Jan Siudecki
PhD, Head of Quality and Certi# cation Centre of the Railway Research Institute
ORCID 0000-0001-7991-5075
jansiudecki@wp.pl

DOI: 10.35117/A_ENG_25_12_05

European Union regulatory framework for railway vehicle (type) configuration management

Abstract: The aim of this article is to analyse how EU regulatory framework for railway vehicle configuration management operates. Difference between configuration of a vehicle type and configuration of an existing vehicle placed on the market has been analysed. A type is to be understood as the design of a vehicle. A vehicle is an existing asset placed on the market. Configuration of both the type and the vehicle depends on its modifications. Configuration of a vehicle depends moreover on how it is maintained. Subsequently the process for configuration management has been described in detail, including responsibilities of key actors and interrelation of configuration management with other obligations related to change management, conformity assessment and use of vehicles. The article concludes with key findings.

Keywords: railway vehicle, configuration management, maintenance, vehicle authorisation

Introduction

A proper configuration management allows an organisation to have control over the status and version of hardware (e.g. bill of materials, spare parts, drawings) and software that are required to be supplied or installed in a system or rolling stock. This is important when changes are required due to, for example, obsolescence [3].

Configuration management is all the more pertinent in an industry like railways. This is capital-heavy industry in which assets are used for a long time [8]. Return from investment in rail and provision of high quality services requires high reliability and availability of assets. This depends on proper handling of the design development, ensuring that introduced changes meet applicable requirements and that reliability and availability remain unaffected. Long lifetime of assets means also that maintenance persists as a challenge and constantly drives the need to search for new solutions for railway appliances conservation. But maintainability depends also on how maintenance is documented and managed.

Railways in the European Union is a highly regulated sector, with plenty obligations related to technical safety and availability addressed at many different actors such as manufacturers, operators, keepers, entities in charge of maintenance or maintenance workshops. Despite this high degree of regulation and pertinence of the configuration management there is not much of scientific literature on the subject, with critical and practical analysis of the regulatory framework – mainly European Parliament and Council Directive (EU) 2016/797 on the interoperability of the rail system within the European Union [2016] OJ L138/44 (henceforth 'Directive 2016/797') and Commission Implementing Regulation (EU) 2018/545 of 4 April 2018 establishing practical arrangements for the railway vehicle authorisation and railway vehicle type authorisation process pursuant to Directive (EU) 2016/797 of the European Parliament and of the Council [2018] OJ L90/66 (henceforth "Regulation 2018/545"). This paper aims at exploring the detailed content of the obligations composing configuration management, discussing the responsibilities of actors involved and their interrelation. Such an analysis should have the potential of aiding concerned

professionals both in establishing or revising implemented processes or resolving disputes that may arise when considering faults in design or maintenance.

When the term ‘vehicle’ is followed in a given statement by the term ‘type’ in brackets in this paper, this is to be understood that the statement concerns both a vehicle and a vehicle type. Although regulation 2018/545 distinguishes also a ‘type variant’ and ‘type version’ this will not be addressed in this paper for two reasons. First one is related to keeping clarity of the argumentation and a second is related to the fact that configuration management is regulated on the level of a type, and not its derivatives.

Type configuration management and vehicle configuration management

According to art. 2 point 3 of Regulation 2018/545 'configuration management' means a systematic organisational, technical and administrative process put in place throughout the lifecycle of a vehicle and/or vehicle type to ensure that the consistency of the documentation and the traceability of the changes are established and maintained so that:

(a) requirements from relevant Union law and national rules are met;
(b) changes are controlled and documented either in the technical files or in the file accompanying the issued authorisation;
(c) information and data is kept current and accurate;
(d) relevant parties are informed of changes, as required.

Analysing this provision vehicle (type) configuration management can be understood as the process of ensuring the availability and integrity (consistency, reliability) of information about the technical characteristics (its designed operating state) of a vehicle (type), in particular what and when has been changed in it or its technical documentation in order to fulfil the relevant legal obligations, in particular:

- certification and authorisation obligations,
- managing the risk of change,

so as to ensure the conformity of the (type of) vehicle with the essential requirements of the rail system, throughout its life cycle.

Regulation 2018/545 does not define the term vehicle configuration. This definition can be reconstructed from the definition of configuration in ISO 10007 Quality management - Guidelines for configuration management [4]. This standard defines configuration as “*interrelated functional and physical characteristics of a product or service defined in configuration information*”. Configuration information means requirements for product or service design, realisation, verification, operation and support. Configuration of a railway vehicle is in principle described in the technical file accompanying EC declaration of verification. The configuration information on the other hand would be identified in the process of requirements capture established in Article 13 of regulation 2018/545.

