

NEWSLETTER

April 2020

Editorial.....	1
NB Rail & COVID-19	2
Safety Culture	2
New TSI procedure	3
New ECM Regulation	3
NSA Monitoring	4
News and announcements	5

Editorial



Dear Reader,

First of all I hope you and those close to you are safe and healthy in these demanding times. We feel strong compassion with those who are adversely affected by the current pandemic.

We fully support the measures taken by the European Commission and the Member States, while at the same time maintaining our services to the European railway sector. Even though working remotely, our staff is doing the utmost to keep all services running.

The emergency measures adopted in different countries to inhibit the spread of COVID-19 are affecting the authorisation/certification processes to the extent that some actors can

no longer fulfill their legal duties and obligations. For example, Notified Bodies can no longer perform the evaluations, audits, visits and inspections as planned, which may affect the issuing and renewal of certificates. Some applicants have difficulty obtaining the necessary files from their suppliers in order to complete application files.

The Agency is continuously publishing clarification notes on its website to assist applicants. We encourage all stakeholders to regularly visit our [website](#) and the website of the [European Commission](#) for updates on the situation.

In addition, we have intensified the exchange of information with the National Safety Authorities (NSAs) and the European Commission, in particular on measures taken during this crisis.

We will also inform you via topical webinars which will be announced on our website. Now that most communication is digital, please make best use of the services we offer: do not hesitate to [contact us](#) with your questions and feedback and allow us to stay in touch with you by creating your [ERA profile](#).

I am pleased that operations run smoothly across the Agency despite the crisis, and I would like to thank all external experts and ERA staff for their continued commitment. In the first quarter of 2020 we managed to successfully build our capabilities in the new tasks, delivering vehicle

authorisations, safety certifications, and ERTMS trackside approvals (see figure on the next page).

The Agency signed bilateral cooperation agreements with the NSAs of the Republic of Latvia and the Republic of Lithuania in March and April 2020, now reaching a total number of 17 of such agreements. ERA envisages the signature of all remaining agreements within the transposition deadline of 16th June 2020.

Especially in times of travel restrictions rail freight proves to be an indispensable function of the economy, ensuring that goods are delivered in a sustainable manner.

It is therefore essential to foster international rail transport, eliminating barriers and ensuring the highest level of safety, using the full opportunities of digitalisation, anticipating customers' needs and shortening the time to market of innovative solutions.

ERA, being a center of competence and an information sharing platform, continues to be a valuable partner for European decision makers and the railway sector. As in every newsletter, we update you on some of our activities. Enjoy reading!

*Josef Doppelbauer,
Executive Director*

ERA supports the Recommendation for Use (RFU) from NB Rail on how to cope with restrictions during the Corona pandemic

The exceptional circumstances and restrictions established by the vast majority of Member States to contain the coronavirus disease (COVID-19), are temporarily preventing Notified Bodies (NoBos) from efficiently carrying out planned

evaluation activities (e.g. visits, inspections, audits or any other on-site activity necessary to issue or renew a certificate).

Mindful of these difficulties and to ensure business continuity, to

mitigate the economic impact of the restrictions put in place and to support stakeholders in the fulfilment of their legal duties and obligations, the Agency has supported an NB RAIL Recommendation for Use, [RFU-STR-704](#), for the remote performance of NoBo activities originally intended to be performed 'on-site'.

Under these circumstances On-site activities may in fact need to be postponed, partially or completely substituted or complemented by equivalent, alternative remote activities.

Together with other relevant documents ([IAF ID3: 2011](#), [IAF MD 4: 2018](#) and [IAF ID 12: 2015](#)), this RFU provides a harmonised approach and good practice for NoBos carrying out remote evaluation activities.

