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RECOMMENDATION FOR USE

NB-RAIL COORDINATION GROUP

Administrative Decision according to Interoperability Directive
(EU) 2016/797 art. 30.6



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RFU-STR-011

Issue 12
Date 05/07/2022

TITLE

CONTENT OF THE NOBo-FILE AND OF THE NOBo-CONFORMITY ASSESSMENT REPORT

ORIGINATOR

NB-RAIL STRATEGY SG

SUBJECT RELATED TO

(EU) 2016/797 AND ALL TSIs

AMENDMENT RECORD:

ISSUE 12: GENERAL UPDATE TO ALIGN REQUIREMENTS FOR NOBo FILE AND NOBo CONFORMITY ASSESSMENT REPORT.

DESCRIPTION AND BACKGROUND EXPLANATION

Introduction

- I. The NoBo shall perform **conformity assessment** (conformity assessment is the combination of **evaluation** and subsequent **certification**) of an **Object of Assessment** against the **Basis of Assessment**. After that conformity assessment the NoBo shall produce
 - a) **reporting** of the evaluation result (reporting on inspection & auditing) and
 - b) **certification** of the identified conformity of the **Object of Assessment** with the **Basis of Assessment**.

Note: Evaluation by a NoBo includes inspection, auditing and testing (where such testing must be performed by the NoBo or under the control of the NoBo). Test-reports however serve as evidence documents and become themselves input into inspection and/or auditing activities (and are therefore not mentioned as an output of element a)).

- II. The **certification** consists of
 - a) the **Certification Level Documents (CLDs)** and
 - b) their **Accompanying Documentation**

(as defined in RFU-STR-001).

- III. The **Accompanying Documentation** includes the
 - a) the **NoBo File** or
 - b) the **NoBo Conformity Assessment Report**.

(as defined in RFU-STR-001)

- IV. The **reporting** consists of either
 - a) individual separate reports (Inspection Report; Audit Report); or
 - b) equivalent **reporting text on inspection or audit which is embedded within the NoBo File** or **the NoBo Conformity Assessment Report**.

The reporting must in any case comply with the related requirements of the ERA-Assessment Scheme (000MRA1044 Ver 1.1 or its subsequent revisions) in combination with ISO17065.



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In relation to reporting these documents refer to the relevant requirements of ISO17020 for Inspection Reports and ISO17021 for Audit Reports.

Purpose

This RFU defines the layout and the content of NoBo-File and NoBo-Conformity Assessment Report to be established by the NoBo (aspects III a)&b) and IV b)) from the afore mentioned Introduction.

Legal context

Article 15(4) of the IOD requires that *'the applicant shall be responsible for compiling the 'Technical File' (TF) that is to accompany the 'EC' declaration of verification of a Subsystem.'*

Annex IV of the IOD describes the 'EC' Verification procedure for subsystems.

Clause 2.3.4 states that *"each notified body involved in the verification of a subsystem shall draw up a file in accordance with Article 15 (4) covering the scope of its activities."*

>>>In order to avoid confusion with the aforementioned TF, NB-Rail decided to refer to this file as the **'NoBo-File'**.

Clause 2.4 describes the Technical File accompanying the 'EC' declaration of verification. Then point 2.4(c) of Annex IV specifies the content of the NoBo-File, referring to points 2.5.2 and 2.5.3 for periodic audit and inspection reports.

Notes:

IOD(EU) 2016/797 introduces in Annex IV clause 2.3.4 the term 'file' (=NoBo-File) in replacement of the previously used term 'NoBo-Technical File' and in Annex IV clause 3.3 the term "file compiled by the designated body and accompanying the certificate of verification in the case of national rules" replacing the previously used term 'DeBo-Technical File'. The term 'file' is also employed in other parts of (EU) 2016/797 for various other dossiers.

In the past, it was the responsibility of the NoBo to establish the Technical File. In 2014 this responsibility was transferred to the applicant (by Directive 2014/106/EU). Several relevant documents (e.g. modules decision 2010/713/EU and some TSIs) are not aligned yet and still refer to a 'Technical File' to be prepared by the NoBo/DeBo, where this now is the responsibility of the applicant.

NB-Rail considers in this situation – supported by feedback received from ERA – that a parallel use of the term NoBo-Technical File and NoBo-File brings no benefit and creates confusion. It is therefore proposed to only use the modern terms 'Technical



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File' (prepared exclusively by the applicant), DeBo-File (prepared by the DeBo) and NoBo-File (prepared by the NoBo).

This RFU is only intending to define the required layout and content for the NoBo-File. Any contents of the Technical File are only listed for general understanding of the concept of Technical File and its distinction from the contents of the NoBo-File.

Any stated Technical File-content is not intended to be a complete set for reference.

One or several individual NoBo-Files form an element within the overall Technical File.