Configuration management is an information management process that covers those technical aspects of a vehicle (type) that are relevant to meeting the essential requirements of the railway system, or in other words its 'design operating state'. According to Article 2 point (31) of Directive 2016/797 design operating state is the normal operating mode and the foreseeable degraded conditions (including wear) within the range and the conditions of use specified in the technical and maintenance files.

Analysis of provisions of Regulation 2018/545 leads to the conclusion that the 'configuration management' actually comprises two separate obligations. Although there is a single definition of 'configuration management', but it describes two obligations, each of which is addressed at a different category of actors and concerns a different subject matter. Their common element lies in the duties they impose - the activities to be undertaken by the actors, i.e. the way in which the process should be carried out.

The first of these obligations is to manage the configuration of the railway vehicle type. The object of this obligation is the vehicle type. According to Article 2(26) of Directive 2016/797, 'type' means a vehicle type defining the basic design characteristics of the vehicle as covered by a type or design examination certificate described in the relevant verification module. A type is therefore a creative work comprising the design of a vehicle defined by its basic design characteristics and described in the type examination certificate. This term does not therefore cover the railway vehicles that are manufactured on the basis of this design, understood as a material asset or *res* in the meaning of civil law. This is an obligation which, according to Article 5(1) of regulation 2018/545, rests on the holder of the type authorisation.

The second obligation contained in Article 5(1) of Regulation 2018/545 is the configuration management of the railway vehicle. This obligation relates to vehicles manufactured on the basis of a given design, placed on the market and subsequently put into service (in other words, vehicles that are called in different guidance texts of the European Union agency for Railways called ‘existing vehicles’, ‘vehicles in conformity to type’, ‘vehicles in service’ or ‘vehicles placed on the market’). The addressee of the obligation to manage the configuration of a railway vehicle, in accordance with Article 16(5) of Regulation 2018/545, is its keeper. Keeper is defined in Article 2(21) of directive 2016/797 as a natural or legal person that, being the owner of a vehicle or having the right to use it, exploits the vehicle as a means of transport and is registered as such in a vehicle register referred to in Article 47 of this directive.

This distinction is highlighted in recitals 5 and 6 of Regulation 2018/545:
“(5) In order to ensure that the vehicle type continues to meet the requirements over time and that any changes to the design that affects the basic design characteristics are reflected as new variants and/or versions of the vehicle type, the process of configuration management of the vehicle type, should be used. The entity responsible for the configuration management of the vehicle type is the applicant that received the vehicle type authorisation.
(6) As far as vehicles are concerned, it is necessary to have a configuration management process limited to changes that are not managed through the configuration management process of an authorised vehicle type.”

The aforementioned recitals indicate that type-related and vehicle-related changes should be managed separately.

This distinction is natural in the light of the fact that the essence of the activity of the vehicle manufacturer, which as a rule is the holder of the type authorisation, is selling vehicles. The manufacturer therefore disposes of the legal title to the vehicle as soon as it is placed on the market and sold to an entity that becomes the keeper of the vehicle under the legislation governing rail transport. It is the keeper who bears the ultimate responsibility for the vehicle as he has the right to decide on its registration status in the vehicle register (and thus, for example, to withdraw the vehicle from service or even to scrap it). The keeper also has the ultimate discretion when it comes to introducing modifications to the vehicle and has therefore the status of an entity managing the change of the vehicle, in accordance with Article 16(5) of Regulation 2018/545. Consequently he bears the obligation to manage the configuration. It would be therefore unfounded to associate the type authorisation holder with obligations to manage the configuration of vehicles, even if they conform to the type that this he has authorised.

According to Article 5(1) of Regulation 2018/545, the type authorisation holder is responsible for managing the type configuration and according to Article 16(4) of Regulation 2018/545, the keeper is responsible for managing the vehicle configuration. Both categories of entities are at the same time ‘entities managing the change’ according to Article 2(5) of Regulation 2018/545. However, this status should not be associated with the responsibilities of the proposer in the meaning of Commission Implementing Regulation (EU) No 402/2013

of 30 April 2013 on the common safety method for risk evaluation and assessment [2013] OJ L 121/8 (henceforth: 'Regulation 402/2013'). Regulation 402/2013 contains in Article 3(11) its own definition of the 'proposer' who is responsible for managing risk of a change introduced in the railway system. The catalogue contained in this provision dos not indicate a keeper nor a type authorisation holder. Article 16(4) of Regulation 2018/545 regulates only responsibilities in terms of the qualification of the modification to one of the categories listed in Article 15(1) of Regulation 2018/545 and therefore for the purpose of determining the scope of activities necessary from a conformity assessment perspective. The entity managing the change in the meaning of Regulation 2018/545 does not have to be an applicant within the meaning of Regulation 402/2013.

