

Organisation intergouvernementale pour les transports internationaux ferroviaires Zwischenstaatliche Organisation für den internationalen Eisenbahnverkehr Intergovernmental Organisation for International Carriage by Rail

> Commission d'experts techniques Fachausschuss für technische Fragen Committee of Technical Experts

TECH-24009-CTE16-6.1

15.04.2024

Original: EN

## **16<sup>TH</sup> SESSION**

Draft Annex D to the EST UR concerning a Common Safety Method for Supervision

### BACKGROUND

In September 2018, OTIF's General Assembly adopted<sup>1</sup> the EST Uniform Rules (UR). According to Article 34 § 2 of COTIF, entry into force of the EST UR requires approval by two-thirds of the OTIF Member States. The requirements for the entry into force of the EST UR have not yet been met.

The General Assembly recommended that the Committee of Technical Experts prepare proposals for annexes to the EST UR before the EST UR enter into force. The proposals could then be adopted by the Committee of Technical Experts without delay after the EST UR enter into force.

At its 15<sup>th</sup> session (Bern, 13-14 June 2023), the Committee of Technical Experts (CTE) mandated WG TECH to draft proposals for a future annex to the EST UR concerning a common safety method (CSM) for Supervision to be applied by the Supervision Authorities (Annex D to the EST UR).

The draft proposal is annexed to this document. It was reviewed at three consecutive sessions of WG TECH (Bern, 15 June 2023; Gümligen, 7-8 September 2023; London, 14-15 November 2023). WG TECH was satisfied with the document and recommended that it be submitted to the CTE for consideration.

Formal adoption of the document is not possible before the EST UR have entered into force.

## **PROPOSALS FOR DECISION**

- The Committee of Technical Experts considered the draft common safety method (CSM) for Supervision as set out in the annex to document TECH-24009-CTE16-6.1 of 15 April 2024[, as modified at the session], which, if adopted at a future session, will become Annex D to the EST UR;
- The Committee of Technical Experts requests the Secretary General to place the adoption of the CSM for Supervision (Annex D to the EST UR) on the provisional agenda of a future session of the Committee of Technical Experts, as soon as the EST UR have entered into force.

<sup>&</sup>lt;sup>1</sup> <u>http://otif.org/fileadmin/new/2-Activities/2A-General-Assembly/2AcNotifications/NOT-18001-Ad2-fde-Appendice-H-EST.pdf</u>



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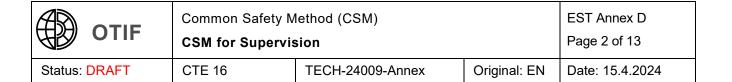
TECH-24009-Annex

# **EST Annex D**

Common Safety Method for Supervision to be applied by the Supervision Authorities

CSM for Supervision

Applicable from



# EST Uniform Rules (Appendix H to COTIF 1999)

## Annex D to the EST Uniform Rules

## "Common Safety Method for Supervision to be applied by the Supervision Authorities"

# (CSM for Supervision)

This CSM for Supervision has been developed in accordance with COTIF 1999 in the version of 1 March 2019 and in particular with Article 8 of the EST Uniform Rules (Appendix H to COTIF).

#### Article 1 Subject matter

This document lays down the Common Safety Method for Supervision in accordance with Article 8 § 3 letter d) of the EST Uniform Rules; it is further referred to as 'this CSM for Supervision'. This Regulation establishes common safety methods ('CSMs'), referred to in point (c) of Article 6(1) of Directive (EU) 2016/798, for the supervision of the management of safety by national safety authorities after the railway undertakings have been granted a single safety certificate and infrastructure managers after they have been granted a safety authorisation.

#### Article 2 Scope and aim

- § 1 This CSM for Supervision shall be applied by the Supervision Authorities when supervising railway undertakings in accordance with Article 6 of the EST Uniform Rules.
- § 2 It is recommended that this CSM for Supervision be applied to the supervision of infrastructure managers<sup>1</sup>.

