

**Guidance for safety
certification and
supervision**



Coordination between national safety authorities

A common approach to supervision

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1. Introduction

Following the granting of a single safety certificate or a safety authorisation, national safety authorities (NSAs) must carry out a level of supervision of the railway undertaking's or infrastructure manager's activities to ensure that what was said in their application for a single safety certificate or a safety authorisation reflects the reality and continues to comply with legal obligations.

Pursuant to Article 17(7) and (9) of Directive (EU) 2016/798, NSAs involved in the supervision of a railway undertaking operating in more than one Member State or of an infrastructure manager with cross-border infrastructure must cooperate with each other to avoid any duplication of supervision and coordinate their approach to supervision to ensure that any key information on the railway undertaking or infrastructure manager is shared. Particular attention should be paid to known issues and the safety performance of the organisation, and the results used to target supervision activities on the areas of greatest risk for the whole operation.

Regulation (EU) 2018/761 establishing common safety methods on supervision provides more detail on what this cooperation involves. In particular, Article 8 requires NSAs to coordinate approaches to supervision to ensure that the safety management system is effective and that such coordination activities involve arrangements on what information to share between the NSAs involved in order to ensure a common approach to the supervision of the relevant railway undertaking or infrastructure manager.

1.1. Purpose of the guide

This document provides guidance to assist NSAs in coordinating their activities when supervising railway undertakings operating in more than one Member State or infrastructure managers with cross-border infrastructures, in accordance with Article 17(7) and 17(9) of Directive (EU) 2016/798, and Article 8 of Regulation (EU) 2018/761.

Note; for the purpose of coordination 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 transport of dangerous goods competent authority. When organising coordination NSAs will need to take this into account.

1.2. Who is this guide for?

This guide is aimed at NSAs when developing and implementing their coordinated or joint approach to supervision.

1.3. Scope

The present document provides examples of the type of information that can be exchanged between NSAs, based on the framework for coordinated and joint supervision set out in Annex II of Regulation (EU) 2018/761.

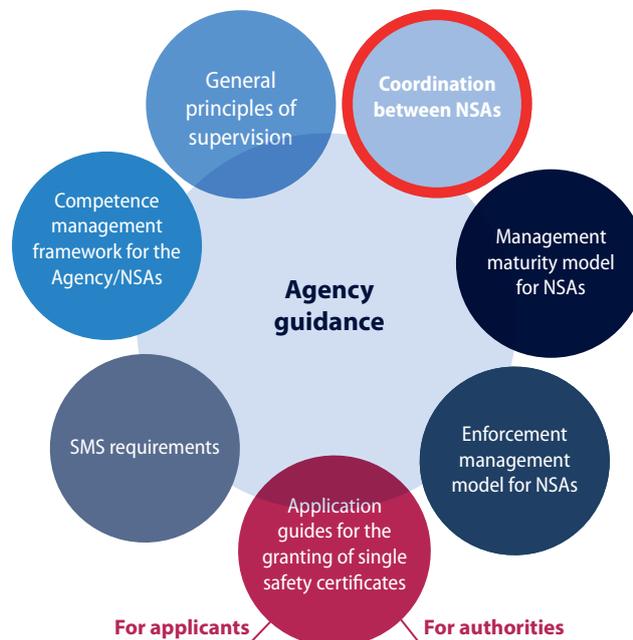
It also provides examples of criteria that may be used by NSAs to determine which NSA should have a leading role for coordinating the supervision of railway undertakings operating in more than one Member State or infrastructure managers with cross-border infrastructures.

The sharing of information gathered during supervision with other relevant NSAs and where appropriate, the European Union Agency for Railways (also named hereafter ‘the Agency’) is not covered by the present document (see *Supervision guide*).

1.4. 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.



The structure of this document is mainly based on the content of Annex II of Regulation (EU) 2018/761 [CSM on supervision].

2. Arrangements for coordinated or joint supervision

2.1. General

NSAs must oversee the safety performance of railway undertakings and infrastructure managers they supervise and take appropriate actions to ensure compliance of those railway undertakings' and infrastructure managers' safety management systems with the regulatory framework. To achieve that purpose, as underlined by Article 17 of Directive (EU) 2016/798 and Article 8(1) of Regulation (EU) 2018/761 establishing the common safety methods on supervision, NSAs must coordinate with each other by sharing relevant information. This co-ordination should cover those Railway Undertakings which have operations within another member state under the specific European provisions for this and also those Railway Undertakings which have partnership or contractual agreements with Railway Undertakings in another Member State to run services under that Railway Undertakings Safety Management System even though the staff or train are from the Railway Undertaking in the first Member State. Coordination should be part of specific arrangements between NSAs.