<p>TF ("Technical File accompanying the EC declaration of verification" as defined in IOD (EU) 2016/797 Annex IV)</p> <ul style="list-style-type: none"> • To be prepared by the Applicant 	<p>NoBo-File or NoBo-Conformity Assessment Report (accompanying the CLDs as defined in RFU-STR-001)</p> <p>To be prepared by the NoBo:</p>
<ul style="list-style-type: none"> • Technical Characteristics (=Design evidence documentation) • List of ICs • NoBo-File(s) (may be a collection of several NoBo-Files) ← • DeBo-File(s)-xx (xx= MS abbreviation, may be a collection of several DeBo-Files) • Certificates relating to other legislation of the Union • AsBo Safety Assessment Report(s) (on the verification of safe integration) <p><i>Note: it may be useful to also include the following information:</i></p> <ul style="list-style-type: none"> • <i>Information required for the relevant registers (e.g. ERATV/ RINF/ NVR)</i> • <i>Other information as required by IOD (EU) 2016/797</i> • <i>Other information as recommended by 2014/897/EU</i> <p>Annex to TF containing all referenced documents</p>	<ol style="list-style-type: none"> 1. Description of Task and Actors 2. Basis of Assessment 3. Object of Assessment 4. Conformity Assessment Reporting 5. Summarising Result

Approach to be used for 'NoBo-File'

An advantage of having a standardised layout of the NoBo-File is that any interested stakeholder will become able to locate information easily at the same section across any NoBo-File prepared in accordance with this RFU. The project-specific content of each section will vary according to the nature of the project, the subsystems involved and the assessment modules used.



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Approach to be used for ‘NoBo-Conformity Assessment Report’

When applying certain modules according to 2010/713/EU ‘*the certificate and its annexes shall contain **all relevant information** to allow the conformity of the subsystem/interoperability constituent with the examined type/design to be evaluated.*’

Despite the different vocabulary, the content of the information required

- a) for the NoBo-File and
- b) for the ‘annexes to the certificates’

is identical, so the same document structure as given in this RFU can and shall be used.

RFU-STR-001 defines further, that such relevant information shall have the format of a ‘NoBo Conformity Assessment Report’.

Note: Approach to be used by DeBos

In accordance with the spirit of (EU) 2016/797 whereas (60) and unless other (e.g. national) requirements apply, the DeBos are invited to use for a DeBo-File or DeBo-Conformity Assessment Report the same structure as defined in this RFU in order to achieve a systematic structure across any NoBo and DeBo activities.

General Note

Further references on the overall relevant legislative background to this RFU are contained in an annex to this RFU.

RFU PROPOSAL

NoBo-File and the NoBo-Conformity Assessment Report

The layout and content defined in this RFU are combining the minimum requirements.

Language

The language(s) used shall be Union official language(s) as agreed between the NoBo and the Applicant.

For ICs:

Note: It is no longer permitted to issue NoBo-Files for ICs.

A single NoBo-Conformity Assessment Report may be prepared, accompanying all CLDs issued by the same NoBo for the same Object of Assessment. If that Object of Assessment has been conformity assessed against several different TSI versions, this must be made clear.



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Option: It is a possible practice – but not recommended – that a single NoBo-Conformity Assessment Report may be prepared, accompanying all CLDs issued by the same NoBo for the same group of Objects of Assessment. If these Objects of Assessment have been conformity assessed against several different TSI versions, the related combinations must be made clear.

For Subsystems:

- I. A **single ‘NoBo-File’** may be prepared, accompanying all CLDs issued by the same NoBo for the same Object of Assessment as long as these CLDs include **only CLD of type 6 or 8.6.**
- II. A combined **‘NoBo-File and NoBo-Conformity Assessment Report’** may be prepared, accompanying all CLDs issued by the same NoBo for the same Object of Assessment as long as these CLDs include **at least a CLD of type 6 or 8.6.**
- III. A single **NoBo-Conformity Assessment Report** may be prepared, accompanying all CLDs issued by the same NoBo for the same Object of Assessment as long as these CLDs do **not include any CLD of type 6 or 8.6.**

Option: It is a possible practice – but not recommended - that in the text above the term ‘Objects of Assessment’ may be replaced by ‘group of Objects of Assessment’. If these Objects of Assessment have been conformity assessed against several different Basis of Assessment, the related combinations must be made clear.

Note: The following contains some typical examples:

Module SG results in CLD type 6.

- *The CLD type 6 is accompanied by a “NoBo-File” (with section 4.2 reporting on the inspection and 4.3 stating that no audit was performed and with section 5.1 indicating the CLD 6).*



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Module SH1 results in CLD type 2 + CLD type 4 + CLD type 6.

