

Making the railway system work better for society.

Annex III bis: Referential Compliance Audit

NSA Monitoring



Making the railway system work better for society.

This document is the reference document to be used to perform a compliance audit.

1. Method

To evaluate the capacity and the effectiveness of the NSA to perform and to take decisions, the audit team assesses whether the requirements listed below are met or not and whether the extent of deviation from the expected level constitutes a minor or a major deficiency¹. The audit team considers the context of the audited NSA, the outputs of the NSA activities (e.g. issued safety certificates and authorisations, supervision activities performed, etc.) and how the NSA is organised to ensure its "performance and decision-making" (Art. 33 of Regulation 2016/796). Documented evidence will be examined.

Below, the proposed list covers only the EU legislation currently in force. ERA will alter this referential in the future to reflect the changing legislative base over the next few years.² The list will be updated at regular intervals as the legal base changes over the next few years. In order to avoid any gap in the applied referential, references to the legal texts shall be considered as dynamic³.

In some cases, the legal requirement is addressed to the Member States and not to the NSA. These are nevertheless mentioned when the provision has an important impact on the NSA. (For example, the Member State shall establish a NSA). The table below should not be read as granting additional responsibilities to NSA compared to those of the EU legal framework.

There will be some safety certificates which have been granted by an NSA before transposition of the new Directive has taken place which will expire afterwards. In such situations for the purposes of Monitoring Supervision ERA will take into account that the legal framework under which Supervision takes place until the expiration of such certificates will be that of the 3rd Railway Package and its associated regulations. In the most extreme case this means that a Certificate granted on 15th June 2020 for 5 years would not expire until 15th June 2025. During this period Supervision will need to be carried out under the arrangements set out in the CSM 1077/2010 and against the Conformity Assessment Criteria set out in 1158/2010.

¹ See Evaluation procedure for the NSA monitoring activity, point 3.12.

² The first review of the document will take place in January 2019 and be completed in time for the entry into force of the 4th RP on 16th June 2019. This timing has been selected because from 16th December 2018 it will be clear which Member States will operate under the existing Railway Safety Directive and Interoperability Directive until 15th June 2020 and which will not, since Member States have to notify the Commission of their desire to delay transposition to the later date six months before the initial deadline for it. It will therefore become clear to Member States at this point, which legal provisions ERA will monitor compliance with at which point in time in the period form 16th June 2019 to 16th June 2020 after which monitoring will be carried out under the 4th Railway Package requirements.

³ This means that if the EU legal framework is updated, the reference shall be read as modified.

Complete texts are not quoted due to lack of space, only key provisions are listed.

The referential is organised by thematic set of criteria:

- General NSA organisation
- NSA reporting
- NSA tasks on safety certification and safety authorisation
- NSA tasks on authorisation to place in service
- NSA tasks on supervision
- NSA task on development of the regulatory framework
- NSA tasks on risk assessment
- NSA tasks on train drivers directive

2. Detailed set of criteria

EU legal framework for NSA		Legal ı	requirements	
organisation	RSD 2004/49/EC Article 16 (1) and (2)	RSD 2004/49/EC Article 16 (1) and (3) and Article 17(1)	RSD 2004/49/EC Article 17	RSD 2004/49/EC Article 17 (4)
	The NSA is established and is organised in order to deliver its tasks	The NSA is independent	The NSA takes decisions in line with decision making principles	The NSA coordinates and cooperates
Criteria	1 Resources (staff and financial) are allocated to the tasks specified in Article 16 (2). 2. Responsibilities for managing the tasks are in place as specified in Article 16 (2). 3. Staff are allocated to specific tasks specified in Article 16 (2) and trained and managed. 4. There is guidance for staff on the delivery of	1. The NSA is independent in its organization, legal structure and decision making from any railway undertaking, infrastructure manager, applicant and procurement entity. 2. The independence of the NSA organisation and the NSA staff towards the industry is ensured (sufficient resources, absence of conflict of interest, internal process).	 The NSA carries out its tasks in an open, non-discriminatory and transparent way. The NSA decisions and actions are continuously verified, monitored and reviewed to ensure that they remain open and transparent, and are applied in a non-discriminatory way. The NSA allows all parties to be heard and it gives reasons for its decisions. The legislation (or process) ensures that all parties can be 	1. The NSA conducts an active exchange of views and experience for the purpose of harmonizing their decision-making criteria with relevant parties. For example, the NSA can show its active involvement in the NSA Network orit can show that it shares urgent safety-relevant information with relevant parties. 2. The NSA can show how this helps with the harmonisation of their decision making

the tasks as specified in Article 16 (2).