<sup>&</sup>lt;sup>1</sup> Although Article 3 § 3 of the EST UR requires both railways undertakings and infrastructure managers to have implemented a safety management system, the EST UR regulate safety certification and supervision for railway undertakings only. The reasons for not harmonising the rules for supervision of infrastructure managers are set out in the Explanatory Report in point 9 to Article 5 (see the final document of the 13<sup>th</sup> General Assembly).

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In such a case, the provisions concerning the supervision of railway undertakings should be applied *mutatis mutandis* to the supervision of infrastructure managers.

#### Article 3 Definitions

The definitions in Article 2 of the EST UR, Article 2 of the APTU UR (Appendix F to COTIF) and Article 2 of the ATMF UR (Appendix G to COTIF) shall apply.

In addition, for the purposes of this CSM for Supervision, the following definition shall apply:

a) 'residual concern' means a minor issue identified during the assessment of an application for a safety certificate which does not prevent it being issued and which can be deferred for later consideration.

#### Article 4 Correlation with other international agreements

- § 1 This CSM for Supervision is based on the provisions of European Union Commission Delegated Regulation (EU) 2018/761 of 16 February 2018 establishing common safety methods for supervision by national safety authorities after the issue of a single safety certificate or a safety authorisation, hereinafter referred to as 'the EU Regulation'.
- § 2 Supervision in accordance with the EU Regulation that takes place after the entry into force of this CSM for Supervision shall be deemed also to comply with this CSM for Supervision.
- § 3 The texts of this CSM for Supervision which appear across two columns are identical in substance to corresponding texts of the EU Regulation. This does not apply to headings, titles of articles and footnotes.

Texts which appear in two columns differ; the lefthand column contains the OTIF rules, the right-

<sup>&</sup>lt;sup>2</sup> For definitions in the EU text, see Article 2 of European Union Commission Delegated Regulation (EU) 2018/761 of 16 February 2018.

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hand column shows corresponding texts from the EU Regulation.

Texts in the right-hand column are strictly for information only and do not necessarily appear in the same order as they appear in the EU Regulation.

For applicable EU law, consult the Official Journal of the European Union.

§ 4 The following table lists the terms used in this CSM for Supervision and the corresponding terms used in the EU Regulation on CSM for Supervision:

This CSM	EU Regulation
This CSM for Supervision	This Regulation
Contracting State	Member State
Supervision Authority	National Safety Authority

For the sake of readability, these terms are not generally presented in a two-column layout.

#### Article 5 Supervision process

- §1 Supervision Authorities shall apply the supervision process set out in Annex I to this CSM for Supervision.
- § 2 Supervision Authorities shall establish internal arrangements or procedures for managing the supervision process.
- § 3 For the purposes of supervision, the Supervision Authorities shall accept the authorisations, recognitions or certificates of products or services provided by railway undertakings

and infrastructure managers

, or their contractors, partners or suppliers, granted in accordance with relevant

COTIF rules

as proof of the ability of railway undertakings

and infrastructure managers

Union law,

to fulfil the corresponding requirements defined in

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Annex A to the EST UR (the CSM on SMS<br/>Requirements).Commission<br/>2018/7623.Delegated<br/>Regulation (EU)

#### Article 6 Techniques for supervision

Supervision Authorities shall adopt suitable techniques, such as audits and inspections, and select the most appropriate ones when planning their supervision activities.

## Article 7 Links between supervision and assessment

§ 1	Supervision Authorities shall share information gathered during supervision activities with the Safety Certification Authority <sup>4</sup> that has issued the safety certificate in question. This concerns in particular information that pertains to the performance of the safety management system. The information should be used by the Safety Certification Authorities when renewing or updating safety certificates.	The national safety authority carrying out supervision shall use and, where relevant, share information gathered on the performance of the safety management system during its supervision activities for the purpose of renewing or updating single safety certificates or safety authorisations.
§ 2	The information referred to in § 1 concerns information that is relevant to the Safety Certification Authority when assessing whether the railway undertaking's safety management system is working effectively. It should include at least:	In cases where the national safety authority referred to in paragraph 1 is not responsible for issuing the single safety certificate or safety authorisation, it shall coordinate promptly with the Agency acting as safety certification body or the relevant national safety authority, in the case of cross-border infrastructure, on its request, after the receipt of an application for renewal or update.
		Based on the outcome of the coordination referred to in the first subparagraph, the national safety authority shall identify and target the information which is relevant to assessing whether the railway undertaking's or infrastructure manager's safety management system is effectively working, 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 since the previous assessment;
- b) the status of the action plan (or plans) established by the railway undertaking

<sup>&</sup>lt;sup>3</sup> Commission Delegated Regulation (EU) 2018/762 of 8 March 2018 establishing common safety methods on safety management system requirements.