Figures & Facts: 16 June '19 – 31 March '20		
Vehicle Authorisations	Single Safety Certificates	ERTMS Trackside Approvals
498 delivered* representing in total 6191 vehicles	9 delivered from which 1 in March '20	5 applications
41 projects ongoing since 1 April '20	6 projects ongoing since 1 April '20	10 initial engagements from which 4 closed
Delivery of conformity-to-type authorisations within an average time of 13 calendar days	Delivery within an average time of 3 months and 3 weeks	
* 464 conformity-to-type decisions; 17 pre-engagement baseline opinions; 17 other authorisation case decisions. In March '20, 75 decisions for vehicle authorisation were taken (63 conformity-to-type) despite Corona-crisis.		

Launching the rail safety culture toolbox for shaping a common positive safety culture in European railways



“Safety is not only about regulation, rules and procedures. Safety is about a living and collective commitment”, states Josef Doppelbauer, Executive Director of ERA. He adds: “We need a positive safety culture to achieve sustainable and safe performance in the Single European Railway Area.”

Some may still find the idea of building a positive safety culture daunting because ‘the way it is’ has fallen into a pattern where so far everything went fine. ERA has now launched the safety culture toolbox

which provides a series of practical guidelines on how to foster a positive safety culture in railways. The first volume of this guidelines, *Introduction to the European Railway Safety Culture Model*, is now available. The aim of this first guide is to develop and understand safety culture in the framework of the European railway safety culture model.

The model allows users to assess safety culture and to define areas for improvement. The target audience is wide, covering regulators, senior managers, rail safety managers, supervisors, researchers and all other individuals interested in the concept of safety culture.

The European railway safety culture model is an effective tool to support all the players to contribute to improving railway safety. It is the

result of the work of a dedicated task force with professionals from diverse backgrounds representing different types of organisations and from a variety of Member States. The model has been successfully tested and practically implemented to evaluate and improve railway safety culture.

By developing useful instruments to support the sector, the European Union Agency for Railways is demonstrating its commitment to developing a positive safety culture. However, we need the commitment of all involved players to achieve a sustainable and safe performance in the Single European Railway Area.

You can find more information on safety culture on our [website](#) where you can also [download the guidance](#). For questions, [contact us](#), selecting Railway Safety as a topic.

New procedure applied to the revision of TSIs supports the European Commission priorities of digitalisation and sustainability

It has always been an important task of the Agency to enhance interoperability in railways in Europe by establishing harmonised technical standards.

Those technical specifications for interoperability (TSIs) have been elaborated in working parties consisting of ERA, sector representatives and experts from the Member States. In 2020 the TSIs cover all subsystems and they apply to the entire EU network.

In the future we will continue to improve these standards and include new transversal topics, like automatic train operation (ATO), interoperability of fuel cells and rapidly charging batteries and digital technologies. That is why a new working method is needed.

One working party will manage the TSIs for all subsystems instead of several working parties for each subsystem individually. In addition, Topical Working Groups will be created according to the needs for technical discussions on specific subjects.

This will allow a better coordination

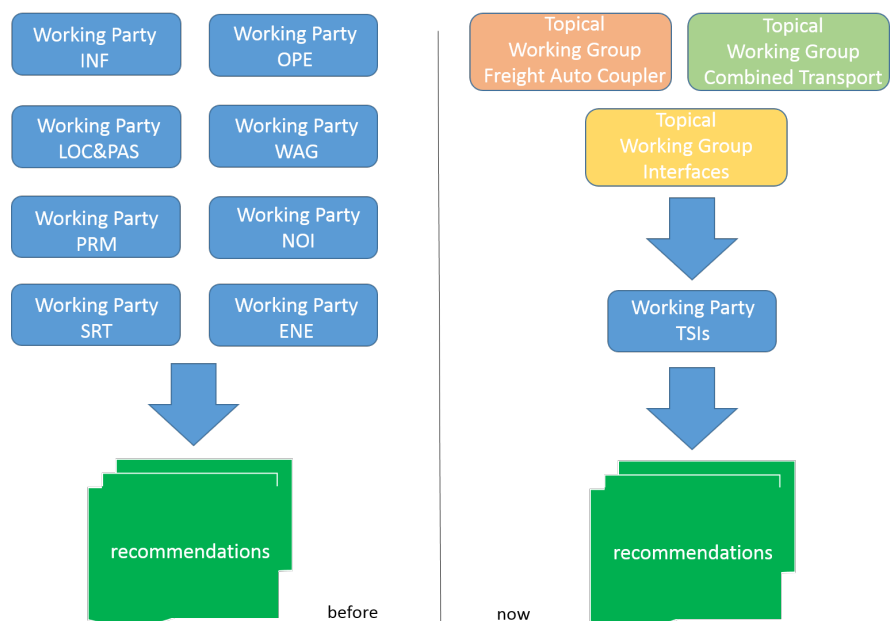
of transversal topics which affect multiple subsystems, like e.g. ATO or combined transport solutions.