- 5. The NSA has staff processes to manage competences needed in order to undertake the tasks specified in Article 16 (2).
- 6. NSA has processes for its tasks as specified in Article 16 (2).

- 3. Staff are aware of and follow the requirements. Conflict of interests are identified and dealt with.
- 4. The legislation is consistently applied, monitored and reviewed to ensure it meets the requirements. In cases where it is not applied, appropriate action is taken by the MS.
- 5. NSA tasks listed under Article 16 (2) of the Railway Safety Directive are not transferred or subcontracted. If technical assistance is requested from the RU, IM or procurement authority, the NSA needs to show that this does not affect its independence; and the assistance does not involve making any decisions on behalf of the NSA.

heard and that the NSA gives reasons for its decisions is continually monitored and reviewed to ensure that it meets the requirements.

- 5. Staff are aware of and follow the requirements in relation to ensure that decisions are open, transparent and applied in a non-discriminatory way.
- 6. The NSA responds promptly to all requests and information from the RU/IM without delay and adopts all decisions within four months after all requested information has been provided. This is monitored and reviewed to ensure it is correctly applied and meets the requirements.
- 7. The NSA communicates its requests for information without delay and adopts all decisions within four months after all requested information has been provided. This is monitored and reviewed to ensure that it is correctly applied and it meets the requirements.
- 8. Applicants are given enough help and guidance in order for

process. This is monitored and reviewed to ensure that it is correctly applied and meets the requirements.

them to know what is expected from them.

- 9. The NSA publishes any necessary information for the RU/IM/ECM/training centers on how it carries out its activities.
- 10. RUs/IMs/ECM/training centers informed as early as possible about any problem or deficiencies.
- 11. Where appropriate (if it is in the NSA tasks, depending on the national legal framework), in the process of developing the regulatory framework, the NSA consults all persons involved and interested parties, including RU, IM manufactures and maintenance providers, users and staff representatives.
- 12. The NSA is free to carry out all inspections and investigations that are needed for the accomplishment of its tasks and it is granted access to all relevant documents and to premises, installations and equipment of IMS and RUs.
- 13. There are means for applicants to appeal against any decision made by the NSA and

	this is communicated to the IM/RU/ECM/ training centers.	
	invitto/ Lcivif training centers.	

EU legal framework		Legal requirements						
for NSA reporting	RSD 2004/49/EC Article 16 (1) and (2)	RSD 2004/49/EC Article 16 (1) and (3) and Article 17(1)	RSD 2004/49/EC Article 17	RSD 2004/49/EC Article 17 (4)				
	Reporting CSIs	Production and delivery of the Annual Report	Reporting on the application of the CSM for Monitoring	Reporting on the CSM for Risk Evaluation and Assessment				
Criteria	 CSIs are collected in the Member State by the NSA. The definitions used for the CSIs are consistent with the ones stated in the Annex I of the Directive 2004/49/EC. The operational scope of the CSIs refers to train operations and shunting. The year N report includes data from year N-1. 	1. The NSA is regularly producing and delivering the annual report. 2. The Annual report includes information on the development of railway safety, including an aggregation at Member State level of the CSIs laid down in Annex I of the Directive 2004/49/EC. 3. The annual report includes information on important changes in legislation and regulation concerning railway safety (if any).	1. The NSA reports on the application of CSM for Monitoring by the railway undertakings, infrastructure managers, and as far as it is aware of it, by the entities in charge of maintenance in accordance with Article 18 (Annual reports) of Directive 2004/49/EC.	1. Each national safety authority shall, in its annual safety report referred to in Article 18 of Directive 2004/49/EC, report on the experience of the proposers with the application of this Regulation, and, where appropriate, its own experience.				

4. The annual report includes
information on the
development of safety
certification and safety
authorisation.
5. The annual report includes
information on results of and
experience relating to the
supervision of infrastructure
managers and railway
undertakings;
6. The annual report includes
information on the
derogations (if any) that have
been decided in accordance
with Article 14a (8) of the
Directive 2004/49/EC
(Alternative measures to certify ECMs).
Certify Ectivisy.

