

Type authorisation and vehicle APOM: Organisation/documentation/lessons learned

Training NSA NO, web conference, 9 October 2020

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APPLICATION DESCRIPTION

Applicant's information

Contact person's information

Authorisation case

Project name

[REDACTED]

Type of application

First authorisation

Reference to pre-engagement baseline

No

Application ID

N/A

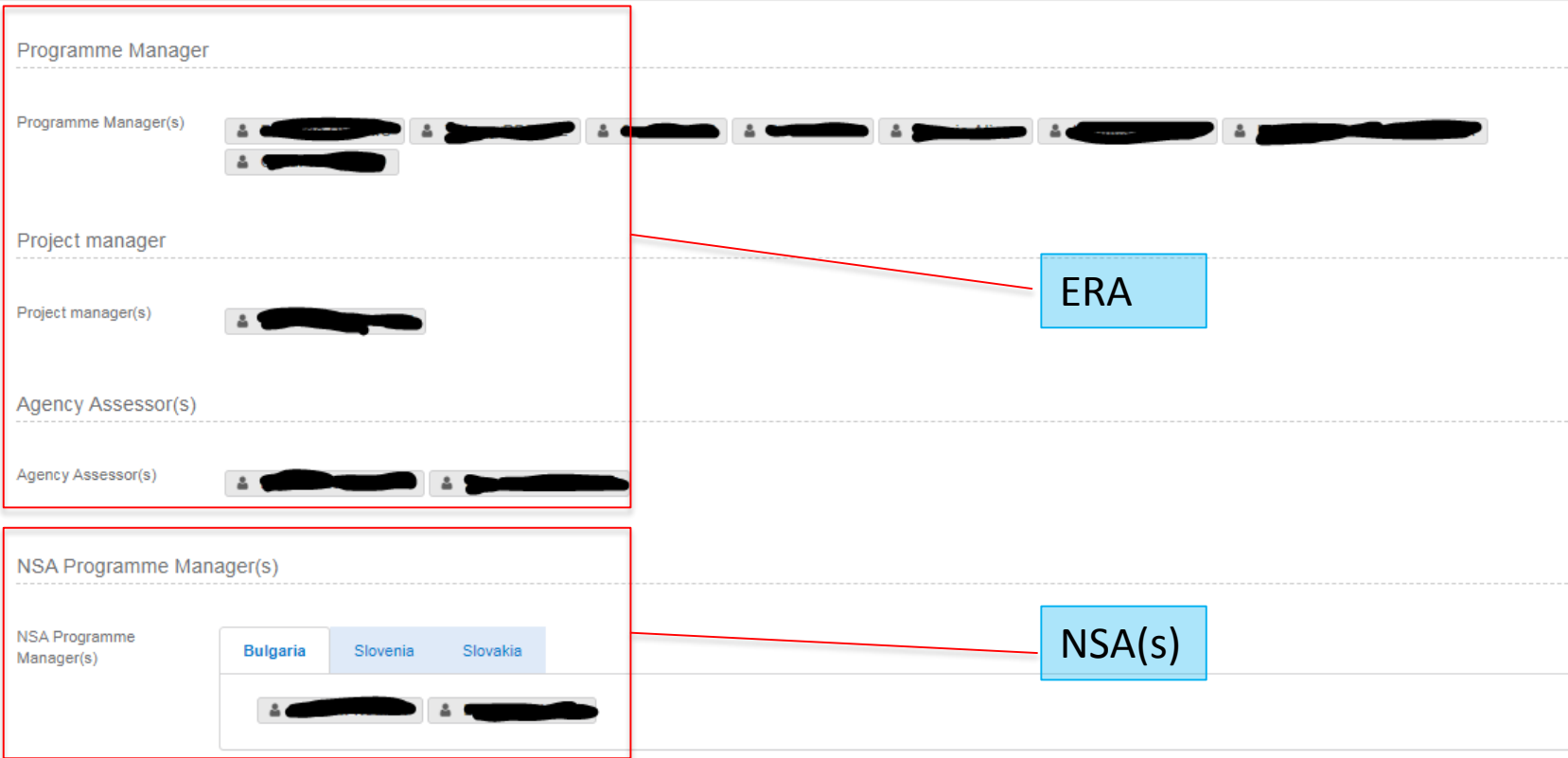
Other relevant Information

[REDACTED]

