPE deals with the process and rules that contribute to safe train operation) in their day to day delivery of their supervision of the SMSs of the organisations they regulate. Guidance published by the Agency on the application and use of the Fundamental Operating Principles set out in the TSI OPE will assist NSAs in carrying out supervision in this area.

NSAs can also face pressures from external sources which are not risk based. These might stem from a public concern about some aspect of railway operations which becomes a political imperative to address the issue. This may or may not tie in with the supervision strategy and the supervision plan but it will need to be accommodated within both. Such issues can have a large positive impact on safety. So for example a Member State might decide to remove all level crossings in its territory within 10 years, whereas the risk based approach might not see all crossings removed but upgraded with modern protection systems. Clearly, if the crossings disappear completely in ten years there is a significant safety gain for the Member State. Conversely, an NSA may face pressure on the grounds of utility of use to retain level crossings where a risk based approach would see them removed.

3. Risk based supervision

It is critical that risk based supervision is linked to the outcomes of safety certificate and authorisation assessment. This is because the assessment of the certificate in most cases will only deal with the application of the safety management system to the activity by a railway undertaking or an infrastructure manager on paper. Whether the application works in practice is a matter for supervision. For existing railway undertakings and infrastructure managers with a long history in the industry supervision can be structured equally over the life of the certificate. For new entrants into the system it may be appropriate to increase supervision at the start of the certificate's lifespan or after the start of the operation to target activities at specific elements of the SMS to make sure that what is written on paper is indeed put into practice in a coherent manner. For both existing companies and new entrants it is essential that the scope of the supervision activities is targeted on a risk basis

As resources within NSAs for supervision are often scarce, in deciding what to supervise and why on a risk basis, it is vital that the question of where supervision will be of most value is addressed. For example, it may be that the infrastructure manager is aware of issues around broken rails and has a programme in place to manage this. For the NSA to spend a lot of time on this may not be the best use of their resource. Instead the NSA may choose to focus on an area where it is perceived the infrastructure manager does not appear to be managing the problem.

4. Supervision strategy

Article 3 of the CSM on supervision requires that NSAs have a supervision strategy which contains the elements set out in Annex I of the CSM. A proposed template for a supervision strategy is set out in the Annex to this guide. The headings in the template are aimed at allowing a consistent approach to the development of supervision strategies across the Member States to develop confidence between NSAs that safety levels are being maintained. In addition, as the Agency has a role in monitoring NSA performance, a common structure to such strategies would assist in the exercising of this function.

4.1. Background

In describing the background a basic description of the size of the railway network within the Member State including the numbers of railway undertakings and infrastructure managers will be sufficient. This section should also deal with the length of time that the supervision strategy is in place for and the arrangements for reviewing it.

4.2. Objective

The objective or goal should refer to the purpose of the strategy, for example 'to work with the industry to continuously improve safety management performance'. The section should also include reference to how the objective will be achieved.

4.3. Supervision principles

The principles are a reiteration of the NSA's commitment to the key values which ensure that decision making during supervision is firm but fair. Annex I of the CSM on supervision states that in setting up the supervision strategy and the plan(s) that follow from it, the NSA shall collect and analyse data/information from a range of sources. Sources include information from the assessment of safety management systems, outcomes of previous supervision activity, expert judgement of inspectors, relevant information from vehicle authorisation, reports from national investigation bodies (NIBs), other accident or incident data, the annual safety reports of railway undertakings or infrastructure manager's, reports from entities in charge of maintenance, complaints from members of the public and other relevant sources. In essence, the NSA should take relevant information from wherever it is to be found in order to work out where the main areas of risk are within the Member States railway system. They will need to assess and analyse the available information to determine which issues are the most significant and then they will need to devise a strategy which addresses these issues along with a plan which seeks to identify how and over what period the strategy will be delivered. The NSA must both work out what resources are required to deliver its proposed strategy and plan and allocate sufficient resources to deliver it. Finally, the NSA must address any issues within its strategy and plan which relate to cross-border operations or infrastructure and coordinate as appropriate with any other NSAs as required.

4. Supervision strategy

The supervision principles that the NSA should apply are mainly derived from Annex I of the CSM on supervision. NSAs should approach their supervision activities using an approach based on firmness and fairness. The supervision principles are designed to help NSAs achieve this.