EU legal framework for Safety Certification and Safety authorisation			Legal requirements		
	RSD Article 10, 11, 12 (1) — request for information Article 12(2) EC Regulation 1158/2010 & 1169/2010 Article 1 Annex 1 1 (a) — Setting up and reviewing the assessment process 1(d) — Timing of the assessment EC Regulation 653/2007	RSD Article 12 (1) – request for information EC Regulation 1158/2010 & 1169/2010 Annex 1 1 (a) – Setting up and reviewing the assessment process 1 (d) – Timing of the assessment 2 – Compliance with EC Regulation 653/2007 is assessed 3 – Assessment of the summary of the SMS system	RSD Article 16 (1) — request for information RSD Article 17 (3) — judicial review EC Regulation 1158/2010 & 1169/2010 Article 1 (a) Annex 1 1 (a) — setting up and reviewing the assessment process 1 (d) — Timing of the assessment 3 — Assessment of the summary of the SMS system 6 — Assessment of Part A and B together 8 — Assessment of Part B apply to the RUs/IMs ability to comply with the requirements needed to operate on a specific network	RSD Article 10 (3) – type and extent on certificate RSD Article 10 (5) – ← up to 5 years validity RSD Articles 10 (6) & 11 (3) – Agency informed RSD Article 12 (1) – deadline of 4 months EC Regulation 1158/2010 & 1169/2010 Annex 1 1 (a) – Setting up and reviewing the assessment process 1 (d) – Timing of the assessment 1 (e) – Decision making during the assessment 4 5 Queries or non-compliances Annex IV EC Regulation 1158/2010 EC Regulation 653/2007 Article 4 (number) EC Regulation 653/2007 Article 6 (replaced)	RSD Article 18 (c)

	General	Initial assessment of the application for deciding on the sufficiency and quality of the application	Formal assessment of the application for a SC or SA	Recording and confirmation of the final decision and links to supervision	Annual Report
Criteria	1. The NSA has a process for the scrutiny of Safety Certificate and Safety Authorisation applications against the Criteria set out in Annex II and III of the relevant CSMs. 2. The NSA checks its own performance for the process in 1 above. 3. The NSA process referred to in 1 above is periodically reviewed. 4. The process in 1 above is appropriate to the risks, character and extent of the operations of individual applicants. 5. The process in 1 above based on the overall ability of the	1. The process for the scrutiny of Safety Certificate and Safety Authorisation applications is capable of being completed within the timescale set out in Article 12(1) of Directive 2004/49/EC. 2. Is the assessment process undertaken by the NSA at the management system level and process driven. 3. The NSA has a procedure to assess whether the applicants summary of their Safety Management System allows an initial judgement on its quality. 4. The NSA as a result of applying the	1. The NSA conducts a formal assessment of the compliance of the applicants Safety Management System with each assessment Criterion. 2. For applications for Part A and Part B Certificates submitted together the NSA ensures that the Part A Certificate is granted first or both Part A and Part B are granted together. 3. For Part B Certificate applications submitted on their own the NSA assessment is limited to the Criteria set out in Annex III of EU 1158/2010. 4. The NSA has process for cooperating where necessary with relevant NSAs to ensure	1. The NSA has a process for recording final decisions against each criteria and where necessary the reasons for rejection of an application. 2. Decisions on whether to accept or reject applications are based on the evidence provided by the applicant against each of the Criteria set out in EU1158/2010 Annex II and III and EU1169/2010 Annex II. 3. The process used by the NSA refers to compliance with the requirements of Annex IV in supervising an applicant after the award of a Safety Certificate or Safety Authorisation.	1. The NSA Annual Report contains information on the development of Safety Certification and Safety Authorisation.

applicant to operate	procedure in 3 above	compliance with Part B	
safely as described in	seeks additional	criteria where this is	
its SMS.	information which it	relevant.	
6. Safety Certificates are issued in accordance with the format laid down in Regulation (EC) No 653/2007.	deems reasonably necessary from the applicant.	1.5. The NSA process allows	