Language

English

Applicant



- **Applicant (AP)**
 - Represents a railway business for the purpose of submitting an application file for VA
 - communicating with ERA/NSAs during the assessment process
- **Program Manager (PgM)**
 - Belongs to ERA or an NSA
 - Assigns the assessment team for her/his organization
 - Monitors and coordinates the overall process of the assessment
- **Project Manager (PM)**
 - Belongs to ERA or an NSA, depending on which organisation will issue the decision
 - Defines and updates the project schedule
 - Coordinates the assessment team(s)
 - Communicates with the AP
 - Creates and updates the Recommendation (VA)
 - Closes the assessment file
 - Manages the project status in cases of arbitrations or appeals

- **Assessor (AS)**
 - Belongs to ERA or an NSA, and in addition can be a member of a PoE
 - Performs Completeness Check
 - Performs Detailed Assessment
 - Prepares assessment reports (checklists, webforms)
 - Communicates with the AP through Issue Log (formal) and phone, email, online meetings (informal)
- **Assuror (AR)**
 - Belongs to ERA or an NSA
 - Performs Quality Assurance Review
 - Prepares Conclusion Report
- **Decision Maker (DM)**
 - Belongs to ERA or an NSA, depending on which organisation will issue the decision
 - Signs off the final decision
 - Signs off the authorisation

- **Observer (OB)**
 - Belongs to ERA or an NSA
 - Has only viewing rights for the application file and all reports and artefacts created during the assessment process
- **User Manager (UM)**
 - Belongs to ERA or an NSA
 - “backstage role”
 - Creates and manages users for the organisation she/he belongs
 - Assigns system wide roles (PgM, UM, CM) to users for the organisation she/he belongs
 - Deactivates/Reactivates users for the organisation she/he belongs

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

ANNEX I

Content of the application

(M) means required information to be submitted by the applicant.

(O) means optional information that may still be submitted by the applicant.

1. **Type of application (M):**

1.1. Type authorisation

- (a) Vehicle type variants (when applicable)
- (b) Vehicle type versions (when applicable)

1.2. Authorisation for placing on the market

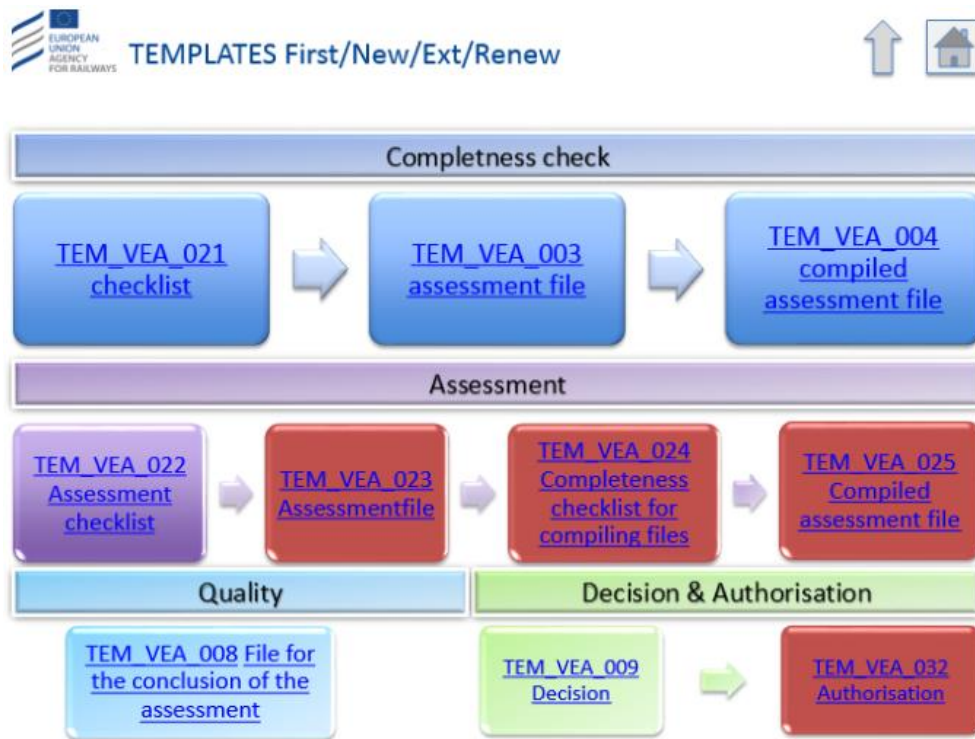
- (a) Single vehicle; or
- (b) Series of vehicles

18. **Annexes (M):**

The information that shall be included in the application is specified per authorisation case. An (x) in the column for the applicable authorisation case indicates that the information is mandatory (M) for this authorisation case.