<sup>&</sup>lt;sup>4</sup> In accordance with Article 4 § 1 of the EST UR, the Supervision Authority and the Safety Certification Authority of a Contracting State may be two separate entities or they may be incorporated into the same organisation.

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or infrastructure manager

to resolve major non-compliances and any other area of concern referred to in point a) and relevant actions that have been taken by the Supervisory Authority to supervise resolution of these issues;

c) an overview of the safety performance of the railway undertaking

operating on the territory of the | or infrastructure manager operating in its Contracting State;

d) the status of the action plan (or plans) established by the railway undertaking

or infrastructure manager

to resolve residual concerns from previous assessment.

#### Article 8 Competence of the staff involved in supervision

- §1 Each Supervision Authority shall ensure that staff involved in supervision have the following competencies:
  - a) knowledge of the relevant regulatory framework as it applies to supervision;
  - b) knowledge of the functioning of the railway system;
  - c) appropriate level of critical analysis;
  - experience in the supervision of a safety or similar management system in the railway sector, or a safety management system in a sector with equivalent operational and technical challenges;
  - e) knowledge of and experience in interviewing skills;
  - f) problem solving, communication and working in a team.
- § 2 In the case of teamwork, the competencies may be shared amongst the team members.
- § 3 With a view to ensuring the correct application of § 1, each Supervision Authority shall put in place a competence management system which shall include:
  - a) the development of competence profiles for each job, position or role;
  - b) the recruitment of staff in accordance with the established competence profiles;
  - c) the maintenance, development and assessment of staff competence in accordance with the established competence profiles.

#### Article 9 Coordination and cooperation

§ 1 Supervision Authorities involved in the supervision of

an infrastructure manager with cross-border infrastructure(s) or of

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#### a railway undertaking

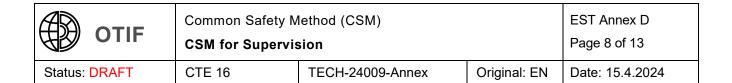
that is operating between two or more Contracting States are recommended to coordinate their approaches to supervision.	operating in more than one Member State shall coordinate their approach to supervision in accordance with Article 17(7) and (9) of Directive (EU) 2016/798.
	After the granting of the safety authorisation or single safety certificate, national safety authorities shall 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, without prejudice to the obligations of the national safety authorities under points (d) and (j) of Article 16(2) and Article 17 of Directive (EU) 2016/798.

§ 2 For the purposes of paragraph 1, the
 Supervision Authorities are recommended to
 develop arrangements based on the framework for coordinated and joint supervision set out in Annex II.

§ 3 Supervision Authorities shall also develop cooperation arrangements

at national level, with entities that investigate with the national investigation bodies, accidents,

certification bodies for entities in charge of maintenance and other competent authorities or bodies.



## Annex I

## **Supervision process**

#### 1. GENERAL

The Supervision Authority shall develop a structured and auditable process for the complete activity which takes into account the elements below. This ensures that the supervision process is iterative and takes into account the need to continually improve, as shown in the diagram below.