- **Option a**

All CLDs together are accompanied by a combined “NoBo-File and NoBo-Conformity Assessment Report” with

- *section 4.2 reporting on the inspection and*
- *section 4.3 reporting on the audit and*
- *section 5.1 indicating all CLDs (2+4+6).*

- **Option b**

The CLDs of type 2+4 together are accompanied by a combined “NoBo-Conformity Assessment Report” with

- *section 4.2 reporting on the inspection and*
- *section 4.3 reporting on the audit and*
- *section 5.1 indicating only CLDs 2+4*

and

the CLD type 6 is accompanied by a “NoBo-File” with

- *both, section 4.2 for inspection and section 4.3 for audit, referring to the above mentioned **NoBo-Conformity Assessment Report** and*
- *section 5.1 indicating all CLDs (2+4+6).*

- **Option c**

The CLD of type 2 is accompanied by an individual “NoBo-Conformity Assessment Report 1” with

- *section 4.2 reporting on the inspection and*
- *section 4.3 stating that the conformity assessment task to which this document relates did not include audit activities and*
- *with section 5.1 indicating only CLD 2*

and

the CLD of type 4 is accompanied by an individual “NoBo-Conformity Assessment Report 2” with

- *section 4.2 stating that the conformity assessment task to which this document relates did not include inspection activities and*
- *section 4.3 reporting on the audit and*
- *with section 5.1 indicating only CLD 2*

and

the CLD type 6 is accompanied by a “NoBo-File” with

- *section 4.2 for inspection referring to the above mentioned **NoBo-Conformity Assessment Report 1** and*



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- *section 4.3 for audit referring to the above mentioned **NoBo-Conformity Assessment Report 2** and*
- *section 5.1 indicating all CLDs (2+4+6).*

For ICs and Subsystems

No IC and Subsystem shall be certified within the same CLD and no combined NoBo-File / NoBo-Conformity Assessment Report for an IC and a Subsystem may be created.

Document Control

To ensure correct and proper document traceability and control, the NoBo-File or NoBo-Conformity Assessment Report shall have:

- A Cover Page identifying whether this is
 - NoBo-File
 - NoBo-File and NoBo-Conformity Assessment Report
 - NoBo-Conformity Assessment Report
- A Cover Page identifying the Object of Assessment to which it relates (here only as high-level description – for details see section 3);
- A Unique document ID;
- A Version Control (incl. a short description of changes in the respective versions);
- A Table of Contents;
- A list of Abbreviations used (optional)

Page Numbers in the format 'n/nn', where 'nn' is the total number of pages (to allow for quick verification of completeness).

In the event that a certain project does not need to use any particular section, this section should be retained and marked as "not used" (or similar text) to keep the section numbers identical across all NoBo-Files or NoBo-Conformity Assessment Reports.

Note: In many cases, the information under the subheadings may be provided as references to relevant documented evidence (e.g. evidence documents supplied by the Applicant to the NoBo).



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Section	Title of section	Explanation
1	Description of Task and Actors	(Heading only)
1.1	Project Task	<p>General project description.</p> <p>Description of the project task (may refer to the Applicant and the TSIs and Modules to be applied). Here this shall be a short and high-level introduction only, as all details are contained in the following sections of the document.</p> <p><i>(e.g:</i> <i>“This project covers the conformity assessment of a new vehicle design - 1st class passenger coach of MANUFACTURER - against the TSIs L&P, NOI, PRM and SRT according to the Modules SB+SD.”</i> <i>“This project covers the conformity assessment an upgrade of a section of fixed installation – installation of ETCS Level 1 on route x from A to B of INFRASTRUCTURE MANAGER - against the TSIs CCS and SRT according to the Module SG.”</i> <i>)</i></p>
1.2	Actors	(Heading only)
1.2.1	Applicant	Identification of the Applicant for certification
1.2.2	Manufacturer(s), Design Organisation(s) and significant Subcontractor(s)	<p>Each entry shall identify the name of the organisation and the address.</p> <p>Identification of the manufacturer(s) >this element is mandatory only where the production process must be evaluated according to the selected Module(s). In other cases this element is optional.</p> <p>Identification of the design organisation(s) >this element is mandatory only where the design process must be evaluated according to the selected Module(s). In other cases this element is optional.</p> <p>Identification of significant Subcontractors</p>