NSAs should apply the principle of **proportionality** between enforcement and risk. Action taken by a national safety authority to achieve compliance or bring railway undertakings and infrastructure managers to account for not meeting their legal obligations shall be proportionate to any risks to safety or to the potential seriousness of any non-compliance, including any actual or potential harm. This principle is critical for National Safety Authorities since by adopting this approach they are demonstrating to those they regulate that they apply the law in a reasonable and fair manner. This reduces the potential fear in regulated organisations that mistakes or errors will face draconian punishment from the NSA which in turn creates a culture of secrecy and fear which does not promote robust risk control.

NSAs should apply the principle of **consistency** of approach to ensure that a national safety authority takes a similar approach in similar circumstances to achieve similar ends. Railway undertakings and infrastructure managers want to be treated in the same way by different personnel carrying out supervision within one NSA and by different NSAs where there are cross-border arrangements. This gives them certainty and allows them to plan better. It also addresses issues around safety culture and reduces the fear on the part of railway organisations of the NSAs.

National safety authority supervision activity should be **targeted** primarily at those activities which a national safety authority believes give rise to the most serious risks or where the hazards are least well-controlled. To do so, the national safety authority shall have methods and tools to assess the safety management performance of the railway undertakings and infrastructure managers. In a situation where resources are scarce and demands on NSAs are many, it is critically important that the focus is on those risks which are the most serious. The mechanism for doing this is the analysis by the NSA of the management performance of railway undertakings and infrastructure managers.

NSAs should decide on their priorities so as to use their **resources** effectively but the decision on how best to do that should rest with each individual national safety authority. Action shall be focused on those who are responsible for the risk and who are best placed to control it. NSAs have scarce resources so it is important that these are used wisely in order to maximize the effectiveness of the NSA in making sure that those responsible manage risk in an appropriate manner.

NSAs should apply the principle of **transparency** to help railway undertakings and infrastructure managers understand what is expected of them (including what they should or should not do) and what they should expect from the national safety authority. For railway undertakings and infrastructure managers it is extremely important that they understand how an NSA makes decisions so that they can understand what the likely outcome will be if they do not control risk in an appropriate fashion.

NSAs should be **accountable** for their decisions in accordance with Article 18(3) of Directive (EU) 2016/798. NSAs shall therefore have internal arrangements against which they can be held to account. Moreover, national safety authorities shall also have a complaints procedure. NSAs have to make decisions some of which will adversely affect railway undertakings and infrastructure managers which do not manage risk effectively. It is important that NSAs have clear criteria for making these decisions so that it is clear how they were arrived at. Secondly it is very important that there is a process for challenging such decisions where a regulated body feels that the NSA has overreached its powers or has not followed due process.

NSAs should develop **cooperation** arrangements with other competent authorities in order to share information and to develop unified approaches to issues that impinge on railway safety. NSAs must have processes in place for sharing relevant information with each other and with other competent authorities. This is critical to ensuring that the correct action is taken by the right body where necessary.

If an NSA applies these principles then those who are supervised will be treated fairly and where appropriate with firmness. It is also worth pointing out that these principles are complementary, working together to present an NSA to the bodies it regulates as a competent and reasonable authority making sound judgements in an open and honest manner. It will be noted that the supervision Strategy template in the Annex to this guide sets these principles out again. This is because this strategy is extremely important for setting the tone for how supervision will be conducted by reproducing the principles here an NSA will reinforce its commitment to them and provide evidence that they are being transparent in their approach.

The Agency has also created a *guide on an enforcement management model* which can be used by those carrying out supervision and reflects the principles set out above. The guide takes the principles and applies them to a matrix which is intended to provide guidance for those carrying out supervision as to what their decisions on enforcement should look like based on an analysis of the risk gap. The larger the risk gap, i.e. between the expected position of an organisation if all rules were properly applied and the actual position then the greater the enforcement action that should be expected.

4.4. Arrangements for supervision

The arrangements for supervision should cover in general terms the governance structure and staffing of the NSA including how the links with safety certification and safety authorisation are managed. The NSA should be transparent about its management structure and how supervision issues are escalated as necessary from operational to a more senior level, including where appropriate for enforcement decisions. The NSA should also be transparent about how it arrives at decisions to regulate risks more in one area than in another. The NSA should indicate what its staffing is and in general terms how it maintains their competence (see *Agency guide on the competence management framework*), and on what basis it deploys staff. The NSA should also indicate how it intends to measure the performance of safety management systems as part of its supervision activities for example by use of a maturity models/safety culture models or by other means. The Agency has produced a guide for one proposed management maturity model that can be used both by authorities and stakeholders of this purpose. (see also *Agency guide on management maturity model*) or other means.

