CRR-G-009-G
Annex 5
Requirements Capture

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1   Introduction

This Annex presents a suitable approach for an Applicant to perform requirements capture. This includes the roles and responsibilities, the legal requirements, the iterative process to identify assessable requirements from the legal requirements and the allocation of assessment activities for those requirements.

'Requirements Capture' means the process of identification, assignment, implementation and validation of requirements which must be performed by the Applicant in order to ensure that relevant Union and national requirements are complied with. Requirements capture may be integrated in the product development processes. [refer to IOD Article 2 (11)]

The approach for Authorisation for Placing in Service (APIS), of Fixed Installation railway sub-systems is presented in Figure 1.The approach for Authorisation for Placing on the Market (APOM) of Vehicle railway sub-systems is presented in Figure 2. Both figures are supported by the description in Section 2.

Decisions and outputs should be recorded. In this respect the Safety Plan (see Annex 1), Hazard Record (see Annex 2), the Safety and Compliance Matrix (see Annex 4), and the Safety Case/s (see Annex 3) should be used.

The information contained within is intended to give guidance, it cannot replace additional self-study of the applicable background documentation. The Applicant and all other applicable stakeholders should ensure that they are familiar with all applicable national and union legislation before starting the authorisation process or making changes to the railway system.

2 Process for Requirements Capture

The following paragraphs correspond to Figure 1 for APIS and Figure 2 for APOM and support the interpretation of the figures.

In Figures 1 and 2, **the outer grey box (1)** represents the entity making a Change to the railway system.

In this **grey box (1)** it is described who this entity may be and their responsibilities.

This entity is responsible for determining if an Authorisation is required.

If no authorisation is required, the process shown in Figures 1 and 2 ends. The safe implementation of the Change may continue in this case under the internal management of the entity while employing its SMS.

If an authorisation is required, the process in Figures 1 and 2 continues into the **inner blue box (2)**. The activities in that **blue box (2)** describe the requirements capture and are the responsibility of the Applicant [(EU) 2018/545 (Art 3)]. It is explained who this Applicant may be, their responsibilities and the requirements for the methodology for requirements capture process.

For Vehicles the requirements capture process shall ensure that all the necessary requirements covering the design of the vehicle for its life cycle have been:
(a) identified properly;
(b) assigned to functions or subsystems or are addressed through conditions for use or other restrictions; and
(c) implemented and validated [(EU) 2018/545 (Art 13)].

The **blue box (2)** then contains a number of further boxes within, which are linked by green arrows. The applicant's requirements capture activities should follow the succession of the arrows shown.

The requirements capture process should start with the Union and National legal requirements as shown. [IOD] [(EU) 545/2018]

Step 1: The Technical Specifications for Interoperability (TSI) and the National Rules (NR) applicable to the project under the Union and National legislation should then be identified.

Step 2: Then an iterative process should be performed to compile a list of assessable requirements based on the Union and National legal requirements. Some requirements from the TSIs and NRs will be directly assessable, but others will not.
For requirements that are not directly assessable these must be supported by further requirements

- a harmonised standard of which the reference has been published in the Official Journal of the EU (refer to (EU)1025/2012) and/or

- an alternative solution.

to generate an accessible requirement **(Step 3)**.

An alternative solution may be another standard, a code of practice or a project specific requirement determined by risk assessment.

It is important to ensure traceability between a legal requirement (TSIs, NRs) and the associated supporting further requirements.

Requirements will be taken from one or more of the following three sources: TSIs, NRs and/or other sources. The requirements will often define in detail the method of demonstration or assessment of conformity.

Step 4: After a comprehensive list of assessable requirements has been generated, they should then be grouped. Grouping of the requirements aims to avoid duplication and to streamline the conformity assessment activities.

At this time, a check should be performed by the Applicant to ensure all of the relevant Union and National legislation is fully satisfied. If there are any unsatisfied or incomplete legal requirements the process should be resumed at step 1.