EU legal framework for authorisation to place into service		Legal requirements						
	IOD 2008/57/EC Article 20	IOD 2008/57/EC Articles 15 and 16	IOD 2008/57/EC Articles 15, 16 and 17	IOD 2008/57/EC Articles 15, 16, 17 and 19	IOD 2008/57/EC Articles 21, 22, 23, 24, 25, 26	IOD 2008/57/EC Article 15 and 16 EC Regulation 1077/2012 Articles 5, 8 and Annex		
	Identification of rules - Decision on new authorization - Derogation from the TSI	Receive complete application from the applicant for an authorisation to place into service	Screen of application for authorisation	Authorisation to place into service	Additional authorisations to place vehicles into service (Where this is required by the MS)	Recording and confirmation to the applicant of the final decision on authorisation to place into service		
Criteria	1. NSA has criteria for deciding what an upgrade is or renewal of a vehicle/subsyste m and this is followed by the NSA. 2. NSA has put in place the process for derogation from the TSIs.	1. NSA has established clear deadline for authorization which are proportionate to the activity. 2. Acknowledgement is given to the applicant of the receipt of the complete application 3. NSA has and applies criteria for	1. NSA undertakes a screen of the application, including checking that the completeness of the application as per the agreed scope (technical file and the Declarations of verification against TSIs & NNTRs from the applicant). 2. NSA checks that there is evidence that the relevant	1. NSA reviews documentation for authorisation. 2. The NSA informs the Member State of any noncompliances with essential requirements so that the Member State can alert the Commission if further checks are required. 3. NSA makes proportionate	1. There are notified national rules that apply to additional authorisation and the NSA uses them. 2. NSA reviews the file submitted by the applicant. Limited to the requirements in Article 23 for TSI conform vehicles and Article 25 for non-TSI conform vehicles. 3. The 2 month for TSI conform vehicles and 4 months for	1. NSA checks the vehicle has been notified to the NVR and that subsystems declarations and EC constituents are present in ERADIS. 2. Issues which are relevant for supervision activities are identified and communicated.		

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differentiating	TSIs, NNTRs have	decisions when	non-TSI conform	
between	been identified and	reviewing the	vehicles deadline is	
subsystems, first	•	application.	applied and	
authorisations for		4. Sufficient	monitored.	
TSI conform	any derogations	evidence	4. NSA co-operates	
vehicles, first	granted by the	(completeness) has	with other NSAs on	
authorisatons for	Member State.	been presented to	the authorisation of	
non-TSI conform		demonstrate the	the vehicle where	
vehicles, additional		project subsystem	that vehicle may	
authorisations for		complies with the	operate.	
TSI conform		relevant TSIs and	•	
vehicles &		NNTRs.	5. For TSI conform	
additional			vehicles there is	
authorisations for			evidence that this is	
non-TSI conform			restricted to	
vehicles,			technical	
authorisation of a			compatibility and	
vehicle conforming			notified national	
to an authorised			rules applicable to	
vehicle type,			specific cases and	
renewal of a vehicle			open points duly	
type authorisation.			identified in the	
			relevant TSIs. Any	
			additional	
			verification relates	
			only to Group B or C	
			rules published in the	
			Agency's reference	
			document that are	
			related to	
			compatibility with	
			the network.	
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		6. For non TSI	
		conform vehicles	
		there is evidence that	
		the NSA has clear and	
		proportionate	
		decision making	
		criteria for	
		determining that the	
		previous	
		documentary and	
		technical evidence	
		related to the first	
		authorisation is not	
		sufficient for the	
		placing into service	
		on the new network	
		because the NSA can	
		demonstrate the	
		existence of a	
		substantial safety	
		risk. This cannot	
		relate to any Group A	
		rule published in the	
		Agency's reference	
		document. Any	
		additional	
		verification relates	
		only to Group B or C	
		rules published in the	
		reference document	
		that are related to	
		compatibility with	
		the network.	
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		7. NSA has to	
		document how it	
		arrives at its final	
		decision and to	
		inform the applicant.	