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		<p>>in cases where their activities have been considered by the NoBo to be of high significance for the creation of the Object of Assessment</p> <p>In case of multiple entries: >For each manufacturer / design organisation / significant sub-contractor the related scope(s) of activities and the related location(s) shall be stated.</p>
1.2.3	Notified Body	That NoBo that performed the conformity assessment and prepared this document (name, NoBo ID number, address).
2	Basis of Assessment	<p>(Heading only)</p> <p>This section summarises the set of conformity assessment requirements against which the conformity of the Object of Assessment is assessed.</p>
2.1	Applied TSIs (with project history)	<p>Identification of applied</p> <ul style="list-style-type: none"> • TSI(s) with exact reference to applied version and amendments <p>In case of TSI CCS also identification of the applied</p> <ul style="list-style-type: none"> • set of specifications. <p>To include a descriptive</p> <ul style="list-style-type: none"> • Overview of relevant aspects of the project history and any phasing of activities <p>This overview shall include all information that is relevant to explain and understand the actual application on specific versions/ amendments of the aforementioned documents, at least:</p> <ul style="list-style-type: none"> • date of application for certification <p>as relevant also:</p> <ul style="list-style-type: none"> • dates of becoming applicable of relevant new TSI versions / amendments since date of application for certification • dates & modification scope where the applicant has changed the scope of Object of



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		<p>Assessment since date of application for certification</p> <ul style="list-style-type: none"> • dates & modification scope where the applicant has changed the scope of Basis of Assessment since date of application for certification (this includes also any 'non-application' of TSIs) <p><i>Note: According to the IOD, NoBos shall normally certify to the TSI(s) which is(are) current at the time of certification (not those current at time of application!). Exceptions to this normal approach are possible under certain conditions (e.g. where transition periods apply and have been selected by the applicant).</i></p> <p><i>In particular for long lasting projects, where designing had started before a current TSI became applicable, certain relevant information of the project history (e.g. start of designing, start of production, etc.) is indispensable to explain which TSI version is used for the project and why it is used.</i></p> <p><i>This relevant information shall contain all justification why certain TSI's are not applied or are only applied in parts, or are resulting in the application of requirements, which are different from the TSI(s) which is current at the date of certification.</i></p> <p><i>It is not necessary to provide in this section a full chronologic description of the activities performed by the NoBo.</i></p>
2.2	Non-Application of TSIs	<p>Reference to documented evidence on any cases of non-application of complete TSIs or parts of TSIs, based on (EU) 2016/797, Art 7.</p> <p>Each case of non-application shall be justified by the applicant through an official document of a Member State or of the European Commission that contains the precise scope of the allowed non-application.</p> <p>If required: In a special situation the non-application can be justified by a declaration of the Applicant only stating the precise scope of an expected allowance</p>



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		<p>for non-application. In this case the NoBo shall state on the CLDs and in section 5.2 of the NoBo-File or NoBo Conformity Assessment Report under Conditions and Limits of use, that the CLDs are only valid if the full scope of expected allowance for non-application of TSIs is later received.</p> <p><i>Note: This is required as the eventually obtained allowance for non-application of TSIs might not cover the full expected extent. In that case it must be clear that the CLDs are not valid and any resulting gaps have to be assessed by a NoBo before a new CLD may be issued.</i></p>
2.3	List of applied Specific Cases	<p>Listing of those 'Specific Cases' which</p> <ul style="list-style-type: none"> • are defined in the relevant TSI(s); and • have been selected by the Applicant to be present at this project; and • were to be assessed by the NoBo. <p><i>Note: A 'Specific Case' which is not listed here has not been selected by the applicant.</i></p> <p><i>Note: Those specific cases that require application of national rules not included in the relevant TSI are in accordance with related IOD requirements expected to be assessed by the respective DeBo(s).</i></p>
2.4	List of applied Specific Environmental Conditions	<p>Listing of those 'Specific Environmental Conditions' which</p> <ul style="list-style-type: none"> • are defined in the relevant TSI(s) and • have been selected by the Applicant to be present at this project and • were to be assessed by the NoBo. <p><i>Note: A 'Specific Environmental Condition' which is not listed here has not been selected by the applicant.</i></p>



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		<p>Note: Where a TSI does not define <i>Specific Environmental Conditions</i> (e.g. TSI CCS), it should be stated:</p> <p><i>“The TSIs applied in this project (refer to section 2.1) do not contain any ‘Specific Environmental Conditions’ that may be selected by the applicant.” (or similar text)</i></p>
2.5	List of applied Optional TSI Requirements	<p>Listing of those ‘optional’ TSI Requirements which</p> <ul style="list-style-type: none"> • are defined in the relevant TSI(s) and • have been selected by the Applicant to be present at this project and • were to be assessed by the NoBo. <p>Note: This topic is strictly(!) related to those requirements which are indicated as options within the TSI text. This topic is not related to optional requirements in other documents (e.g. standards or specification documents that are not a TSI).</p> <p>Note: An ‘optional’ TSI Requirement which is not listed here has not been selected by the applicant.</p> <p>Note: Where a TSI does not define ‘optional’ TSI Requirements, it should be stated:</p> <p><i>“The TSIs applied in this project (refer to section 2.1) do not contain any ‘optional’ TSI Requirements that may be selected by the applicant.” (or similar text)</i></p>
2.6	Detailed Conformity Assessment Requirements	<p>This section shall contain the Detailed Conformity Assessment Requirements associated to the ‘TSI sections’ to be applied during conformity assessment.</p> <p>These must have been provided by the applicant to the NoBo (e.g. after the requirements capture).</p> <p>These may be provided by referring to the systematic presentation of all Detailed Conformity Assessment Requirements within section 4.2 of the NoBo-File.</p> <p>Note: Where this information is included in a pre-engagement file, then that file may be used as an</p>