4. Supervision strategy

One of the key issues for NSAs is how new entrants to the market are managed given that there is no historical information on the quality of their SMS. This has led to some NSAs giving first entrants to the railway market a safety certificate covering a shorter period of time than 5 years. Other NSAs have decided to carry out a more comprehensive audit of a new entrant before issuing a safety certificate or to carry out such an audit immediately afterwards. Any restricted period of validity has to be justified on the grounds that it is necessary in order to ensure the effective control of risks affecting the safety of railway operations. NSAs can carry out more detailed examination of new entrants following certification to ensure that their safety arrangements are fit for purpose. The NSA should set out clearly within their supervision strategy and plans what the arrangements are.

4.5. Risk levels within the Member State

The next section on risk levels within the Member State should deal with how these are arrived at e.g. the use of risk and/or maturity models and any issues surrounding why certain risks are covered within the strategy and others are not.

4.6. Strategic priorities for supervision

The following section should deal with how Strategic Priorities are set these should cover:

- ▶ How SMSs are to be supervised. Here the NSA should indicate the supervision techniques (see section 4.7 below), that it is likely to use and why it favours some areas over others;
- ▶ How co-ordinated and/or joint supervision with other NSAs if appropriate will be carried out (see the section on co-ordinated supervision and co-operation below);
- ▶ Higher level risks. For this bullet point the NSA is expected to indicate what they believe the highest safety risks within the system are and how they have arrived at this conclusion;
- ▶ Lower level risks will be supervised in general terms. For this bullet point the NSA is expected to indicate what it considers its second order risks are and indicate why it has arrived at this conclusion.

4.7. Supervision techniques

Article 4 of the CSM on supervision requires the NSAs to adopt suitable techniques and identify these techniques when planning their supervision activities. Supervision techniques have a broad meaning encompassing both information gathering (a related activity) for the purpose of examining the safety outcomes of the management system and referring directly to specific activities such as interviewing people. As supervision of railway undertakings and infrastructure managers for the purpose of making sure that they comply with EU and national law is a wide ranging task for the NSA, there are correspondingly many different approaches which can be used to gather information on the level of compliance. However, all these approaches involve the acquisition of information in various ways followed by an analysis of what it tells you about the safety management system of the organisation being supervised and its level of compliance with the law.

There are various specific techniques that can be used to deliver supervision activities on or off site. These include:

- ▶ Inspection of physical assets on site such as rolling stock or infrastructure elements;
- ▶ Inspection of safety management procedures and documentation to ensure that they are fit for purpose;
- ▶ Interviews with staff at all levels in a Railway Undertaking or Infrastructure Manager to identify their understanding of how procedures and rules are delivered in practice and to make a judgement on the safety culture of the organisation;
- ▶ Audits to a defined management system standard e.g. OHSAS 18001:2007;
- ▶ Audits to a model defined by the NSA;
- ▶ Audits/inspections of an activity or process following an incident;
- ▶ Safety Management capability/maturity audits;
- ▶ Data analysis;
- ▶ Sampling of products or activities;
- ▶ Task observation (e.g. cab rides to observe driver behaviour);
- ▶ NSA attendance at key management meetings of an RU or IM (e.g. on level crossings or new infrastructure projects).
- ▶ Surveys of organisations requiring completion of self-assessment questionnaires e.g. for assessment of safety culture or compliance with legislation or checklists;
- ▶ Any other relevant activities which add to the sum of the NSAs knowledge of a particular RU or IM, its' safety management and its' safety culture.

For the purposes of this paper:

- ▶ **Inspection** means the use of an authorised and competent staff member of the NSA to examine a particular and limited aspect of the activity of an RU or IM. Inspection should be for the purpose of establishing compliance with European and National law or for verifying that what has been said or recorded in documents supporting the safety management system, actually happens in practice. An inspection in the sense intended here both verifies that the process is in place and examines how well it works. It does not mean the 'tick-box' verification of the presence of certain documents or equipment, because this can only tell the Inspector that something is present not that it is being used in practice.
- ▶ **Audits** mean the structured interventions where the RU or IM is examined against a particular safety management standard or against a particular audit protocol.
- ▶ **Safety Management Capability Maturity Model Audits** are a structured method of carrying out an audit of the SMS of the organisation being audited using a management

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capability/maturity model to examine how effective they are at managing safety (see also the Agency guide on its management maturity model). Such a model if used correctly by competent supervision staff can give a picture of the performance of the SMS. It can therefore be a useful tool for an NSA to use to provide information about the functioning of a particular SMS to the safety certification body when a renewal application is being considered.