#### 2. SETTING UP THE SUPERVISION STRATEGY AND PLAN(S)

The Supervision Authority shall:

 a) collect and analyse data/information from a variety of sources as an input to the strategy and the plan or plans. Sources could include information gathered during the assessment of safety management systems, outcomes of previous supervision activities, information from authorisations of subsystems or vehicles, national investigation bodies accident reports/recommendations, other accident/incident reports or data, railway undertakings'

or infrastructure managers'

annual safety reports, annual maintenance reports from entities in charge of maintenance, complaints from members of the public and other relevant sources;

- b) identify in the supervision strategy risk areas for targeted supervision activities, including those emerging from the integration and management of human and organisational factors, where relevant;
- c) develop a supervision plan or plans showing how it will give effect to the supervision strategy during the lifecycle of valid

safety certificates;

single safety certificates and safety authorisations;

- d) produce an initial estimate of resources required to give effect to the plan or plans, based on the target areas identified;
- e) allocate resources to give effect to the plan or plans;
- f) address in the supervision strategy and plan(s) any matters relating to cross-border operations

or infrastructure(s)

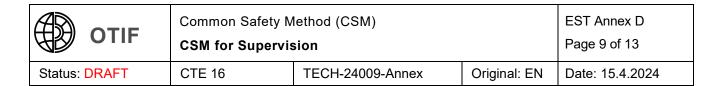
through coordination with other Supervision Authorities.

#### 3. COMMUNICATING THE SUPERVISION STRATEGY AND PLAN(S)

The Supervision Authority shall:

a) communicate the overall objectives of the supervision strategy and overall explanation of the plan or plans to relevant railway undertakings

or infrastructure managers



and, where appropriate, more widely to other stakeholders;

b) provide relevant railway undertakings

or infrastructure managers

with an overall explanation on how the supervision plan or plans will be undertaken.

#### 4. DELIVERING THE SUPERVISION ACTIVITIES

The Supervision Authority shall:

- a) give effect to the plan or plans;
- b) take proportionate action(s) to deal with failure of a railway undertaking

or an infrastructure manager

to comply with its legal obligations, including issuing any urgent safety alerts and applying temporary safety measures when necessary;

c) evaluate how adequately a railway undertaking

or an infrastructure manager

has developed and implemented an action plan or plans to remedy any non-compliance or residual concern within a specified time period;

d) document the results of its supervision activities.

#### 5. OUTCOMES OF SUPERVISION ACTIVITIES

The Supervision Authority shall:

a) share results of its supervision activities with the relevant railway undertaking

or infrastructure manager,

including identifying areas of non-compliance on the part of the railway undertaking

or infrastructure manager,

and any areas of good practice to support safety improvement;

b) have an overview of the safety performance of the individual railway undertakings

operating on the territory of the or infrastructure managers operating in its

Contracting State;

c) publish and communicate

to relevant parties its views on the safety performance of railway operations in the scope of the EST UR taking place on the territory of the Contracting State.

d) publish and communicate

EST UR and its Annexes.

to the Committee of Technical Experts its to relevant stakeholders its views on the experience and views on the effectiveness of the effectiveness of the safety regulatory framework;

to relevant stakeholders its views on the overall

safety performance in the Member State;

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e) use and when relevant, share information on the performance of the safety management system gathered during the supervision of railway undertakings

or infrastructure managers,

prior to reassessing the application for a renewal or an update

	of the safety certificate with the issuing Safety Certification Authority;	of the single safety certificate or the safety authorisation, with the Agency acting as safety certification body or the relevant national safety authority, in the case of cross-border infrastructure;
`	where appropriate take any enforcement actions	identify whether there is a case for restricting or

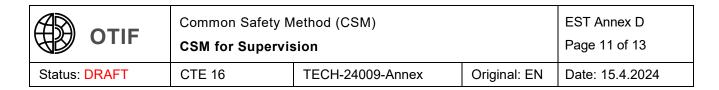
f) where appropriate, take any enforcement actions, identify whether there is a case for restricting or revoking the