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		<i>input for this section to explain which 'Detailed Conformity Assessment Requirement' (e.g. version of harmonized standards, voluntary standards, alternative solutions...) has been associated to which 'TSI section'.</i>
3	Object of Assessment	(Heading only)
3.1	Detailed Technical Description	<p>The Object of Assessment may be either:</p> <ul style="list-style-type: none"> • one or several product designs • one or several products <p>The Object of Assessment may include</p> <ul style="list-style-type: none"> • an associated Quality Management System for designing • an associated Quality Management System for production <p>As relevant/applicable, this section shall identify for the Object of Assessment:</p> <ul style="list-style-type: none"> • its status relating to <ul style="list-style-type: none"> ○ Subsystem CCO/CCT/ENE/INF/RST ○ Part of subsystem defined in TSI CCS ○ IC (as defined in the TSI) ○ New or Upgrade/Renewal • the precise product design identification, relevant properties / interfaces <i>Note: in this context the definition of levels type/variant/version for RST/CCO according to (EU) 2018/545 may be used for informative purposes, but are not sufficient as precise identification, as (EU) 2018/545 defines a further level of design differentiation below version.</i> • the precise name / serial number / ID / line location / etc. of the products • in case of application for an ISV, detailed description of the parts / stages that were to be conformity assessed • etc. <p>Individual TSIs may require also certain information to be provided by the Applicant to the NoBo and</p>



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		<p>stated here (e.g. identification that one or more 'optional functions' in TSI CCS have been employed by the applicant; identification on certain classifications of properties which relate to a specific TSI).</p>
3.2	Documented Evidence	<p>This section shall contain all documented evidence (provided by the Applicant to the NoBo) which was</p> <ul style="list-style-type: none"> • supplied to the NoBo by the Applicant, • used during the NoBo assessment activities as evidence for the conformity of the Object of Assessment with the conformity assessment requirements. <p><i>Note: For ease of traceability this may be subdivided into e.g.</i></p> <ul style="list-style-type: none"> • <i>Design documents</i> • <i>(Type-)Testing Reports to evidence design properties</i> • <i>QMS documents</i> • <i>Production related test-results</i> • <i>Evidence related to declaration and/or certification of ICs, ISVs</i> • <i>AsBo reporting</i> <p><i>Note: NoBo shall include at least references to all documented evidence used in the project. Please refer to figure "Documents flow chart" on Annex E of ERA Assessment Scheme (000MRA1044 Ver 1.1 or its subsequent revisions). The actual documentation may be attached as well (not recommended, as this is part of the Technical File which accompanies the declaration)</i></p>
4	Conformity Assessment Reporting	<p>(heading only)</p> <p><i>Note: To avoid misunderstandings the following vocabulary is recommended for use:</i></p> <p>Object of Assessment = <i>the product design(s)/ product(s) as defined on the CLDs. A fixed installation is a form of product.</i></p>



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		<p>Method of Assessment = how the Object of Assessment is conformity assessed</p> <p>Finding = in a clause-by-clause checklist, a finding is the outcome of the conformity assessment of one single clause. A finding can state conformity or otherwise.</p> <p>Result = is the summary of a group of / all findings. Depending on the status of the included findings, the result can state conformity or otherwise.</p>
4.1	Applied Conformity Assessment Method(s)	<p>Description on the applied conformity assessment method(s).</p> <p>Refer to the relevant IOD (including related amendments) and the module(s) selected by applicant from 2010/713/EU.</p> <p><i>Note: It may be stated e.g.:</i></p> <p><i>“The conformity assessment for the Object of Assessment employed the methods as defined within the Module(s) XXX of 2010/713/EU and included: (select)</i></p> <ul style="list-style-type: none"> • <i>Inspection of the Object of Assessment and its associated documented evidence</i> • <i>Auditing of the quality management system for designing of the Object of Assessment and the associated documented evidence</i> • <i>Auditing of the quality management system for production/ installation of the Object of Assessment and the associated documented evidence,</i> • <i>Certification of the Object of Assessment based on the results of the aforementioned activity(ies).</i> <p><i>The conformity assessment was performed within the context of IOD (EU) 2016/797.”</i></p>
4.2	Reporting on performed Inspections	<p>Either:</p> <ol style="list-style-type: none"> a) State: “The conformity assessment task to which this document relates did not include inspection activities.” (or similar text)



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- b) Provide the reporting text for the performed inspection activities in this section
- c) Provide a reference to separate NoBo Inspection-Report(s) which contain(s) the reporting text for the performed inspection activities
- d) Provide the reporting text for the performed inspection activities in an Annex to this NoBo-File/ NoBo-Conformity Assessment Report

Note: The NoBo may use cases b)+c)+d) at their own preference. Also, the cases b)+c)+d) may be used in combination (e.g. separate Interim Reports are referenced and the final (summary) reporting text is included in this section).