The techniques used, such as interviews, document review or verification inspection can be undertaken in greater or lesser depth across a smaller or larger range of processes and mixed to give a picture of the organisation's safety performance as well as to identify underlying failings.

Interviews with individuals, examinations of documents and verification inspections can then be used to form a judgement of the management maturity of the organisation and the system's ability to control the risks it faces. The competent person carrying out the audit then applies their own judgement using a management capability or maturity model to assess how good the organisation's safety management system is at managing safety.

Task observation and attendance at management meetings are activities which act to increase the store of knowledge in the NSA on a particular railway undertaking or infrastructure manager and its safety culture.

For an NSA the use of a mixture of supervision techniques is suggested as the ideal situation. Each NSA should aim to achieve a good balance between top down activity (audits of the SMS) and bottom up activity (on the ground inspections observing what is going on). Supervision approaches can draw together existing inspection activities and blend them with SMS audits in order to sample the management arrangements. This will negate some of the weaknesses of particular techniques and create a more genuine overall picture of how the subject of the supervision is performing in practice.

The techniques described above can also be used by the NSA to conduct cross-cutting examinations of the interfaces between railway undertakings and/or infrastructure managers for the purpose of gaining an overall picture at Member State level of how various issues are managed across the railway system.

The table and the figure below show how general inspection and management systems audits are related, especially the techniques of interviewing, reviewing documentation and observation. These types of techniques feature in standards such as ISO 19011 on "Guidelines for auditing management systems" and NSAs have the freedom to decide whether to follow the requirements of the standard or not. The table below sets out the types of techniques associated with the different types of activities.

Table 1: Relationship between on and off-site activity in management systems audits and inspections

	On site activity	Off-site activity
Interaction with people	<ul style="list-style-type: none"> Conducting interviews. Completing checklists and questionnaires with auditee participation. Conducting document review with auditee participation. Sampling 	Via interactive communication means: <ul style="list-style-type: none"> ▶ conducting interviews; ▶ completing checklists and questionnaires; ▶ conducting document review with auditee participation.
Limited/No interaction with people	<ul style="list-style-type: none"> Conducting document review (e.g. records, data analysis). Observation of work performed. Conducting on-site visit. Completing checklists. Sampling (e.g. products). 	<ul style="list-style-type: none"> Conducting document review (e.g. records, Data analysis). Observing work performed via surveillance means, considering social and legal requirements. Analysing data.

4.8. Supervision plan(s)

The supervision plan(s) should deliver the practical application of the supervision strategy over the duration of that strategy. Because the supervision plan is derived from the supervision strategy it should be based on the risks identified as requiring supervision in the supervision strategy. The supervision plan should also highlight how the links between the safety certification and authorisation assessment process and the supervision process for railway undertakings and infrastructure managers over the length of the safety certificate or authorisation will work including where necessary the need to co-ordinate with the Agency when it is the safety certification body and with other NSAs. The supervision plan should include information about the process for its creation and review and the links with the supervision strategy including how the results of the plan result in changes to the strategy. The supervision plan should detail which railway undertakings and infrastructure managers are to be supervised in the year to which the plan relates as well as the reasons for the supervision. The resources to be allocated to supervision should be specified within the supervision plan. The supervision techniques to be applied during supervision should also be indicated. Where the supervision plan addresses issues around human factors the NSA should be looking to see within the SMS's of the railway undertakings and infrastructure managers how these matters are managed.

4.9. Enforcement

The CSM on supervision states in Article 7(1) that the NSA must have criteria for managing non-compliances identified in the SMS of the Railway Undertaking or Infrastructure Manager and Annex 1 states that an NSA should take enforcement action where appropriate. This action will depend upon what sanctions individual national laws allow an NSA to take. In the context of the CSM on supervision, failures to comply will be instances where the railway undertaking's or infrastructure manager's SMS is not fulfilling the key requirement of controlling risks. The sanctions that an NSA might apply should be based on the key principles of supervision (see

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section 4.3). The NSA must show that any action it takes is proportionate and targeted at the perceived risk. The CSM on Supervision (Article 5(2)(a)) divides issues which the NSA should target into major non-compliances and other areas of concern. The level of sanction that an NSA might seek to impose should reflect the level of non-compliance or concern. The organisation being enforced against must be able to understand why a sanction is being applied and how it can improve. NSAs may use any enforcement management model which covers the key principles of supervision to give a structured and transparent process to taking enforcement action under national or EU law. To assist NSAs the Agency has developed as a Guide an enforcement management model which can be used in conjunction with different national regulations. (see *Agency guide on enforcement management model*).