Note: The use of CRR guidelines on subsystem parameters CRR-G-015, CRR-G-020, CRR-G-024, CRR-G-026 are considered as good practice for informing and structuring of the requirements capture activities.

Once **step 4** is complete all of the assessable requirements will be categorised into the three categories: TSIs, NRs and/or other sources.

- TSI sourced requirements for which Notified Body (NoBo) assessment is required,

- NR sourced requirements for which Designated Body (DeBo) assessment is required and

- all other requirements for which self-assessment is required.

Note: It is possible for an assessable requirement to fit in more than one category. In this case more than one assessment activity may be required for the same assessable requirement.

I.e. an assessable requirement may have stemmed from both a TSI requirement and a NR requirement. In this case assessment of this requirements must be covered in both the NoBo and DeBo assessment reports.

Note: It is highly recommended, that the Requirements Capture process should be integrated in the product development processes.

NoBo Assessment: A NoBo is required to perform assessment on all TSI derived Requirements.

DeBo Assessment: A DeBo is required to perform assessment on all NR derived Requirements.

AsBo Assessment: An AsBo assessment may arise in up to 4 areas. These AsBo activities may be conducted by the same AsBo but must be supported by a separate report for each of the areas:

> Area 1: If the project is significant in accordance with CSM 402/2013 an AsBo is required for evaluation of the project SMS activities (Figures 1 and 2 grey box (1));

> Area 2: Where CSM 402/2013 is used as the methodology for Requirements Capture activities within the authorisation scope of a project [(EU) 2018/545 Art 13] (Figures 1 and 2 outer blue box (2));

> Area 3: For the risk assessment activities within the authorisation scope of a project (Figures 1 and 2 blue box Step 3);

> Area 4: TSI CSM AsBo assessment actitivties (Figures 1 and 2 yellow TSI requirements box).

See CRR guidance CRR-G-009 for further details.

3   Requirements Capture Diagrams

The following two diagrams in Figures 1 and 2 should each be read in coordination with Section 2.

(1) Entity managing Changes to the railway system affecting Fixed Installations (new or existing)

The entity must be an Infrastructure Manager (IM).

The entity managing the Change is responsible for:

- Configuration management (new or existing);
- Placing in service (PIS) after the change:
    - Assessment for significance of the Change[(EU) No 402/2013];
    - If the Change is significant must use AsBo otherwise AsBo is optional [(EU) No 402/2013];
    - All changes must be managed in accordance with the IMs SMS.
- Determine if authorisation is required for the Change.

If authorisation is required see box (2).

(2) Application for APIS

The applicant is a contracting entity (public or private entity which orders the design and/or construction or the renewal or upgrading of a subsystem) or a manufacturer, or its authorised representatives [IOD].

The applicant may be the body in box (1);

The Applicant must identify the requirements applicable to the project by using the following approaches:

- The risk management process [(EU) No 402/2013] shall be used by the applicant as the methodology for requirements capture as regards the Essential Requirement 'safety' related to the Fixed Installation (effected by the Change) and safe integration of its subsystems:
- The project should consider a similar systematic methodology for the other requirements related to the Fixed Installations (effected by the Change).

The applicant shall identify and apply for the relevant authorisation.

It is recommended that the process for identification of requirements should take a similar approach to what is shown below:

> The Applicant must identify the requirements applicable to the project which are necessary to meet the Essential Requirements referred to in Annex III of the IOD covering the design for its complete life cycle including:
> a) the technical compatibility of the subsystems with the system into which they are being integrated, established on the basis of the relevant TSIs, national rules and registers;
> b) the safe integration of the subsystems, established on the basis of the relevant TSIs, national rules, and the common safety methods ('CSMs') set out in Article 6 of Directive (EU) 2016/798;
> c) in the case of trackside control-command and signalling subsystems involving European Train Control System (ETCS) and/or Global System for Mobile Communications — Railway (GSM-R) equipment, the positive decision of the Agency issued in accordance with Article 19 of this Directive; and, in the case of a change to the draft tender specifications or to the description of the envisaged technical solutions that occurred after the positive decision, the compliance with the result of the procedure referred to in Article 30(2) of Regulation (EU) 2016/796; and,
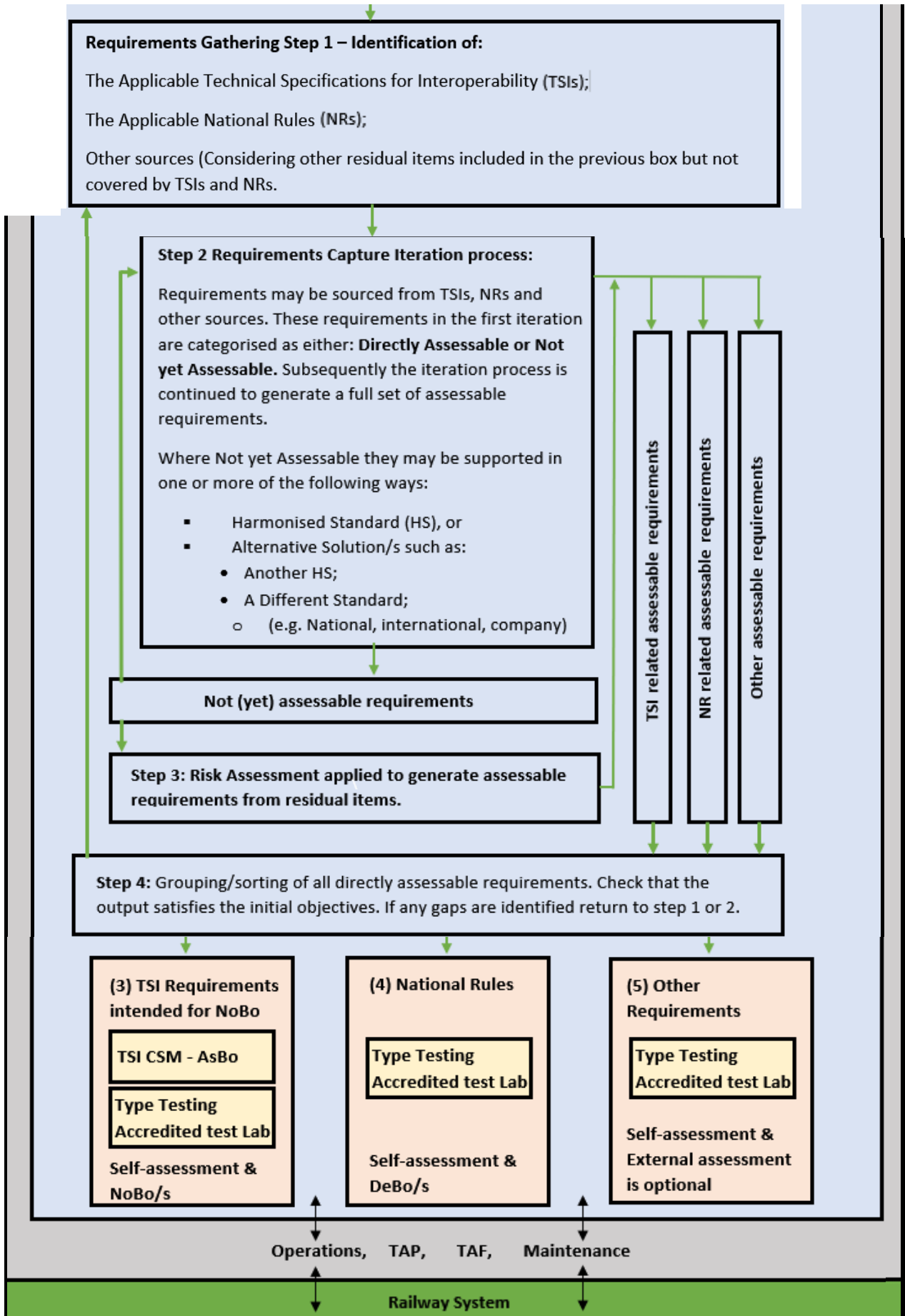> d) any other requirements which apply by Union or national legislation.