In any case, the combination of b)+c)+d) must in combination contain all NoBo inspection reporting

The inspection reporting shall include the information as required by the 'ERA – Assessment scheme' (000MRA1044 Ver 1.1), section "7.4.ISP.A Inspection methods (or its subsequent revisions), procedures and requirements". The following items shall be systematically presented (e.g. in a matrix or table or clause by clause):

- (1) The reference to those '**TSI sections**' which are related to the project scope and which are intended by the IOD/TSI for conformity assessment by the NoBo;
- (2) The '**Detailed Conformity Assessment Requirements for NoBo assessment**' related to the individual 'TSI sections' (see sub-item (1)), which have been determined by the Applicant for NoBo conformity assessment of the essential requirements in connection with the aforementioned TSI sections;
- (3) The references to those **evidence documents** which have been determined by the Applicant and have actually been used by the NoBo in the conformity assessment against the individual 'TSI sections' (see sub-



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item (1)) and the 'detailed conformity assessment requirements for NoBo-assessment' (see sub-item (2));

(4) The NoBo conformity assessment findings, relating to the aforementioned 'TSI sections', (see sub-item (1)), which shall be either:

- **compliant** (where the NoBo has found this as result of the own conformity assessment requirements);

Where applicable this may be:

- i. **compliant via IC** (where the Applicant has supplied IC Declarations for certain TSI sections or parts of them);
 - ii. **compliant via ISV** (where the Applicant has supplied ISVs for certain TSI sections or parts of them) (may as applicable be standing alone or in combination with 'compliant');
- **not compliant or partially compliant** (where this is present, no EC Certificate/QMS Approval may be issued, only an ISV may be issued for the compliant parts);
 - **not applicable by design** (e.g. TSI sections on tunnel where the assessed line has no tunnel);
 - **non-application of TSI** (where the applicant has informed the NoBo on this – see section 4.4 of NoBo-File).

Notes:

Compliant, compliant via IC, compliant via ISV may, as applicable in a given project, be used alone or in a combination.

Compliant, compliant via IC, compliant via ISV may, in a given project, be dependent on the application of certain conditions and limits of use.



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		<p>For ISVs:</p> <p>If only certain</p> <ul style="list-style-type: none"> • stages of the development and production process • parts of the Object of Assessment <p>have been conformity assessed, then this shall be clearly stated.</p> <p>Optional: A NoBo may additionally state for added clarity which TSI sections / parts of TSI sections / phases have not been assessed or which sections are not (yet) compliant.</p>
<p>4.3</p>	<p>Reporting on performed Auditing</p>	<p>Either:</p> <ol style="list-style-type: none"> a) State: “The conformity assessment task to which this document relates did not include audit activities.” (or similar text) b) Provide the reporting text for the performed audit activities in this section c) Provide a reference to separate NoBo Audit-Report(s) which contain(s) the reporting text for the performed audit activities d) Provide the reporting text for the performed audit activities in an Annex to this NoBo-File / NoBo-Conformity Assessment Report <p><i>Note: The NoBo may use cases b)+c)+d) at their own preference. Also, the cases b)+c)+d) may be used in combination (e.g. separate Interim Reports are referenced and the final (summary) reporting text is included in this section.</i></p> <p><i>In any case, the combination of b)+c)+d) must in combination contain all NoBo audit reporting</i></p> <p>The audit reporting shall include the information as required by the ‘ERA – Assessment scheme’ (000MRA1044 Ver 1.1 or its subsequent revisions) in conjunction with ISO17021-1 and the Modules selected by the applicant from 2010/713/EC.</p>