5. Referral of supervision information and interdependences with the assessment of single safety certificate and vehicle authorisation

It is clear that supervision is the means by which an NSA ensures that the SMS of a railway undertaking or an infrastructure manager functions according to the arrangements set out in the original application for a single safety certificate or safety authorisation. Article 17(5) of Directive (EU) 2016/798 and Annex I of the CSM on supervision makes it very clear that if an NSA finds during supervision that a holder of a single safety certificate no longer satisfies the conditions for certification then they can either restrict or revoke the certificate or request the Agency does so where it is the safety certification body (one structured method of working through this is set out in the Agency Enforcement Management Model Guide). According to Article 17(7) of the same Directive, the NSA shall ensure that the structural subsystems are in compliance with the essential requirements and the safety authorisation of an infrastructure manager can be restricted or revoked it or the Safety Certification Body if the conditions under which it was issued are no longer fulfilled.

Article 5 of the CSM on supervision explains the need for exchanging information gained during supervision with the part of the NSA responsible for safety certificate assessment or with the Agency for the purposes of the renewal or update of a single safety certificate or safety authorisation. The same Article goes on to say that the NSA should pass to the safety certification body or the NSA for cross-border infrastructure relevant information including at least:

- (a) *A description of major non-compliances, which may affect safety performance or create serious safety risks, and any other area of concern identified during supervision activities. This information can be retrieved from audits, Safety Management Maturity Model Audits and inspections reports and summarised for the purpose of re-assessment;*
- (b) *The status of the action plan (or plans) established by the railway undertaking or infrastructure manager to resolve major non-compliances referred to in point (a) and relevant actions that have been taken by the national safety authority to supervise resolution of these issues. This information can be retrieved from follow-up audits, Safety Management Maturity Model Audits and inspections;*
- (c) *An overview of the safety performance of the railway undertaking or infrastructure manager operating in its Member State. This information can be retrieved from a capability/management maturity model (if any) or even by expert judgement, evaluating the safety management system processes performance and capability (i.e. how well they perform to fulfil their legal obligations and continually improve in controlling risks);*
- (d) *The status of the action plan or plans established by the railway undertaking or infrastructure manager to resolve residual concerns from previous assessment.*

5. Referral of supervision information and interdependences

The NSA provides the safety certification body with information which is relevant to an understanding of how well the SMS is working in practice and whether there are any weak areas. This will allow the safety certification body to better target its assessment activity.

In order to meet these requirements the NSA will need to consider what information on the organisation being regulated is relevant under the four headings above. For point (a) it is clear that the information should include issues identified by the NSA as important for the control of risk (through the safety management system) and from point (b) and (d) the action and timescales that have been agreed between the parties to address the issues concerned either voluntarily by the organisation itself or through action taken by the NSA to require the organisation to remedy the situation. Point (c) requires the NSA to supply the safety certification body or NSA for cross-border infrastructure with a pen picture of the safety performance of the organisation. This could be achieved for example via a report of supervision undertaken on the organisation concerned or by providing the outputs from a management maturity model for the organisation which will provide an overview of the relative performance of the SMS.

In addition to the list above, the following may also give an indication of the sort of information which may also be useful for a safety certification body in understanding how an SMS works:

- (a) *History of the different supervision activities since the previously granted single safety certificate or safety authorisation and follow-up of the NSA's recommendations raised as a result of its supervision activities. This information can be retrieved from the NSA supervision plan(s) and follow-up table of NSA recommendations for the relevant railway undertaking or infrastructure manager;*
- (b) *Outline of future NSA's supervision activities planned for the relevant railway undertaking or infrastructure manager. This information can be retrieved from the prospective NSA supervision plan(s);*
- (c) *Any results of the collection and analysis of accidents/incidents and complaints submitted to the NSA, which relate to the performance of the safety management system, including a brief summary of each event and any action that has been taken by the NSA to supervise resolution of the issues raised. This information can be collected and analysed from the railway undertaking's or infrastructure manager's annual safety report, reporting of incidents/accidents from the railway undertaking or infrastructure manager to the NSA and also from databases or registers such as ERAIL for railway accident and incident investigations;*
- (d) *Information on serious safety risks raised during internal auditing and other monitoring activities of the railway undertaking or infrastructure manager, status of the action plan to close out the issues and any action that has been taken by the NSA to control its completion and effectiveness since the previously granted single safety certificate or safety authorisation. This information can be collected and analysed from the railway undertaking's or infrastructure manager's annual safety report (i.e. report on the application of CSM on monitoring);*