		First authorisation	Renewed type authorisation	Extended area of use	New authorisation	Authorisation in conformity to type
18.1	The supporting evidence for the requirements capture in accordance with Article 13(1). If the applicant uses the methodology set out in Annex I of Regulation (EU) No 402/2013, the supporting evidence consists of the declaration by the proposer referred to in Article 16 of Regulation (EU) No 402/2013 and the safety assessment report referred to in Article 15 of Regulation (EU) No 402/2013.	X		X	X	

- **Templates**
 - examples see below
 - NSAs may choose to use ERA templates (but with own credentials /logo) or create their own
- **Webforms in OSS** (currently C2T only, later for all authorisation cases)



- **Supporting evidence for Requirements Capture (Art. 13 of (EU) 2018/545) missing/not complete:**
 - Two options to address requirements capture:
 - Option A: apply the methodology set out in Annex I of (EU) 402/2013 for ALL essential requirements, not just safety
 - Option B: another methodology, providing the same level of assurance as the methodology set out in Annex I of (EU) 402/2013.
 - Option A - supporting evidence: AsBo assessment report + proposer`s declaration
 - Option B - supporting evidence: documentary evidence sufficiently demonstrating that this other methodology provides the same level of assurance as the methodology set out in Annex I of (EU) 402/2013. Such evidence shall include information/ documents outlined in (EU) 2018/545 Annex II, items 6.2, 7.2 and Annex III, item 5.1. No AsBo involved.

(common shortcomings, errors, omissions in VA applications – in no particular order)

➤ Evidence for applicable regulations and rules not correctly/completely provided:

- TSI derogations acc. Art. 7 “Non-application of TSIs” in (EU) 2016/797:
from MS(NSA)/EC – provide evidence; must cover the project, time frame, type and/or vehicle(s) subject to the application for authorization
- Other applicable Union law:
Evidence required (declarations/certificates/test reports/etc.
(Typical examples: Simple pressure vessels directive (SPVD); Diesel emissions directive; Directive 2008/68/EC on the inland transport of dangerous goods in conjunction with RID (2019).

(common shortcomings, errors, omissions in VA applications – in no particular order)

➤ **Conditions for use and other restrictions not correct:**

- Coded restrictions (ERATV point 3.1.2.3): see current version of ERA document ERA/TD/2011-09/INT “List of harmonised and national restriction codes” Appendix 1
- Non-coded restrictions (ERATV point 3.1.2.4): from Assessment bodies, NSA(s), Authorising Entity

➤ **Not all mandatory information and documents provided:**

- see **Annex I of (EU) 2018/545**
- For subsystem(s) AND ICs: the **accompanying technical files** are required (not only the EC declarations and certificates – see LTT ERA1209/001)!

(common shortcomings, errors, omissions in VA applications – in no particular order)

➤ **Authorisation Case not correct:**

- While many other entries (fields) in OSS can be amended or corrected during the assessment process, the selection in the field “Type of application”, section “Authorisation case” of OSS CAN NOT!
- If the applicant selects the wrong case, the application must be terminated and a new application with the correct authorisation case submitted!

➤ **Area of use not identified correctly/completely:**

- If an area of use has several networks, they must be identified as exact as possible.
- Neighbouring border station(s), if applicable, not identified.
- “All EU” – (currently) for wagons only – TSI WAG 7.1.2. *Mutual recognition of the first authorisation of placing on the market*

(common shortcomings, errors, omissions in VA applications – in no particular order)

- **No Type ID specified for authorisation case “ First Authorisation”:**
 - Applicants are encouraged to apply for draft type ID prior to submitting the application.
 - See FAQ (for OSS) on ERA website “How to provide the information about the type for ERATV? Where can I get the TYPE ID?”

- **Translations missing:**
 - NSAs have the right to address documents pertaining to the assessment in a language of its Member State, without any obligation to translate them.
 - NSAs may request that documents (or parts of them) be translated into their Member State`s own language.

➤ **ERADIS not updated:**

- Art. 50(2) of (EU) 2018/545 requires ERADIS to be updated as appropriate before delivering a vehicle type authorisation and/or APOM.
- The applicant is to ensure that it is indeed updated by all stakeholders involved in the design, manufacturing and conformity assessments (see list of documents for ERADIS above) of the vehicle type and/or vehicle(s) subject to the application for authorisation.
- If ERADIS is not updated appropriately – Type 4 issue!
- If ERADIS is not updated appropriately by the end of the assessment and Type 4 issue still open: the “Decision” may be done by the Authorising Entity, but no “Authorisation” delivered!

Questions?



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