It will also enhance efficiency by securing an overhead coordination and prioritisation of the change requests for all subsystems in the Working Party, combined with in-depth specialist discussions in the Topical Working Groups.

Applying this new procedure should

enable the Agency and the sector to allocate expert resources more efficiently and to react rapidly on emerging technologies to considerably shorten their time-to-market. For more details please [contact us](#).

Even though restrictions apply during the Corona pandemic, the Topical Working Groups and Working Party meetings continue by skype.



From 16 June 2020 onwards a new regulation for Entities in Charge of Maintenance (ECM) starts to be applicable

A reason to interview Nathalie Duquenne and Aleksandra Perkuszevska, the ERA project officers dealing with this topic

Why is a (new) regulation on the certification of ECMs necessary?

The maintenance of vehicles is an important part of the safety system as a whole. In the past the lack of a system for certification of ECMs has led to increased costs for the sector and journeys without loads.

The management of maintenance was not defined clear enough, not sufficiently controlled and the absence of harmonised rules

hampered international competition on the market and international traffic, mainly for freight.

The first step on certification of ECM was the regulation 445/2011 imposing a certificate to all ECMs maintaining freight wagons.

After 7 years of implementation of this regulation, the majority of the railway stakeholders requested an extension of the certification to all

ECMs. This resulted in the new regulation [\(EU\) 2019/779](#).

All ECMs have the duty to be in conformity with the annex II of the new Regulation by 16 June 2020 according to the art 3 §1 of this new regulation. This annex II groups requirements for organising and delivering the maintenance. Those requirements are recognised by stakeholders as the good practices of the maintenance business.

Which are the major changes compared to the old regulation?

The new regulation applies to all railway vehicles, including e.g. high speed trains, locomotives, (passenger) multiple units, passenger carriage, freight wagons and on-track machines (OTM).

In addition:

- the use of the SAIT safety alert tool by ECMs becomes mandatory;
- the ECMs have to define the SCC (safety critical components) and communicate them to the vehicle keepers and manufacturers so they can include them in the technical file;
- each ECM has to submit an annual report of its activities to the certification body following annex V of the new regulation;
- certification bodies have to deliver their activity reports to ERA every 3 years.

What does 'voluntary certification' in the new regulation mean?

The principle is the same as in the previous regulation 445/2011. Entities offering other maintenance functions (maintenance delivery, maintenance development and fleet maintenance management) can ask

for a voluntary certification. The requirements for each function are detailed in the annex II of the regulation (EU) 2019/779.



Voluntary certification is a benefit for those entities that would like to work for different ECMs and it reduces the number of audits by ECMs. Indeed the voluntary certificate for a maintenance function is a presumption of conformity for the ECM to fulfil a part of its maintenance system. Consequently it helps opening the EU market of railway services.

What is the major impact of this new regulation on the ECMs?

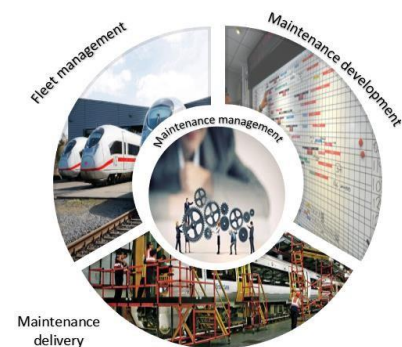
All ECMs have to be in conformity with the annex II of regulation (EU) 2019/779. The compliance is

checked either via the ECM certificate or, in case of RUs and IMs maintaining exclusively their fleet, via the assessment of their SMS. The novelty is also a definition of the safety critical components and the provisions related to their management by ECM.