Requirements Gathering Step 1 – Identification of:

The Applicable Technical Specifications for Interoperability (TSIs);

The Applicable National Rules (NRs);

Other sources (Considering other residual items included in the previous box but not covered by TSIs and NRs.

Step 2 Requirements Capture Iteration process:

Requirements may be sourced from TSIs, NRs and other sources. These requirements in the first iteration are categorised as either: **Directly Assessable or Not yet Assessable.** Subsequently the iteration process is continued to generate a full set of assessable requirements.

Where Not yet Assessable they may be supported in one or more of the following ways:

- Harmonised Standard (HS), or
- Alternative Solution/s such as:
  - Another HS;
  - A Different Standard;
    - (e.g. National, international, company)

TSI related assessable requirements

NR related assessable requirements

Other assessable requirements

Not (yet) assessable requirements

Step 3: Risk Assessment applied to generate assessable requirements from residual items.

Step 4: Grouping/sorting of all directly assessable requirements. Check that the output satisfies the initial objectives. If any gaps are identified return to step 1 or 2.

(3) TSI Requirements intended for NoBo

TSI CSM - AsBo

Type Testing Accredited test Lab

Self-assessment & NoBo/s

(4) National Rules

Type Testing Accredited test Lab

Self-assessment & DeBo/s

(5) Other Requirements

Type Testing Accredited test Lab

Self-assessment & External assessment is optional

Operations, TAP, TAF, Maintenance

Railway System

Figure 1 Requirements Capture Diagram for Fixed Installations

(1) Entity managing Changes to the railway system affecting Vehicle(s)' (new or existing Vehicles)

The entity may be a Keeper or an RU and must perform the Change in coordination with the applicable ECM(s).

The entity managing the Change is responsible for:

- Configuration management for the Vehicle (new or existing) type, variant, and version;
- Placing in service (PIS) of the Vehicle after the Change:
    - Assessment for significance of the Change[(EU) No 402/2013];
    - If the Change is significant must use AsBo otherwise AsBo is optional [(EU) No 402/2013];
    - All Changes must be managed in accordance with the SMS and MMS.
- Determine if the change affects type, variant, and/or version and if authorisation is required.

If authorisation is required see box (2).

(2) Application for APOM

The applicant may be any natural or legal person but is typically the RU or the Manufacturer.

The applicant may be the body in box (1);

The Applicant is Responsible for the 'requirements capture' [(EU) 2018/545 (Art 3]:

- The risk management process [(EU) No 402/2013] shall be used by the applicant as the methodology for requirements capture as regards the essential requirements 'safety' related to the Vehicle and subsystems as well as safe integration between subsystems for aspects not covered by the TSIs and the national rules [(EU) 2018/545 Art. 13]. Note, in this regard an AsBo must be used.
- The same methodology including the risk management process and an AsBo may be used for the other areas or the applicant may choose to develop an alternative approach and demonstrate its equivalence.

The applicant shall identify and choose the 'relevant authorisation' for the application [(EU) 2018/545 Art. 14].

The requirements capture should take a similar approach to what is shown below:

> The requirements capture shall in particular include all the necessary requirements covering the design of the Vehicle for its complete life cycle:
> a) Essential requirements for subsystems referred to in Articles 3 and 13 of (EU) 2018/545 and specified in Annex III of the IOD;
> b) Technical compatibility of the subsystems within the Vehicle;
> c) Safe integration of the subsystems within the Vehicle;
> d) Technical compatibility of the Vehicle with the network in the area of use; and
> e) Any other requirements which apply by Union or national legislation.