EU Legal framewor k for NSA supervisio n				Lega	l requirements				
	RSD Article 16 (2) (e) and (f) RSD Article 25 (2) and (3) EC Regulation 1077/2012 Article 3 and Annex	RSD Article 16 (2) (e) and (f) and Article 21 (1) EC Regulation 1077/2012 Articles 4 , 7 and Annex	RSD Article 16 (2) (e) and (f) EC Regulation 1077/2012 Article 3 and Annex	RSD Article 16 (2) (e) and (f) EC Regulation 1077/2012 Article 3 and Annex	RSD Article 16 (2) (e) and (f) EC Regulation 1077/2012 Article 5, 8 and Annex	RSD Article 16(1) EC Regulation 1077/2012 Article 6,	RSD Article 16 (2) (e) and (f) Article 17 (1) and (3) EC Regulation 1077/2012 Article 7	RSD Article 17(4) EC Regulation 1077/2012 Article 8,	RSD Article 18 (d)
	Supervision Strategy and Plan	Communicati ng and delivering the plan	Outcomes of the supervision plan	Reviewing supervision activities	Linking supervision plan to the reassessme nt	Competenc e	Decision Making	Coordinatio n and Cooperation	Annual Report
Criteria	1. There is a Supervision Strategy and Plan which follows the structure of the Annex to the CSM. 2. The Strategy and Plan is understood by the Railway Undertakings	1. The NSA has adopted Supervision techniques. 2. The NSA checks the effectiveness of the SMS as a whole 3. The NSA checks the effectiveness of individual	1. The NSA collects and uses data gained from the outcomes of Supervision. 2. The NSA communicat es the Supervision Strategy and Plan to	1. The NSA regularly reviews its Supervisio n Strategy and Plan. 2. The NSA takes into account informatio n from Supervisio n when	1. The NSA uses information from Safety Certificate or Safety Authorisation renewal applications to inform its Supervision activities.	1. The NSA employs competent people to carry out Supervision Activities. 2. The NSA has a system in place to ensure that staff	1. The NSA has decision making criteria in place for how it monitors and, promotes the safety regulation framework.	1. Where cross-border activities take place the NSA coordinates Supervision activities with the relevant NSAs. 2. The NSA has	1. The NSA reports the result of and experience relating to the Supervision of Railway Undertaking s and Infrastructur e Managers in its Annual Report

and	or partial	stakeholders	reviewing	2. The NSA	carrying	2. The NSA	cooperation	submitted
Infrastructure	elements of		its	uses the	out	has decision	arrangemen	to the
Managers.	the SMS.		Supervisio	information	Supervision	making	ts with	Agency.
_	the sivis.	3. The NSA	n Strategy	gained	are	criteria in	National	Agency.
3. The Strategy		uses the	and Plan.	during	competent.	place for	Investigatio	
and Plan		results of the	and Flan.	Supervision	competent.	how it	n Bodies,	
explains how the		Supervision		in		enforces	Certification	
NSA identifies		Strategy and						
and targets its		Plan to		reassessing		compliance with the	Bodies for	
activities at the		inform future		at Safety			ECMs and	
areas of greatest		Strategies		Certificate		safety	other	
risk.		and Plans.		or Safety		regulatory	competent	
4. The NSA				Authorisatio		framework where	bodies.	
ensures that				n renewal.				
safety						appropriate.		
recommendatio						3. The NSA		
ns issued by the						has a		
NIB are taken						complaints		
into						procedure		
consideration						for use by		
and where						Railway		
appropriate						Undertaking		
acted upon. The						s and		
NSA reports						Infrastructur		
back at least						e Managers.		
annually to the								
NIB on measures								
that are taken or								
planned as a								
•								
consequence of the								
recommendatio								
n.								

EU Legal framework for promoting the safety regulatory framework	Legal requirements					
	RSD Article 16 (2) (f) RSD Article 17 (1)	RSD Article 16 (2) (f) Article 17 (1) EC Regulation 1077/2012 Article 7	EC Regulation 1077/2012 Annex, 5 (c)	EC Regulation 1077/2012 Article 8		
	Promotion of the safety regulatory framework	Decision Making	Contribution	Coordination and cooperation		
Criteria	1. The NSA monitors, promotes and where appropriate develops the safety regulatory framework including the system of national safety rules. In practice, the NSA can show that it provides information and guidance about the safety regulatory framework to the sector, that rules are shared (e.g. via Notif-IT), that lessons learnt from safety recommendations are shared, that it provides guidance and	 The NSA has decision making criteria in place for how it monitors and, promotes the safety regulation framework. These decision-making criteria are published. 	1. The NSA contributes when necessary with its views and any proposals to its Member State to overcome any deficiencies in the safety regulatory framework.	1. The NSA develops cooperation arrangements with NIBs, certification bodies for ECM and other competent authorities in order to share information and to coordinate their response to any failure to comply with the safety regulatory framework.		

support to individual stakeholders when needed.		
2. The NSA has a process is place for the requirement in 1 above.		
3. In this process, the NSA consults all parties involved and interested parties, including IMs, RUs, manufacturers and maintenance providers, users and staff representatives.		