Because each obligation is carried out by a different entity in relation to a different subject, these obligations are not mutually exclusive. The fact that the type authorisation holder manages changes to the type (understood as a vehicle design) does not mean that the keeper is relieved of the obligation to manage the configuration of vehicles conforming to that type. Three situations can be distinguished in which the obligation to manage the type configuration and to manage the vehicle configuration may arise should be considered:

1. The change is introduced at the initiative of the type authorisation holder (the entity managing the change within the meaning of Article 5(2) of Regulation 2018/545 is the type authorisation holder) only in the type. So in practice the design is changed. In this case, only vehicles that are yet to be manufactured and placed on the market will conform to the changed type. In this situation, only type configuration management takes place.
2. The change is introduced at the initiative of the type authorisation holder in the type and then vehicles conforming to that type (already placed on the market) are adapted to that change. This type of situation may arise when a manufacturer (who is the type authorisation holder) identifies a design or implementation fault in the vehicles he has already delivered to the contracting entities (keepers) and informs them that this fault needs to be corrected.

In this situation, the holder of the type authorisation remains responsible for managing type configuration. The modification of the type conform vehicles on the other hand may in practice be carried out either the type authorisation holder or by the keeper (or by operator of the vehicle or the entity in charge of its maintenance acting on behalf of the keeper). Regardless of who modifies the vehicle in practice, the keeper will remain responsible for managing the configuration of the vehicles adapted to the changed design.

While the keeper may in this situation entrust the type authorisation holder with managing the vehicle configuration, on basis of Article 16(5) of regulation 2018/545, which will be relevant to the obligations set out in this provision and may facilitate the practical implementation of the changes, this will not transfer the responsibility for the configuration management of the vehicle from the keeper, as it is the entity with ultimate responsibility for the vehicle. The opposite conclusion cannot be accepted because the type authorisation holder, which is generally the manufacturer, no longer holds any legal title to vehicles in service and cannot make any decisions on introducing changes to them. This is confirmed in paragraph 3.3.4.4 of the Guidelines to Practical Arrangements for Vehicle Authorisation Process [6].

The situation where vehicles conforming to a type described in the type-examination certificate are produced by an entity other than the entity that has obtained that certificate (and has become the type authorisation holder) raises some questions. It is a situation in which the type test module (SB module) is performed by one entity (which is the type authorisation holder) and the SD module is performed by another entity (Such a situation is described in the NB rail recommendation for use RFU-STR-700 [7]). There seems to be no doubt here that in

such a situation the responsibility for type configuration management remains with the type authorisation holder. Questions arise in a situation where it would appear that the vehicle produced is not actually in conformity with the type (its configuration does not correspond to the design operating state, i.e. the type configuration has not been properly managed). It seems that in such a situation, the responsibility should be borne in the first and foremost by the entity that performed the SD module on the basis of the issued declaration of conformity to type.

3. A change is only made to vehicles placed on the market. In practice, such a change may be made on the initiative of the keeper, but it may also be made at the request of another body, e.g. a railway undertaking or an entity in charge of maintenance (henceforth: 'ECM'). This may be the case when, based on experience gained, it appears that a different technical solution to that envisaged in the original design of the vehicle should be applied. However, from the point of view of the obligations under consideration, it is the keeper, as the entity responsible for vehicle configuration management, who will be responsible for implementing such a change as the change manager. It is then the responsibility of the keeper to manage the configuration. If these changes result in the need to obtain a new type authorisation in accordance with Article 15(1)(4) in conjunction with Article 16(2) of Regulation 2018/545, an obligation to manage the type configuration will arise for the keeper (once the type authorisation has been obtained), but this will be a new obligation (unrelated to the configuration management of the vehicle type that is subject to the change) due to the creation of the new type and the taking up of the role of type authorisation holder by the keeper.

Vehicle (type) configuration management process

The common element of type and vehicle configuration management is the essence of the process e of this obligation (information management) and its purpose (ensuring conformity with requirements). However, in both cases the scope of the information to be managed will be different. This difference in the scope of information that is to be managed is due to the fact that the vehicle type is not subject to maintenance. Only an existing, material asset can be subject to the maintenance process. The type, as an intangible manifestation of human creative activity, cannot be subject to maintenance in the sense of replacement of worn-out components, cleaning, replacement of fluids, lubrication, etc. Type configuration management will therefore only cover information concerning modifications to the type (design changes). Vehicle configuration management, on the other hand, will include information from both the maintenance process and the vehicle modification process.