- (e) *Information reported by the relevant NIB on current investigations into any events relating to the activities of the railway undertaking or infrastructure manager and still open recommendations from previous investigations that are not addressed by the railway undertaking or infrastructure manager. This information can be collected and analysed from the railway undertaking's or infrastructure manager's annual safety report but also from databases or registers such as ERAIL for railway accident and incident investigations. In accordance with Article 8(3) of the CSM on supervision, the NSA should also coordinate with the NIB. It should be expected that relevant information is shared between the NSA and the NIB during this coordination;*
- (f) *Outline of any NSA enforcement action, as set out in the national legislation, which relates to the performance of the safety management system that has been taken against the railway undertaking or infrastructure manager since the previously granted single safety certificate or safety authorisation. This information relates to NSA actions taken to enforce its decisions, e.g. improvement/prohibition notice, penalties, temporary safety measures (in the meaning of Article 17 of Directive (EU) 2016/798);*
- (g) *Any additional information that the NSA considers important for the purposes of the assessment. Additional information can be collected and analysed from the railway undertaking's or infrastructure manager's annual safety report and from the NSA annual report.*

The general expectation is that the above information will be provided to the safety certification body by the NSA at the time of an application to renew a single safety certificate. If the NSA during its supervision decides to take enforcement action including prosecuting a railway organisation and it believes that the safety certification body should consider the revocation of the single safety certificate then it should refer the matter directly to the safety certification body and not wait until the application for the renewal of the single safety certificate.

This therefore implies some co-ordination activity between those carrying out supervision and those carrying out certification. It is clearly important to make sure that relevant information is shared between those carrying out supervision and those carrying out safety assessment so that issues relating to the SMS of a railway undertaking or an infrastructure manager are properly dealt with by the appropriate party. NSAs within their supervision strategies and plans should have arrangements in place to manage this.

Article 11(3) of Commission Implementing Regulation (EU) 2018/763 [*practical arrangements for issuing single safety certificates*] makes clear that following assessment the safety certification body shall agree with the NSA what residual concerns are outstanding from the assessment and which can be deferred for later assessment during supervision.

5. Referral of supervision information and interdependences

For vehicle authorisation, it is important that there is also a mechanism for those approving vehicle authorisations to pass on relevant information from vehicle authorisation to those carrying out supervision particularly in relation to restrictions on the conditions of use of vehicles. Similarly, NSAs should also have a mechanism for those carrying out supervision to pass information back to those who authorised a particular vehicle where there are concerns about whether that vehicle still complies with the conditions under which the vehicle type authorisation or vehicle authorisation for placing on the market was granted. It should be noted that during the operation of a vehicle it may be that defects are found which affect all the vehicles of that type or series. If so then a safety alert could be raised depending on the defect using the Safety Information System (SIS). The NSA should also take action to control how the RU/IM has controlled the risk and alert the ECM (if there is one).

6. Coordination among NSA(s)

Article 8 of CSMs on supervision requires that NSAs coordinate their supervision activities with those of other NSAs where there are cross-border operations. This coordination is necessary to avoid duplication of effort by NSAs and not to burden the supervised organisations with multiple contacts from different countries safety regulators. It is also there to make sure that the various NSAs supervising cross-border operations share relevant information to allow them to supervise effectively. In the case of coordination of supervision activities it will be necessary for the NSAs to decide amongst themselves who will be the 'lead' NSA. In this context the 'lead' NSA is the one acting as the overall coordinator of the supervision activities and the main contact point for the railway undertaking or infrastructure manager involved. The 'lead' NSA may be the NSA from the MS where the largest volume of activity takes place or where the organization being supervised is registered. The NSAs should agree the key areas to examine during supervision over the life cycle of the single safety certificate or a safety authorisation and develop a plan for delivering what they have jointly agreed. The NSAs should also agree a dispute arbitration process for managing any disagreements between the NSAs carrying out the supervision activity.

Annex II of the CSM on supervision gives a framework for coordinated and joint supervision which can be used by NSAs as a guide to managing this process. Key points are that the supervision should be coordinated in such a way that unnecessary inconvenience is not caused to the railway undertaking for example by making sure that key personnel in the railway undertaking are not required by different NSAs at the same time or that the same location is subject to multiple information gathering visits in a short space of time. Where the NSAs are operating under legal provisions which do not envisage or permit 'joint supervision' this should be reflected within the agreements between them. In this case it will be necessary for the 'leading' (or coordinating) NSA with the other NSAs concerned to develop a joint plan to implement the necessary supervision activities within each Member State.