This sharing of information is to be contemplated in a wider context than the NSA supervision activities. The overall certification process consists of the safety assessment, the safety certification, the post-award supervision, the re-assessment followed by the re-certification (or renewal). These different activities are interrelated. The safety assessment informs the supervision activities that in turn inform the re-assessment and subsequent re-certification (or renewal). Because the Agency is entrusted to deliver single safety certificates in accordance with Article 10(5) of Directive (EU) 2016/798, the coordination arrangements should also be extended to the Agency as appropriate (i.e. when the Agency acts as safety certification body responsible for the issue of the single safety certificate).

2.2. Guidelines

The following table provides further explanations on the relevant item listed in Annex II of Regulation (EU) 2018/761 [*CSM on supervision*].

Item	Description	Commentary
1	Agree which railway undertakings and infrastructure managers are operating in such a manner as to require coordinated or joint supervision.	For railway undertakings, ERADIS allows a search for those railway undertakings with an area of operation in more than one Member State. But note: if an railway undertaking operates in another member state under a contractual or partnership arrangement with another railway undertaking ERADIS will not show this
2	Agree on common language(s) and the level of confidentiality of the information to be used for the purposes of their coordination arrangements.	The arrangements should consider any relevant national and EU regulation in force regarding confidentiality and data protection.
3	Agree what information to exchange and a timetable for the exchange: (a) exchange relevant information on railway undertakings and infrastructure managers identified under point 1 and share results from their assessment activities	The information includes: – The operations in other Member States regardless of how the company is managing them (e.g. subsidiaries in other Member States, train services operated under the safety certificate of another partner railway undertaking).

<p>(b) provide copies of safety authorisations where appropriate;</p> <p>(c) share results from related supervision activities, including enforcement decisions and actions, where relevant;</p> <p>(d) share information on the safety performance of railway undertakings and infrastructure managers identified under point 1 in each Member State.</p>	<ul style="list-style-type: none"> – The risks that are prevalent within the railway system of the different Member States and that are used in each Member State for conducting their risk based supervision. – The major changes (operational, technical, organisational) managed by the RU. – The queries or concerns if it suspects deficiencies or non-conformances with the safety management system arrangements. – The outcome of and weaknesses noticed during the safety management system assessment (e.g. issue log). <p>The NSAs are encouraged to exercise discretion as to how they will define and apply the exchange of information, e.g.:</p> <ul style="list-style-type: none"> • Regular e-mail exchanges; • Regular meetings; • Secure database, file hosting service (cloud storage). <p>Final report of management system audits and inspections or a summary of findings, conclusions and recommendations (if any) can be disclosed to the concerned NSAs.</p> <p>An action plan agreed with the company may lead to a coordinated follow-up with other NSAs.</p> <p>The company's annual report may assist the NSA in developing its supervision plan. It is expected that this report describes how effectively the company delivered, monitored and improved its safety performance and subsequently, how it has implemented the action plan resulting from weaknesses noticed during previous safety management system assessment and/or supervision activities.</p>
<p>4 Share decision-making criteria:</p> <p>(a) share information on how each national safety authority targets its activities for each railway undertaking and infrastructure manager concerned as part of the supervision plan;</p> <p>(b) establish a dialog between relevant national safety authorities on the proposed response to dealing with major compliance gaps.</p>	<p>Different NSAs may have a different legal basis for their response to compliance gaps and may also have different opinions on the criticality of a specific non-conformity. A fully harmonised way of dealing with compliance gaps is perhaps not achievable for the time being. A dialogue between relevant NSAs should always take place on the appropriate response. As a minimum, an exchange of information should occur between relevant NSAs on the action taken to deal with a compliance gap in one member state so that the other NSA(s) have an opportunity to check whether a similar non-compliance exists within their member state (see also item 3(a)).</p>
<p>5 Manage coordination:</p> <p>(a) share existing supervision strategies and plans;</p> <p>(b) establish common points of interest and/or common issues;</p> <p>(c) plan efficiently individual, coordinated or joint initiatives without causing unnecessary inconvenience to the railway undertakings and infrastructure managers and by avoiding overlaps in the scope of these initiatives.</p>	<p>The exchange of supervision strategies allows the NSAs to understand how the targeting of supervision is driven by the relevant NSAs (e.g. quantitative risk-based prioritisation tool for assessing the risk associated with a RU and the subsequent need for supervision activity, planning based on a number of visits within a period of time to ensure the RU is supervised at least once a year) and what are the greatest risks to be managed for that specific company. The exchange of supervision plan should give an insight into the type of supervision activities, the time plan and the areas of concern targeted by each NSA.</p>