The design operating state of a newly developed type or of a vehicle placed on the market for the first time can be called a baseline configuration. ISO 22163:2023Railway applications — Railway quality management system — ISO 9001:2015 and specific requirements for application in the railway sector standard [5] (henceforth 'IRIS') indicates that the baseline configuration is to be understood as approved configuration information that establishes the characteristics of a product or service at a point in time that serves as reference for activities throughout the life cycle of the product or service. With regard to a railway vehicle, the baseline configuration (i.e. as-built configuration) will be the characteristics of the type as it was developed by the manufacturer and as it is described in the EC type examination certificate. This is because the starting point for analysing any modification of the vehicle (type) to ensure conformity with the essential requirements is how it is described in the type-examination certificate. The base configuration should also be defined as that configuration resulting from modifications to an existing vehicle which lead to a change of type, since this situation leads to a new type and a new type-examination certificate has to be

obtained (as-upgraded configuration). An as-modified configuration will result from modifications that do not lead to a change of vehicle type. On the other hand, a configuration resulting from a replacement as part of maintenance may be referred to as as-maintained. These rules should be applied to both the existing vehicle and the type.

The configuration of an existing vehicle is defined by two factors: its maintenance and the introduced modifications. Vehicle maintenance aims to maintain the vehicle in its designed operating state. Change management aims to ensure that the design operating state of the modified vehicle meets all applicable requirements. Any modification to a vehicle will lead to an update of what is referred to as the designed operating state. In other words, it is these processes that determine the technical characteristics of the vehicle, understood precisely as the configuration described in the relevant documentation (design operating state) as defined in Article 2(3) of Regulation 2018/545.

Regarding what defines the configuration and, at the same time, the scope of the information that is subject to configuration management, the base configuration is described in the documentation accompanying the EC declaration of verification issued for the new vehicle type. The scope of the required content of the technical file is defined in point 2.4 of Annex IV of Directive 2016/797, and is further specified in paragraph 4.2.12 of Commission Regulation (EU) 1302/2014 of 18 November 2014 on the technical specification for interoperability relating to the rolling stock subsystem - locomotives and passenger rolling stock of the rail system in the European Union (OJ L 356 12.12.2014, p. 228, henceforth: TSI ‘1302/2014’) and in paragraph 4.5.1. of Commission Regulation (EU) No 321/2013 of 13 March 2013 concerning the technical specification for interoperability relating to the subsystem rolling stock — freight wagons of the rail system in the European Union (OJ L 104 12.4.2013, p. 1).

The same documentation describes the configuration (as-upgraded) when a new type is created as a result of modifications made to the vehicle or type. The documentation accompanying the "EC" declaration of verification will also define the as-modified configuration, since Regulation 2018/545, in Article 15(1)(b) and (c), provides for the situation where modifications made to the vehicle which do not result in a new type have to be subject to conformity assessment and, ultimately, a new "EC" declaration of subsystem verification preceded by new accompanying documentation. However, it should be borne in mind that this documentation will form the basis for the configuration management as part of the change management in accordance with Article 15(1) of Regulation 2018/545, which states that the starting point for the qualification of changes is the impact on the technical file accompanying the EC declaration of verification.

On the other hand, configuration management in relation to maintenance will take place on the basis of the maintenance file, which, on the basis of the documentation supporting the EC declaration, is developed by an ECM (Guide for the application of Article 14 of Directive (EU) 2016/798 and Commission Implementing Regulation (EU) No 2019/779 on a system of certification of entities in charge of maintenance for vehicles [2]). The ECM is responsible for managing the maintenance file by adapting it to the actual operating conditions, required performance and return on experience of operation and updating it throughout the vehicle life cycle. In the case of an existing vehicle, the ECM is also responsible for managing and updating the maintenance documentation (see Article 14(3)(b) of Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety [2016] OJ L 138/102 (henceforth: ‘Directive 2016/798’) throughout the vehicle's life cycle. This is because it is this documentation that describes the configuration of the existing vehicle. It is more detailed than the documentation accompanying the EC declaration of verification of the subsystem in that it also covers the performed maintenance, and substitution in the framework of maintenance in particular (defined in Article 2(17) of

Directive 2016/797 as any replacement of components by parts of identical function and performance in the framework of preventive or corrective maintenance).

It should be emphasised that the obligation of configuration management relates precisely to the legal requirements for the content of the technical documentation and not its actual content. The technical documentation may in practice contain information not required by the legislation, not related to compliance with the essential requirements, but which is included in the documentation because of the manufacturer's business practices or the specific requirements of the entity ordering the rolling stock. There is no justification for requiring traceability management of such information under Article 15 of Regulation 2018/545.