Where a partnership agreement (or contract) between railway companies exists which allows a train from one Member State to become a train from another at the moment that it crosses the border (even though the crew and train are from the railway company in the first Member State), then the NSAs concerned should coordinate between themselves to make sure that the risks associated with matters at the interface between the railway company's such as training in relevant national or international rules and maintenance of the trains involved are managed correctly. If one NSA discovers problems with the arrangements with a railway company in these circumstances they should liaise with the relevant neighbouring NSA as to the action that they intend to take to deal with the matter.

More information can be found in the *Agency guide on coordination between NSAs*.

7. Human factors and safety culture

For both the purposes of safety assessment and supervision, NSA staff should be able to identify the human factors and safety culture strategy and how the organisation being supervised incorporates such issues within its SMS (see Annex I and Annex II of the CSM on SMS). Following on from this the NSA should build up a store of knowledge on how human factors and safety culture issues are taken into account which can be used to inform the supervision strategy and the supervision plan(s) (see also *Agency guide on SMS requirements* and *Agency guide on management maturity model*).

8. Cooperation with other competent authorities or bodies

It is expected that an NSA acting in its capacity as safety regulator in a Member State will have on occasion to liaise and cooperate with other competent authorities or bodies during the course of the fulfilment of their functions.

Article 8(3) of the CSM on supervision states that the NSA must develop cooperation arrangements with relevant other bodies such as the NIB, the certification body for ECMs, or other competent authorities so that relevant information is shared and serious safety risks are properly addressed. The purpose of this provision is to make sure that those with a measure of authority and who may need to take specific actions are properly informed and can react accordingly.

For example, it may need to cooperate with authorities tasked with the regulation of dangerous goods, labour inspectorates, police (criminal enforcement), environmental regulators, ECM certification bodies, railway regulatory bodies, authorising or certification bodies and licensing authorities.

The following are illustrative examples of such cooperation. NSAs should ensure that where necessary their strategy and plans are aligned as appropriate.

8.1. Authorising or certification bodies

NSAs are expected to cooperate with other authorising (e.g. bodies responsible for the authorisation of vehicles) or certification bodies (e.g. bodies responsible for the certification of train driver training centres) as appropriate. From the supervision perspective, an NSA carrying out supervision should accept certificates or authorisations presented as evidence of compliance with EU or other regulations to the extent that they cover the matter being supervised. If the NSA becomes aware during the course of its supervision activity that there is a serious safety issue involving a matter for which an authorisation or certificate is presented it should take temporary remedial action (e.g. suspension of vehicle use) as appropriate and refer the matter to the relevant body responsible for issuing the certificate or authorisation.

8.2. Workplace safety issues

Some NSAs are responsible for workplace safety issues within their Member State regulatory systems whilst other NSAs are not. In the first case where workplace safety issues arise during supervision these should be dealt with by those carrying out the supervision. Where in the second case NSA staff carrying out supervision become aware of workplace safety issues, they should make the supervised organisation aware that they have seen something of concern and should then refer the matter to the relevant competent authority for follow up. The NSA should also coordinate and liaise as appropriate with the responsible regulatory authority for workforce safety to ensure their respective strategies and plans are aligned.

8.3. Train driver, working, driving and rest time rules

Article 17(4) of Directive (EU) 2016/798 requires that a competent authority is responsible for ensuring compliance with train driver working, driving and rest time rules. Where this competent authority is not the NSA then that authority should co-operate with the NSA to allow the NSA to carry out its supervision activity. It follows from this that if the NSA is not the competent authority for compliance with such rules but it becomes aware through its supervision activities of issues concerning them in a particular organisation, it should inform the competent authority at the earliest opportunity of its findings.

8.4. Cooperation between an NSA and other regulatory bodies

Article 56(3) of Directive 2012/34/EU states the following:

The regulatory body shall also cooperate closely with the national safety authority within the meaning of Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community, and the licensing authority within the meaning of this Directive.

Member States shall ensure that these authorities jointly develop a framework for information-sharing and cooperation aimed at preventing adverse effects on competition or safety in the railway market. This framework shall include a mechanism for the regulatory body to provide the national safety and licensing authorities with recommendations on issues that may affect competition in the railway market and for the national safety authority to provide the regulatory body and licensing authority with recommendations on issues that may affect safety. Without prejudice to the independence of each authority within the field of their respective competences, the relevant authority shall examine any such recommendation before adopting its decisions. If the relevant authority decides to deviate from these recommendations, it shall give reasons in its decisions.