EU Legal framework for NSA tasks on risk assessment		Legal requirements				
	Regulation (EU) 402/2013 Article 7 & 8 + Annex II	Regulation (EU) 402/2013 Article 13.3 Art.18	Regulation (EU) 402/2013 Article 6.4	Regulation (EU) 402/2013 Article 11 Directive 2004/49/EC Art. 16(2)e		
	Recognition	Information - Report	Assessment Body	Supervision/surveillance		
Criteria	1. Criteria defined in Annex II (e.g. organisation, methodology) are used in a systematic way. 2. Accreditation or recognition is accepted when done in accordance with article 7. 3. The administrative procedure to follow in order to get the recognition as assessment body is well established.	1. NSA has informed about the names of the assessment bodies recognised together with their area of competence; 2. NSA includes in its annual report a section on the experience of the proposer in the application of risk management process.	 If the NSA is assessment body, see annex 3. If the NSA is assessment body, measures are in place in order to ensure separation of activities with the other tasks of the NSA. 	 Establish a surveillance plan of the assessment bodies recognised. Establish a section on the implementation of Regulation (EU) 402/2013 in its supervision plan. 		

EU Legal framework for NSA tasks on TDD	Legal requirements						
	Dir. 2007/59/EC	Dir. 2007/59/EC	Dir. 2007/59/EC	Dir. 2007/59/EC	Dir. 2007/59/EC	Dir. 2007/59/EC	Dir. 2007/59/EC
	Art.14	Art. 5, 21, 29 & 30	Art. 20	Art. 24 & Annex IV	Art. 26	Art. 19 & 29	Art. 22
	Issuance of licence	Sanctions	Recognition/accredi tation	Training/examina tion	Quality system	Supervision	Register
Criteria	1. A procedure to issue licences is set up. 2. The procedure is communicate d and transparent to all relevant stakeholders. 3. The procedure is	 Anti-fraud measures are adopted and applied. A procedure of suspension and withdrawal is developed and applied. A procedure to review the decision of the NSA (appeal procedure) related 	In case where the national legislation provides that the NSA is the competent authority: 1. Criteria for recognition are developed following the commission decision 2011/765/EU; 2. Procedure of recognition is	1. EU requirements are fully integrated in the training scheme and applied.	1. Quality system set up, monitoring plan developed and both are regularly reviewed (all activities associated with training, the assessment of skills and the updating of licences and certificates are subject of continuous monitoring).	1. Measure set up, applied and continuously improved to monitor the drivers' certification process. 2. Inspection plan is established in relation to	1. Register exists, contains the relevant information and is rightfully updated. 2. Knowledge about Internal Market Information system and

4. If stringent requirements are applied, it does not impact the recognition of licences issued 4. Penalties rules in case of infringement to the licensing scheme are established and used appropriately. Commission recommendation 2011/766/EU; 3. On-board controls are made. 3. The list of recognised bodies is published and accessible.	continuously	to the issuance of a	establmished		drivers'	use it
4. If stringent requirements are applied, it does not impact the recognition of licences issued 4. Penalties rules in case of infringement to the licensing scheme are established and used appropriately. 5. The list of recognised bodies is published and accessible. 6. Penalties rules in case of infringement to the licensing scheme are established and accessible. 7. Controls are don't controls are made. 8. The list of recognised bodies is published and accessible.	improved.	licence exists.	following the		licences.	appropriatel
in other reque	requirements are applied, it does not impact the recognition of licences issued in other	case of infringement to the licensing scheme are established and used appropriately.	recommendation 2011/766/EU; 3. The list of recognised bodies is published and		controls are	Information is provided to the train driver when