For the practical implementation of the duty of configuration management by the keeper it is essential for him to have access to adequate documentation that enables him to ensure (and bear the responsibility) that either the configuration is maintained or that configuration changes are properly managed. This documentation, according to the reference in Article 16(2) of Regulation 2018/545, should be the documentation accompanying the EC declaration of verification. In practice, the implementation of this obligation may be hampered because, according to clause 4.2.12.1 of TSI 1302/2014, it is the obligation of the type authorisation holder (authorisation applicant) to make available the documentation required for the management of the maintenance file, which is only part of the operation and maintenance file, which in turn is only part of the documentation accompanying the EC declaration of verification (according to Annex IV of Directive 2016/797 and clause 4.2.12 (3) of the TSI 1302/2014) and which in practice often contains sensitive and protected information of the entity that issued the EC declaration of verification. Keepers may therefore have limited access to all the documentation accompanying the EC declaration of verification, which is the basis for proper vehicle configuration management in accordance with Article 16(2) in conjunction with Article 15(1) of Regulation 2018/545. The lack of access to of this documentation does not constitute a legal barrier to the implementation of the configuration management obligation, in the sense that this lack of access does not prevent the implementation of a change to the vehicle and the management of the configuration after the change (moreover there are still many vehicles on the market that do not have such documentation due to having been placed on the market at a time when the European Union legislation governing their conformity assessment was not yet in force). Nevertheless, it should be recognised that the lack of access to this documentation may impede proper configuration management. Therefore, in order to ensure the practical feasibility of the compliant (with requirements of Article 2(3) of Regulation 2018/545) of the configuration management, it may be necessary for the holder to ensure that it has access to all the necessary documentation through appropriate contractual arrangements with the type authorisation holder (which is, in principle, the issuer of the EC declaration of verification). Point 7.1.2.1 of the Loc&Pas TSI states that "*the holder of the vehicle type authorisation shall provide, under reasonable conditions, the information necessary for assessing the changes to the entity managing the change*". The keeper is an entity managing the change. Clause 7.1.2.1 of the Loc&Pas TSI should therefore be understood as legally sanctioning the exchange of information between the type authorisation holder and the keeper, for the proper implementation of the latter's configuration management obligation. The keeper cannot therefore absolve himself of the responsibility for compliant configuration management by invoking a lack of access to the documentation accompanying the EC declaration of verification. A contracting entity that does not grant itself access to the necessary documentation, in particular in the light of the type authorisation holder's obligation to make it available (under reasonable conditions), and thus fails to manage the change in accordance with the requirements, is in breach of its configuration management obligations.

Vehicle configuration management and maintenance

When analysing further the essence of vehicle configuration management, it is necessary to clarify the understanding of the concept of maintenance, already presented at a certain level of generality above, and to define the concept of change. Clarifying these concepts, as defining the content of configuration management, will be key to establishing the responsibilities of those involved in configuration management.

Maintenance in relation to a railway vehicle will consist of upkeeping it in a state (or restoring it to a state) in which it performs the required functions in accordance with the technical file accompanying the EC declaration of verification and the maintenance file drawn up on the basis thereof. It is about maintaining the vehicle in the design operating state, because it is in this state that the vehicle can perform the required functions.

Maintenance includes activities such as condition monitoring, cleaning, replenishment of fluids and lubricants and replacement of used up parts. Associated with the replacement of parts is the institution of substitution in the framework of maintenance. This term is significant for delimiting what activity is to be considered and managed as maintenance and what as a change. Substitution in the framework of maintenance is well described in the guide Guidance on Practical Arrangements for the Vehicle Authorisation Process.

"*Article 16(1) of the Regulation (EU) 2018/545 covers changes in vehicles (not vehicle types) related to maintenance, i.e., replacing broken, malfunctioning or worn out components. Where the replacement is 100% identical to the substituted one, such change does not require an authorisation nor any other update in technical files or ERATV. However, in some cases, it is not possible to find 100% identical spare parts in the market (e.g., due to obsolescence, bankruptcy of the manufacturer etc.), and there is a need to use other components with identical functions and performances, although not identical. In this framework, "identical functions and performances" should be understood as follows: the new component does not have new functionalities itself or add new functionalities to the system into which it is integrated, does not trigger a change in performance (be it an increase or a decrease) nor impacts adversely safety (the level of safety is at least kept, without new hazards/risks). It´s meant to be a one to one replacement (same input, same output, same working principles), linked to maintenance (preventive or corrective), and following a "plug & play" approach: remove the old component, install the new one, no other modification or adaptation is needed. The operations to fit the new component shall be identical to those that would be needed to replace it by another 100% identical components. In other words, it´s the substitution of an element by an identical one, which may be slightly different due to evolution over time, obsolescence, change of provider etc.) but still equivalent*".