In practice this could mean:

- (a) *In a situation where an incumbent railway undertaking is asked by the regulatory body to 'open' services to competition and it refuses citing 'safety' as a reason, the regulatory body should ask the NSA as the 'safety regulator' for its view as to whether this is a justified reason for not opening services. The Regulatory Body should then take the view of the NSA into account in coming to a decision on what action to take;*
- (b) *In a situation where an infrastructure manager intends to apply to the NSA for an authorisation to place in service an ETCS Level 1 trackside subsystem which implements some of the optional functionalities (e.g. loop infill, radio infill) that require vehicles to be fitted with relevant equipment in order to be able to run on this line, the NSA should ask the regulatory body to confirm that this does not discriminate against railway undertakings and that the relevant information has been made available to all interested parties giving them the necessary time to adapt their rolling stock accordingly.*

8.6. Cooperation between an NSA and a licensing authority

Directive 2012/34/EU states the following:

Art. 24(3): *Notwithstanding paragraph 1, where a licence is suspended or revoked on grounds of non-compliance with the requirement for financial fitness, **the licensing authority may grant a temporary licence** pending the reorganisation of the railway undertaking, **provided that safety is not jeopardised**. A temporary licence shall not, however, be valid for more than six months after its date of issue.*

Art. 24(5): *In the event of a change affecting the legal situation of an undertaking and, in particular, in the event of a merger or takeover, **the licensing authority may decide that the licence shall be resubmitted for approval**. **The railway undertaking in question may continue operations, unless the licensing authority decides that safety is jeopardised**. In that event, the grounds for such a decision shall be given.*

In practice, in order for the licensing authority to make its licensing decision it must consult with the NSA as the safety regulator. The question the licensing authority will need to answer is whether safety is likely to be jeopardized. If it asks a railway undertaking to operate under a temporary licence (see Article 24(3)). A second question that will need to be considered, is whether a licence application has to be resubmitted for approval (see Article 24(5)). In reaching its decisions, the licensing authority shall take the views of the NSA as the safety regulator into account.

8.7. Cooperation between an NSA and an ECM certification body

NSAs and ECM certification bodies should cooperate in order to avoid duplication of activities. This means that when an NSA during its supervision comes across a vehicle (freight wagon) that is poorly maintained and thus has doubts on the ability of the particular ECM to comply with the requirements under which was certified, it should pass this information to the relevant ECM certification body, as stated in Article 9 of the ECM Regulation. Likewise, if the ECM certification body declines to certify an existing ECM they should pass this information to the relevant NSAs. Such information will help the NSAs to adjust their supervision strategy and plan accordingly.

9. Competence management framework

In accordance with Article 6 of CSMs on supervision, NSAs shall ensure that staff involved in supervision have the necessary competence. The NSA should select, train and maintain the competence of those staff through a competence management system. It is up to each individual NSA to create and build their own competence management system in accordance with article 6 in the CSM regulation. To help the NSA to manage this issue, the Agency has created guidance on the Competence Management System and the guide will give advice on what constitutes a suitable competence management system and what issues the NSA needs to consider in developing one (see *Agency guide on competence management framework*). The guide will not however, specify exactly what the competence management system looks like as this will be a matter for each individual NSA.

ANNEX I

Proposed template for a supervision strategy

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- b. **Consistent** in approach across the range of activities of the (name of NSA);
- c. **Targeted** at the effectiveness of the safety management system of businesses, checking that the people in each business use their management system to achieve safe outcomes;
- d. **Transparent** and open about the policy, practices and approach adopted by (name of the NSA), whilst respecting the need for businesses to keep certain matters confidential between themselves and the Member State;
- e. **Fair** and **accountable** under the law for activities, particularly enforcement, which will be in line with the enforcement policies of the (name of the NSA);
- g. **Cooperation: the NSA will cooperate with other competent authorities to ensure that issues of mutual concern around safety are being addressed;**
- h. **Informed by** intelligence from many sources, such as the assessment of safety certificates, and the findings of any investigations by the NIB.

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8. How Supervision plans are constructed

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Guidance for Safety certification:

- ▶ Application guide for the granting of single safety certificates - A guide for the applicants
- ▶ Application guide for the granting of single safety certificates - A guide for the authorities
- ▶ Safety management system requirements for safety certification or safety authorisation
- ▶ **Supervision guide**
- ▶ Management maturity model
- ▶ Enforcement management model
- ▶ Coordination between national safety authorities – A common approach to supervision
- ▶ Competence management framework for authorities