> **Requirements Capture Step 1 – Identification of:**
>
> The Applicable Technical Specifications for Interoperability (TSIs);
>
> The Applicable National Rules (NRs);
>
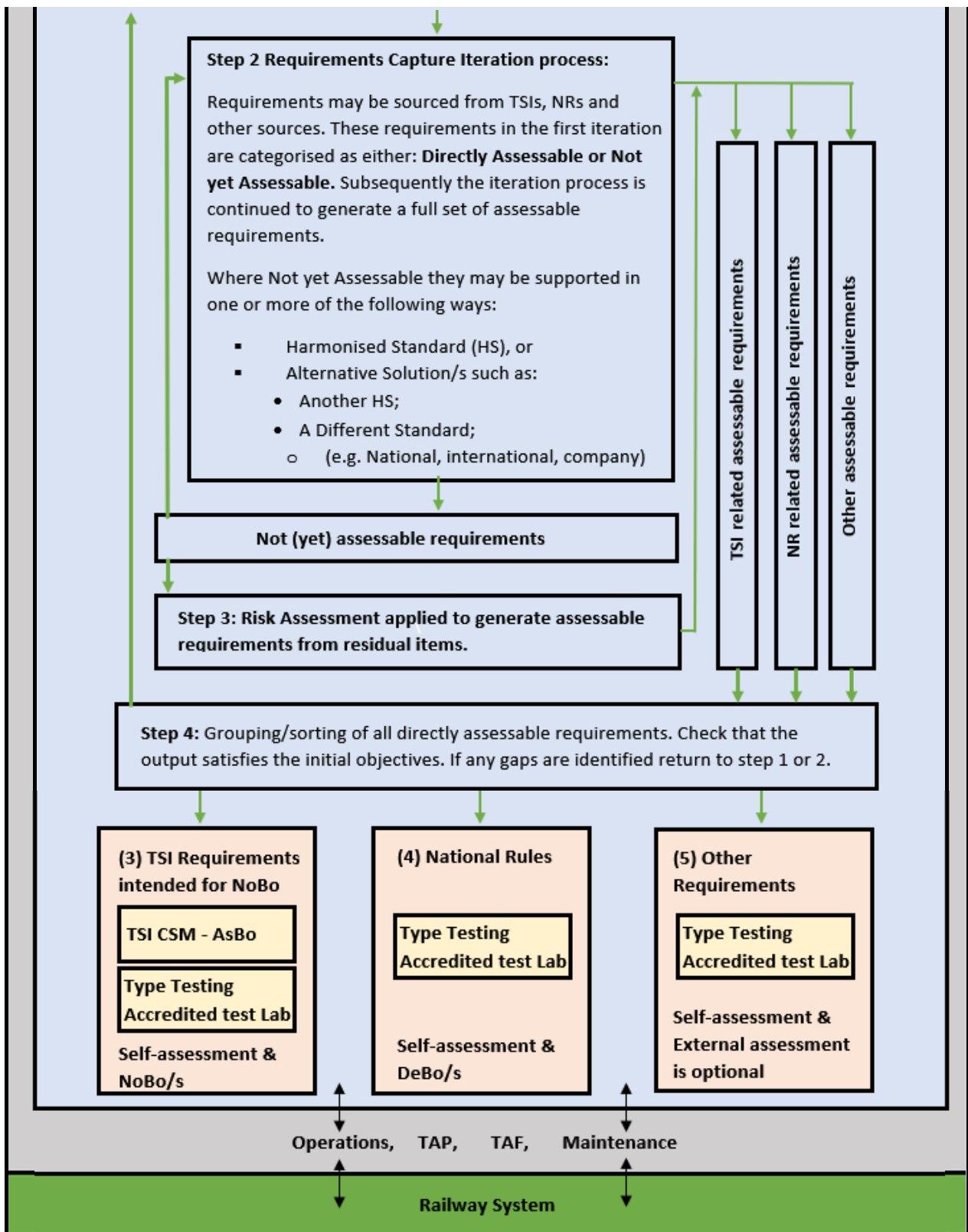> Other sources (Considering other residual items included in the previous box but not covered by TSIs and NRs.

Figure 2 Requirements Capture Diagram for Vehicles