2. Arrangements for coordinated or joint supervision

		<p>For example, the NSA could detect deficiencies in the railway undertaking's competence management system for which a single safety certificate was issued by the Agency. As a consequence, it may judge it necessary to look at the supervision plan of the NSA in charge of coordinating the supervision of the safety management system, check whether there was any specific supervision activity conducted recently and then coordinate with the other NSA to discuss what has been done and what additional activities need to be planned and by whom.</p>
6	<p>Agree on which national safety authority (or authorities) should follow up actions for which completion is deferred for supervision where appropriate.</p>	<p>Following the assessment, the company may be required to set up an action plan to address pending issues after the granting of the single safety certificate (or safety authorisation). In the case where the Agency is acting as safety certification body, NSAs are required to report, (at the Agency's request) on the follow-up of the action plan by the company when a renewal application is submitted. Based on this report, the Agency can review its issue log and close the related issues where appropriate.</p>
7	<p>Agree what areas to target in a coordinated or joint manner:</p> <ul style="list-style-type: none">(a) identify key risks for the relevant railway undertakings and infrastructure managers to be addressed in a coordinated or joint manner by national safety authorities;(b) agree which national safety authority will lead activities on what issues, where relevant, on the basis of well-established criteria;(c) agree what types of joint supervision activities to undertake, where relevant;(d) agree how railway undertakings and infrastructure managers should be made aware of the arrangements and agreements national safety authorities are reaching.	<p>A coordinated or joint approach is not limited to developing co-ordinated approaches to dealing with non-compliances. NSAs are also encouraged to be more pro-active.</p> <p>NSAs may decide to undertake on a voluntary basis joint activities and if so define what joint activities to undertake and what topics to deal with (including which NSA will lead on what issue). They may also organise joint communication with the railway undertaking (ensuring all parts of the railway undertaking operating in the relevant Member States are addressed at the same time). The outcome of these joint activities could be an agreed joint supervision plan for the relevant railway undertaking.</p> <p>Any agreed common approach to supervision needs to be transparent.</p>
8	<p>Share good practice:</p> <ul style="list-style-type: none">(a) develop arrangements to review and coordinate on a regular basis the supervision activities for the relevant railway undertakings and infrastructure managers;(b) develop arrangements to evaluate the effectiveness of the coordination and cooperation between national safety authorities, including the Agency as appropriate.	<p>Cooperation and coordination arrangements of NSA activity in supervision activities may differ depending on the location of the relevant NSAs. Neighbouring Member States may develop specific arrangements to help achieve their plans.</p>

2.3. Sharing of information

The following is a non-inclusive list of the information that may be shared between NSAs supervising railway undertakings operating in more than one Member State or infrastructure managers operating cross-border infrastructures.

2.3.1. Practical arrangements and general information

- ▶ Model agreements between relevant organisations;
- ▶ Contact point(s) in each organisation;
- ▶ Communication arrangements (e.g. setting of coordination meetings), including the timetable for the exchange of information and the language policy for the coordination and cooperation;

- ▶ Practical arrangements (e.g. a plan) for the sharing of information for a specific coordinated or joint supervision activity including:
 - Contact point(s) (if there is a specific contact for each activity);
 - Purpose, type and scope of the exchange (e.g. a joint inspection on the wheel calibration of a given type of vehicles in a specific maintenance workshop), including any specific communication arrangements (e.g. a specific contact point or communication details such as email or phone);
 - Security clearance needed to access a particular site (or depot);
 - Site safety rules including personal protective equipment required;
- ▶ List of railway undertakings (and infrastructure managers as appropriate) with an area of operation in more than one Member State. This includes the start and end validity of the safety certificate (or safety authorisation), the respective area of operation and the associated type and extent of service delivered, the identification of relevant contractors and partners with their associated safety certificates (or authorisations) as appropriate;
- ▶ List of Entities in Charge of Maintenance associated with the above railway undertakings (and infrastructure managers), their contractors and partners. This includes the start and end validity of the certificates where appropriate;
- ▶ Information on the supervision strategy and plan(s), including any relevant background information relating to the national legal framework, terminology, supervision techniques, decision-making criteria, good/best practice inherited from experience, supervision activities of the Entities in Charge of Maintenance where appropriate etc.;
- ▶ Information on database(s) or register(s) where relevant (e.g. the NSA may provide credentials to other NSAs to retrieve information from a database/register where supervision results are stored);
- ▶ The method of dealing with any compliance gap when cooperating NSAs have a different legal basis or different opinions on the criticality of a specific non-conformity;
- ▶ Records of the evaluation of the effectiveness of the coordination and cooperation arrangements between NSAs, including any measures taken to improve them and good practice.