Does the new regulation change the role of ERA?

ERA's role does not change compared to the Regulation 445/2011, ERA continues to organise the cooperation of certification bodies and to maintain the schemes of accreditation and certification.

ERA will also prepare implementation reports for the European Commission, the first one is due on 16 June 2024.



Focus on ERA activities: 2019 NSA monitoring 1st audit cycle

Promising results from the first audits

The National Safety Authorities (NSAs) have a pivotal role to ensure safety in European railways. They are also an essential partner of ERA for issuing safety certificates and vehicle authorisations. In addition, their activities significantly contribute to achieving the Single European Railway Area (SERA) by enabling non-discriminatory access to new market entrants.

That's why the Agency has been tasked to monitor the performance and decision-making of the NSAs (Reg. [2016/796](#), Art. 33).

The Agency's Management Board approved the tools and methods and set the scope of this monitoring task to include potentially all the tasks allocated to NSAs.

For the years 2019 and 2020, however, the scope of the audits was reduced to how NSAs are managing staff competences and how NSAs are performing their supervision activities.

In the future it is envisaged to broaden again the scope of the audits to include all NSA tasks and to

perform targeted audits prioritising the most challenging issues for NSAs.

Each NSA should be monitored every three years, which means in average nine NSAs per year.

As provided by the Agency Regulation and to reinforce common trust, mutual exchange, understanding and collaboration between the NSAs and the Agency, ERA has invited NSA experts to participate in a pool of auditors and provided training on the auditing

method. Experts accepted the invitation.

After successfully conducting two pilot audits in 2018, ERA has audited eight NSAs in 2019. Audits are announced well in advance and NSAs are requested to provide to the audit team documentary evidence. During an on-site visit (generally 4 days), auditors interview relevant job holders and the members of the NSA management. In order to be able to discuss or, if necessary, adjust findings, feedback on the past day(s) is given to the NSA.

After the on-site visit, the auditors draft a report including non-conformities (observations and deficiencies) and a review committee within ERA checks the report before it is sent to the

auditee (NSA). Subsequently the audit report is discussed with the NSA and eventual diverging opinions are added.

Depending on the classification of findings, the NSA makes an action plan to improve the situation. Afterwards, the final audit report, containing this action plan and ERA's suggestions for follow up, is communicated to the NSA, the European Commission, and the permanent representations of the respective Member State.

The implementation of the action plans is checked in the next audit cycle after three years or, in critical cases, by dedicated follow-up activities.

The results from 2019 are very promising: most NSAs audited so far

have voluntarily developed action plans. At the end of the first audit cycle, ERA will report to the Management Board providing in an anonymised way a summary of the main findings and proposing further improvements to the NSA monitoring tools and methods.

ERA may also use these findings to provide opinions and advices, to support other NSAs or for targeted dissemination activities.

Ten more audits are planned in 2020. Due to the restrictions applied during the Corona pandemic, the audit plan for 2020 is being adapted to face the extraordinary circumstances that limit the 'on-site' part of the audits.

News from ERA



Update on IPA activities

Despite the measures taken to inhibit the spread of the Corona pandemic, many activities of the IPA Project continue.

We are preparing e-learning activities. For autumn 2020 the Agency has planned several trainings and meetings. Details will be provided as soon as available. For

more information please contact ipa@era.europa.eu

Dates and announcements

ERA will be launching shortly topical webinars – watch out for announcements on our website.

Making the railway system work better for society.

© 2020, European Union Agency for Railways. All rights reserved.

European Union Agency for Railways
120 rue Marc Lefrancq
FR-59307 Valenciennes Cedex
Tel. +33 (0) 327 09 65 00
e-mail: communication@era.europa.eu