As can be seen from the above, only one condition is relevant for an activity to qualify as substitution in the framework of maintenance: identical function and performance (or in other words: efficiency). No other condition (type of component, component manufacturer, indication in the technical documentation, etc.) is relevant. Maintenance thus involves replacing parts with parts that are the same (identical) or different, but with identical functions and performance to the part being replaced.

According to Article 16(1) and (2) of Regulation 2018/545, changes to an already authorised vehicle which are linked to substitution in the framework of maintenance and limited to replacement of components by other components fulfilling identical functions and performances in the framework of preventive or corrective maintenance of the vehicle do not require an authorisation for placing on the market. Any other changes to a vehicle shall be analysed and categorised in accordance with Article 15(1).

Article 16(1) and (2) of Regulation 2018/545 form the basis for distinguishing between maintenance and change management. The concept of a change is not defined in any provision of the European Union legal framework for railway safety and interoperability.

However, on the basis of Article 16(1) and (2) of Regulation 2018/545, it can be concluded that all activities undertaken towards a vehicle that do not fall within the scope of maintenance constitute a change. With that said, a change requiring management will be any change that leads to differences in the documentation accompanying the EC declaration of verification (its obsolescence) because this is the starting point for the qualification of changes in accordance with Article 16(2) in conjunction with Article 15(1) of Regulation 2018/545. Furthermore the essence of configuration management is to ensure that the change does not undermine the compliance with essential requirements (in light of the designed operating state) and the documentation accompanying the EC declaration of verification provides a complete basis and evidence of compliance with essential requirements.

The above conclusion gives rise to a precise description and delimitation of the responsibilities of the ECM, the maintenance workshop and the keeper for configuration management, set out essentially in the provisions of Directives 2016/798 and 2016/797 and their implementing acts.

The basis for the ECM's responsibility for vehicle maintenance is Article 14(2) of Directive 2016/798, according to which, without prejudice to the responsibility of railway undertakings and infrastructure managers for the safe operation of the train, as provided for in Article 4 of Directive 2016/798, the entity in charge of maintenance shall ensure that the vehicles for which it is in charge of maintenance are, through the maintenance system, in a safe state of running (or putting it differently it is in its design operating state). All other ECM responsibilities, such as those concerning the establishment of a maintenance management system, the implementation of risk control measures or the exchange of information, are derivative to this core ECM responsibility i.e. the responsibility for vehicle maintenance. The ECM does not have any responsibilities that go beyond the implementation of maintenance. In doing so, the responsibility for vehicle maintenance lies with the ECM and not with the railway undertaking, as confirmed in recital 72 of the Recommendation of 5 December 2014: "*in view of the fact that railway undertakings and infrastructure managers are the only entities obliged to hold safety certificates and safety authorisations, supported by safety management systems, these organisations should have a key role in managing the input of others and in making appropriate decisions on their input. When railway undertakings or infrastructure managers make such decisions or actions as part of their safety management systems, this is without prejudice to the responsibilities of others, such as keepers, entities in charge of maintenance, manufacturers*." The responsibility of railway undertakings and infrastructure manages is without prejudice to the responsibility of ECMs for maintenance, or manufacturers for the conformity of their products with the essential requirements.

With regard to the responsibility of the maintenance workshop (i.e. the entity performing at least ECM function 4 and possibly functions 2 and 3), according to Article 9(3) of Commission Implementing Regulation (EU) 2019/779 of 16 May 2019 laying down detailed provisions on a system of certification of entities in charge of maintenance of vehicles pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council (OJ L 139I, 27.5.2019, p. 360–389, henceforth: 'Regulation 2019/779'), the ECM remains responsible for the outcome of outsourced maintenance activities. Considering this provision, and the location of the full responsibility for vehicle maintenance on the ECM it can be concluded that the maintenance workshop does not bear any responsibility for the outcome of maintenance, i.e. for ensuring that the vehicle maintains the configuration in accordance with the maintenance file (the file accompanying the EC declaration of verification). This responsibility is borne by the ECM and considering only the ECM's responsibility in this respect is appropriate. This does not mean, of course, that the maintenance workshop is not responsible for the proper execution of the tasks it performs within its ECM functions.