2.3.2 Other information

- ▶ Information to be exchanged between assessment and supervision activities (see Supervision guide);
- ▶ Important changes within the organisation and/or the safety management system of the relevant railway undertakings (and infrastructure managers), including significant changes (operational, technical, organisational) managed by the railway undertakings (and infrastructure managers) and substantial changes which require the update of the safety certificate or safety authorisation, if not already made available in the relevant company's annual safety report(s) (when reporting on the application of the relevant common safety methods);

2. Arrangements for coordinated or joint supervision

- ▶ Specific issues identified with railway undertakings (and infrastructure managers) that are relevant (e.g. a company is not taking the necessary risk control measures) and should be shared with other NSAs;
- ▶ Analysis results from safety information system's alerts (national and/or EU level);
- ▶ Internal NSA procedures, manual or instructions where appropriate (e.g. in case joint supervision is planned);
- ▶ Supervision reports (or relevant parts of them) and other supporting documents where appropriate;
- ▶ Other information relating to the supervision of Entities in Charge of Maintenance where appropriate, including any decisions taken against them.

Some of the above information relating to the ability of the company to deliver their business objectives in safety through the effective implementation (maintenance and continual improvement) of their safety management system can be retrieved from the company's annual safety report, e.g. in the reporting on the application of the relevant common safety methods. It is however assumed that the railway undertakings and infrastructure managers provide their annual safety report to the relevant NSA(s) performing supervision activities for their respective area of operation.

In any case, as part of their coordination arrangements, the NSAs are advised to share between them the railway undertakings' and infrastructure managers' annual safety reports where relevant. Even if the latter may not be specific to their area of operation, it may still contain relevant information. It is however recommended that the companies provide the relevant NSAs with a one-off annual safety report covering the area of operation (if the latter is not limited to one Member State).

2.4. Criteria for selecting a leading NSA

Before issuing a single safety certificate for railway undertakings operating in more than one Member State or a safety authorisation for infrastructure managers with cross-border infrastructures, relevant NSAs must promptly, decide which of them is to have a leading role for coordinating the supervision of the correct application and effectiveness of the safety management system in order to avoid duplication of supervision. This should take place before starting supervision and after receiving information from the Safety Certification Body on residual concerns to be passed to supervision. In accordance with Article 8 of the common safety methods on supervision, criteria have to be established by the NSAs as part of their coordination arrangements (see item 7(b)).

A leading role does not mean that the responsibility for carrying out the supervision of these railway undertakings or infrastructure managers is handed over to the selected NSA. Each NSA remains responsible for the supervision activities within its respective Member State. However, duplication of inspections and audits is to be avoided and this requires a coordination between NSAs. It is always a good practice to invite the relevant NSAs to participate to supervision activities with a role of observer and to share the results from its supervision activities (see item 3(c) above).

The NSA of the Member State where the railway undertaking (or the infrastructure manager) is registered may appear a good option by default because the NSA firstly masters the language of the railway undertaking's (or infrastructure manager's) safety management system which eases the understanding of the safety management system and the control of its application and effectiveness and secondly, has close relationships with the railway undertaking (or infrastructure manager) due to geographical proximity with the headquarters, i.e. where the operations are managed.

However, in some case, the railway undertaking or the infrastructure manager may have its documentation in another language (e.g. English), in particular if it has limited operations in the Member State concerned but has significant cross-border operations. In addition, some NSAs may levy a fee for their supervision activities which could also impact the decision.

Therefore, it might be interesting to consider also other criteria than the one where the company is registered (i.e. where its headquarters are located), such as:

- ▶ the volume of operation in each Member State (train kilometers);
- ▶ the size of the organisation (number of staff) in each Member State;

The above criteria can also be prioritised depending on national considerations.



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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