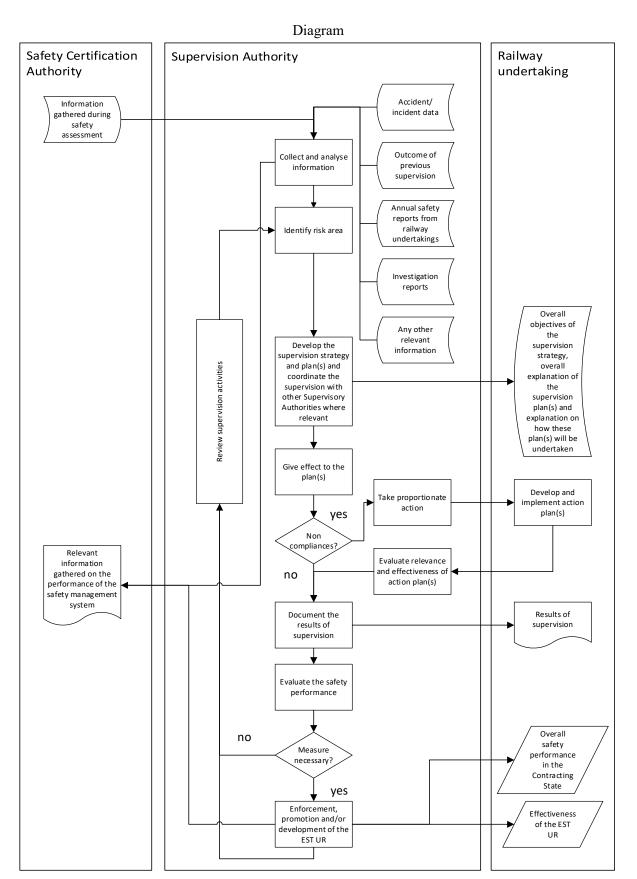
safety certificate and inform the competent	single safety certificate or safety authorisation
Safety Certification Authority accordingly.	and in cases where it is not responsible for issuing
	the single safety certificate or safety
	authorisation, inform the competent authority
	accordingly.

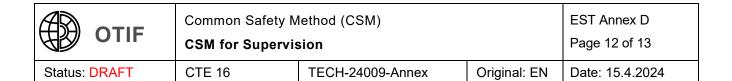
#### 6. REVIEWING SUPERVISION ACTIVITIES

On the basis of information gathered and experience gained during supervision activities and the safety performance both at individual level and at Contracting State level, the Supervision Authority shall at regular intervals:

- a) conduct a review of the supervision strategy and plan(s) to check that the original targeted activity, use of data/information from a variety of sources, supervision outcomes and resource allocation are appropriate, changing priorities as necessary;
- b) revise the plan or plans if needed and consider the impact of the changes on the supervision strategy;
- c) contribute when necessary with its views and any proposals to its Contracting State to overcome any deficiencies in the safety regulatory framework.







## Annex II

# Framework for coordinated and joint supervision

If two or more Supervision Authorities develop arrangements for coordinated and joint supervision, as referred to in Article 9 § 2 of this CSM for Supervision, it is recommended that these arrangements be

The relevant national safety authorities shall develop arrangements

based on the following principles and specific elements:

1. Agree which railway undertakings

and infrastructure managers

are operating in such a manner as to require coordinated or joint supervision.

- 2. Agree on common language(s) and the level of confidentiality of the information to be used for the purposes of their coordination arrangements.
- 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;

- b) provide copies of safety authorisations where appropriate;
- c) share results from related supervision activities, including enforcement decisions and actions, where relevant;
- d) share information on the safety performance of railway undertakings

and infrastructure managers

identified under point 1 in each Contracting State.

- 4. Share decision-making criteria:
  - a) share information on how each Supervision Authority targets its activities for each railway undertaking

and infrastructure managers

concerned as part of the supervision plan;

- b) establish a dialogue between relevant Supervision Authorities on the proposed response to dealing with major compliance gaps.
- 5. Manage coordination:
  - a) share existing supervision strategies and plans;
  - b) establish common points of interest and/or common issues;

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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.

- 6. Agree on which national safety authority (or authorities) should follow up actions aimed to address residual concerns which have been deferred for supervision where appropriate.
- 7. Agree what areas to target in a coordinated or joint manner:
  - a) identify key risks for the relevant railway undertakings

and infrastructure managers

to be addressed in a coordinated or joint manner by Supervision Authorities;

- b) agree which Supervision 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 Supervision Authorities are reaching.

- 8. Share good practice:
  - 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 Supervision Authorities

and, with a view to sharing experience, inform the Committee of Technical Experts as appropriate.