At this point some comments are necessary as to the provisions of Regulation 2019/779, which require ECMs to have 'configuration management'. Annex II(II)(2)(e) of Regulation 2019/779 states that an organisation applying for an ECM "*shall have procedures to guarantee conformity with the essential requirements for interoperability, including updates throughout the lifecycle, by* […] *managing the configuration of all technical changes affecting the system integrity of the vehicle*". Annex II(II)(7)(b) of Regulation 2019/779 states moreover that when the documentation process is applied to the maintenance development function, the traceability of at least the following elements needs to be guaranteed the configuration of vehicles, including, but not limited to, safety-critical components and on-board software modifications. These specific 'configuration management' responsibilities of the ECM are to be considered within the framework of the ECM's overall responsibility, which is limited to vehicle maintenance. Configuration management by the ECM is intended, in this light, to ensure traceability of maintenance activities and parts used in connection with the substitution in the framework of maintenance. These provisions are not intended to make the ECM responsible for configuration management in the second dimension of the process, i.e. the change management dimension.

This is due, firstly, to the fact that ECM is responsible for maintenance, which does not include the implementation of changes but, on the contrary, the preservation of the vehicle in a certain configuration, and, secondly, to the need to maintain a clear and unambiguous division of responsibility in the railway system. Indeed, safety in the railway system is based on a clear division of responsibilities (as can be seen, for example, from recitals 7 and 8 of Directive 2016/798). A situation in which two categories of actors are responsible for the same thing would be unacceptable from this point of view. The ECM is therefore responsible for configuration management in the sense of its behaviour and only in relation to the traceability of the maintenance activities and the technical characteristics of the vehicle (design operating state) that result from the maintenance activities. In connection with the ECM's obligations regarding information exchange, this responsibility is intended to ensure that the duty of the keeper to carry out 'end-to-end' configuration management throughout the vehicle's life cycle can be fulfilled (which is particularly relevant in the context of the possibility of even multiple changes of the ECM during the vehicle's life cycle). The responsibility of the ECM is secondary to that of the keeper. In other words the ECM is responsible for undertaking certain configuration management activities, only to a certain extent and in order to provide a basis for holding the keeper ultimately responsible for configuration management.

In the context of the above conclusion, it remains to be considered whether the legal framework foresees that the ECM may be responsible for changes to the vehicle that may have to be made in connection with the implementation of maintenance activities (primarily the situation of non-availability of spare parts with identical functions and performance). Given the previous conclusions contrasting maintenance and change, it can be assumed that the ECM is not responsible for changes made to the vehicle and therefore has no authority to initiate and implement them (this is not its role in the railway system). Regulation 2019/779 refers to change management by the ECM in a number of provisions, but more often than not, this obligation relates to the management of a change to the maintenance file rather than to the vehicle itself (and therefore to the introduction of operational rather than technical changes in the sense of Regulation 402/2013) or is unspecified in terms of scope. ECM is also listed as one of the categories of applicant that performs the change risk management process in Regulation 402/2013, but this status can also only be referred to the implementation of operational or organisational changes within the meaning of the Regulation, in line with the ECM's overall responsibilities and tasks. The ECM's change management tasks in application of Regulation 402/2013 should be considered through the prism of its responsibility and role

in the railway system, and therefore it should be concluded that these tasks are limited to changes made to the maintenance management system or maintenance documentation, but do not include technical changes to the vehicle under maintenance itself. This conclusion is confirmed by the EUAR explanatory note on safe integration [1], which does not foresee any responsibility of the ECM in for the safe integration of vehicle changes and, in the only place it mentions the ECM, is limited to indicating that safe integration is necessary at the level of the ECM in order to develop processes and procedures for its maintenance system or for the safe life management of spare parts. Under Regulation 2018/545, the ECM is not a change management entity (Article 2(5)), which also highlights its lack of responsibility and role in the implementation of changes to railway vehicles.

The implementation of changes to vehicles must be the responsibility of the keeper, as the one who has the ultimate responsibility for configuration management and as the change management entity within the meaning of Regulation 2018/545. In doing so, the keeper should, at the very least, accept any change to be implemented on the vehicle regardless of which entity the impetus for its implementation comes from in practice (whether it is the carrier in relation to operational experience and operation, or the ECM in relation to maintenance experience and implementation) and which entity will actually implement it. Such acceptance is the expression and proof of the implementation of the vehicle configuration management obligation. In order to fulfil the obligation of configuration management, the keeper must therefore provide himself with the appropriate tools for the ECM to pass on the information, which is consistent with the with the requirements of Annex II, point I(7) of Regulation 2019/779 regarding the exchange of information. A change made by the ECM without the approval of the authorising officer is therefore in breach of the ECM's obligations regarding, inter alia, the exchange of information. At the same time, it should be emphasised that the fact that the authorising officer has not provided himself with these tools or that the ECM has not fulfilled its obligation to pass on the relevant information does not remove the responsibility of the authorising officer for configuration management.