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		<p>For ISV:</p> <p>If only certain stages / phases have been conformity assessed, then this shall be clearly stated.</p> <p>Optional: A NoBo may additionally state for added clarity which TSI sections / parts of TSI sections / phases have not been assessed or which sections are not (yet) compliant.</p>
5	Summarising Result	<p>Summary of the results of the evaluation of section 4.</p> <p><i>Note: It may be stated e.g.:</i></p> <p><i>The Object of Assessment (refer to section 3) has been assessed in relation to its conformity with the TSI(s) and the associated detailed conformity assessment requirements (as determined by the Applicant, refer to section 4).</i></p> <p><i>Based on the conformity assessment findings indicated in section 4, the NoBo's evaluation team has recommended to the NoBo's certification team to issue the CLD(s) indicated in section 5.1.</i></p> <p><i>In this context the Conditions and Limits of use as indicated in section 5.2 and the ISV-related project stages / parts of the Object of Assessment as indicated in section 4 shall be considered.</i></p>
5.1	Notified Body Certification Level Documents	<p>This section shall contain</p> <ul style="list-style-type: none"> – copies (without the attached documentation as defined in RFU-STR-001), or – references to all CLDs issued by the NoBo for this project.
5.2	Conditions and Limits of use	<p>This section shall contain Conditions and Limits of use or precise references to separate documents containing Conditions and Limits of use.</p> <p>According to IOD the Conditions and Limits of use shall have been declared by the Applicant to the NoBo.</p> <p>If necessary, the NoBo must state also any further Conditions and Limits of use, if these were identified during the conformity assessment.</p>



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Individual TSIs may require specific information on Conditions and Limits of use to be provided by the Applicant (e.g. the Applicant's choice from a range of environmental parameters permitted by a TSI).

Also those Conditions and Limits of use resulting from the application of 'specific cases' or 'specific environmental conditions' – where used in a project and where these were to be assessed by the NoBo - shall be stated.

Note 1: When respecting these Conditions and Limits of use full compliance with all relevant TSI requirements must be reached. This section shall not be misused for statement of any Conditions and Limits of use where a relevant TSI requirement is not fulfilled (e.g.: "operation is limited to networks, where compliance with the TSI evacuation requirements is not necessary").

Note 2: The Conditions and Limits of use as included in the detailed conformity assessment requirements for the NoBo may overlap with required information relevant for the 'area of use' compatibility evaluation of a vehicle as defined by IOD. No other information, which may become necessary for the area of use compatibility evaluation of a vehicle, is provided by the NoBo in this section of the NoBo-File.

Note 3: For vehicle authorisation this section shall contain also the information related to the requirements of Art. 21 10(d) of IOD (EU) 2016/797

Note 4: The evaluation of data for registers (e.g. RINF, NVR, ERATV) is not a task which is assigned to a NoBo by the IOD or the TSIs and shall not be contained in the NoBo-File or NoBo-Conformity Assessment Report (even if performed by the same legal entity as a separate and unrelated activity to the NoBo tasks).



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THIS RFU WAS AGREED ON

PLENARY MEETING 65 – 23/06/2022

THIS RFU ENTERS INTO FORCE ON

05/07/2022 (DATE OF PUBLICATION)

FROM THIS DATE ON THIS RFU CAN BE APPLIED INSTEAD OF THE PREVIOUS MANDATORY VERSION.

RFU APPLICATION IS MANDATORY STARTING FROM

31/01/2023

AT THIS DATE ANY PREVIOUS VERSIONS OF THIS RFU WILL BE WITHDRAWN.

RFUs SHALL BE APPLIED BY ALL NOBOS. PLEASE REFER TO RFU-STR-702, CHAPTER 3 OF THE SECTION "DESCRIPTION AND BACKGROUND EXPLANATION", FOR THE LEGAL BASIS SUPPORTING THIS OBLIGATION.

ERA COMMENTS

PLE 65 – No COMMENTS



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ANNEX 1

The lists below provide an overview of the legal framework dealing with the topic of NoBo-File and how this is distinguished from the TF.

These lists are intended for the general information of Applicants and NoBos and are not intended to be complete.