The obligation of vehicle configuration management goes further in practice in terms of scope of documentation than the obligation of type configuration management. Type-configuration management only covers the technical documentation accompanying the EC declaration of verification - it is concerned with the type, and not the documentation produced for specific vehicles (even if in conformity with the type). In practice, vehicle configuration management requires the documentation of maintenance activities that may affect conformity with the essential requirements. According to Annex II, Section II of Regulation 2019/779, an organisation applying for an ECM certificate or for a maintenance development function certificate must have procedures in place to ensure that the essential requirements for interoperability are met, including updates throughout the lifecycle, by managing the configuration of all technical changes affecting the integrity of the vehicle system. In addition, the ERA Guidelines for ECM certification indicate that the ECM should maintain a configuration file that enables the configuration management of a specific vehicle

It should be noted here that these responsibilities of the ECM do not modify the keeper's responsibility for vehicle configuration management, but are merely intended to enable the keeper to provide the relevant information for the performance of his duties. Indeed, the obligations arising from Regulation 2019/779 relate to the maintenance of railway vehicles and not to the management of their changes which is governed by Regulation 2018/545. The primary responsibility of the ECM, in accordance with Article 14(2) of Directive 2016/798, is to ensure that vehicles are maintained in such a way that they are able to be operated in a safe manner. Maintenance, or substitution in the framework of maintenance, is the replacement of parts with other parts of identical function and

performance as part of preventive or corrective maintenance of a vehicle. It therefore does not include changes. Furthermore, the change management obligations set out in Regulation 2019/779 relate to the management of a change in the technical file, not in the vehicle itself.
In other words, the ECM's responsibility for configuration management is therefore primarily to maintain the vehicle in the configuration adopted in the technical documentation. Only if changes are required due to identification of hazards associated with vehicle components or, for example, the unavailability of parts, the ECM's has duties to enable the keeper to initiate and manage the change. However, these duties are secondary to those of the keeper and do not change the keeper's responsibility for vehicle configuration management as established in Article 16(5) of Regulation 2018/545. Furthermore, neither the ECM nor the entity performing the maintenance function is an entity managing the change within the meaning of Regulation 2018/545 and as such it cannot be responsible for vehicle configuration management.

Conclusions

Configuration management of railway vehicles is a different obligation from configuration management of a type. Although both share a definition contained in Article 2 point (3) of Regulation 2018/545 the former is addressed at the keeper while the latter at the type authorisation holder. Moreover a type is a different concept than a railway vehicle. The term “vehicle type” should be understood only a design of a vehicle that does not cover vehicles that conform to the type themselves. Existing, material assets in the form of railway vehicles are named as such in the legal framework. This impacts the scope of the obligation. While configuration management of a type comes down to managing the changes made to the design, configuration management of a vehicle covers not only introduced changes but also maintenance activities.

The starting point of defining configuration of both a type and a vehicle is the technical file accompanying the ‘EC’ declaration of verification. This file defines all the necessary technical characteristics and establishes the first “design operating state” that is a point of reference in configuration management. It serves as a configuration reference for change management. For existing vehicles configuration management should be also performed at a higher level of detail because of the need to ensure all the maintenance activities are duly identified and processed. This is done on basis of maintenance file elaborated by an ECM.

The ECM's configuration management responsibilities do not modify the keeper's final responsibility for vehicle configuration management. ECMs task is to document and perform all the maintenance activities in a way that enables the keeper to manage the configuration of a vehicle. As ECM is not entitled to introduce any changes on the vehicle (only keep it in the design operating state as described in maintenance file) it cannot bear responsibility for configuration management of a vehicle. Reading the Regulation 2019/779 as dividing responsibility for configuration management between the ECM and a keeper would weaken the effectiveness of the legal framework.

Source materials

[1] ERA1209/063. Clarification Note on Safe Integration v1.0, European Union Agency for Railways
[2] Guide for the application of Article 14 of Directive (EU) 2016/798 and Commission Implementing Regulation (EU) No 2019/779 on a system of certification of entities in charge of maintenance for vehicles v9.0, European Union Agency for Railways
[3] IRIS Guideline 3: Maintenance, 2020 rev. 1
[4] ISO 10007 Quality management - Guidelines for configuration management

[5] ISO 22163:2023 Railway applications — Railway quality management system — ISO 9001:2015 and specific requirements for application in the railway sector standard
[6] Practical arrangements for the vehicle authorization process – Guidelines v2.1, European Union Agency for Railways
[7] RFU-STR-700. Guidance for application of type examination (CB/SB) and conformity to type based on quality management system of the production process (CD/SD) by two different applicants. NB Rail, Issue 04
[8] 2015/2887(RSP). Resolution of 9 June 2016 on the competitiveness of the European rail supply industry, European Parliament