I. Requirements for Content of NoBo-File:

2016/797 2(31)	'design operating state' means 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;	>Requirement for NoBo-File section 5.2
2016/797 Annex IV clause 2.3.4	Each notified body involved in the verification of a subsystem shall draw up a file in accordance with Article 15 (4) covering the scope of its activities.	>General Requirement for NoBo-File. All content of the NoBo-File shall be limited to the relevant TSIs and the verifications the NoBo has carried out.
2016/797 Annex IV point 2.4(c)	the files referred to in Article 15(4), compiled by each of the notified bodies involved in the verification of the subsystem, which shall include:	Introduction
2016/797 Annex IV clause 2.4(c)-1.1	copies of the 'EC' declarations of verification [= conformity] and, where applicable, 'EC' declarations of suitability for use established for interoperability constituents referred to in point (d) of Article 4(3)	>Requirement for NoBo-File section 5.1
2016/797 Annex IV clause 2.4(c)-1.2	and accompanied, where appropriate [=as defined in the TSIs] the corresponding calculation notes and a copy of the records of the tests and examinations carried out by the notified bodies on the basis of the common technical specifications,	>Requirement for NoBo-File section 4.2
2016/797 Annex IV clause 2.4(c)-2.1	where available, the [relevant] ISV[s] that accompany the [Subsystem's] certificate of verification,	>Requirement for NoBo-File section 3.2
2016/797 Annex IV clause 2.4(c)-2.2	Including the result of verification by the notified body of the ISV[s] validity [=Is/are the ISV(s) presented actually valid and applicable for this subsystem?]	>Requirement for NoBo-File section 3.2 with 4.2
2016/797 Annex IV clause 2.4(c)-3.1	the certificate of verification, accompanied by corresponding calculation notes and signed by the notified body responsible for the verification, stating that the subsystem complies with the requirements of the relevant TSI(s) and mentioning any reservations recorded during performance of the activities and not withdrawn;	>Requirement for NoBo-File section 5.2. 'CLDs according to RFU-STR-001 will satisfy this.
2016/797 Annex IV clause 2.4(c)-3.2	<i>corresponding calculation notes</i> [accompanying the EC Certificate of Verification]	>Requirement for NoBo-File section 4.2
2016/797 Annex IV clause 2.4(c)-3.3	the certificate of verification should also be accompanied by the inspection and audit reports drawn up by the same body in connection with its task, as specified in points 2.5.2 and 2.5.3;	>Requirement for NoBo-File section 4.2. It is considered that this relates only to those periodic audits/ unexpected



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		visits performed up to the date of issuing the CLDs identified in section 5.2.
2016/797 Annex IV clause 2.8	The files and correspondence relating to the 'EC' verification procedure must be written in a Union official language of the Member State in which the applicant is established or in a Union official language accepted by the applicant.	>General Requirement for the NoBo-File
2018/545 Art.15(2)	(3) '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: (b)changes are controlled and documented either in the technical files or in the file accompanying the issued authorisation;	>This is a requirement for the Applicant. It must be considered together with the additional requirements of Art 15 and Art 16. The Applicant may demand in this context the NoBo to perform additional conformity assessment activities and (if possible based on the results) the NoBo may update the NoBo-File or NoBo-Conformity Assessment Report (new Version) >General Requirement for NoBo-File. Depending on the individual scope of a change, this may establish requirements for an update of any section of the NoBo-File or NoBo-Conformity Assessment Report.
2018/545 Art.15(2)	When a change falls under point (b) or (c) of paragraph 1, the technical files accompanying the EC declarations for verification for the subsystems shall be updated and the holder of the vehicle type authorisation shall keep available the relevant information upon request of the authorising entity and/or the NSAs for the area of use. Note: (b) = a change that introduces a deviation from the technical files accompanying the EC declarations for verification for the subsystems which may require new checks and therefore require verification according to the applicable conformity assessment modules but which do not have any impact on the basic design characteristics of the vehicle type and do not require a new authorisation according to the criteria set out in Article 21(12) of Directive (EU) 2016/797; (c) = a change in the basic design characteristics of the vehicle type that does not require a new authorisation according to the criteria set out in Article 21(12) of Directive (EU) 2016/797;	>It is a requirement for the Applicant to determine, if a change of type (b) actually requires new conformity assessment according to the applicable modules by a NoBo. Based on this determination the Applicant may require to order conformity assessment work from a NoBo (or DeBo). Upon performing this work, the NoBo (DeBo) will provide EC Certification and a related NoBo-File or NoBo-Conformity Assessment Report for the scope of the conformity assessment [=limited to the change]. Where the NoBo is the same NoBo that has previously issued EC Certification for



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		<p>the vehicle type prior to the change, the NoBo may alternative create revised EC Certification (new CLD number) and a revised NoBo-File or NoBo-Conformity Assessment Report (new version).</p> <p>>General Requirement for NoBo-File. Depending on the individual scope of a change, this may establish requirements for an update of any section of the NoBo-File or NoBo-Conformity Assessment Report.</p>
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II. Requirements for Files other than the NoBo-File

2014/897/EU 2(m)	'technical file accompanying the "EC" declaration of verification' means the combination of all files and documentation gathered by the applicant as required by all applicable EU legislation for a subsystem.	>This is a requirement for the Applicant.
2014/897/EU 11	(Vehicles) technical characteristics of the vehicles' design operating state , including limits and conditions of use and indicate the network(s) of the Member State(s) for which the vehicles of that type are authorised . The technical characteristics referred to in the authorisation should be: — declared by the manufacturers or contracting entities, in their role as applicant for authorisation of the vehicle or vehicle type, — verified and certified by the assessment bodies, and — documented in the technical file accompanying the EC declaration of verification .	>This is a requirement for the Applicant.
2014/897/EU 23	(fixed installation Subsystem) fixed installation subsystems should refer to its technical characteristics, including limits and conditions of use . The technical characteristics referred to in the authorisation for placing in service should be: — declared by the applicant, — verified and certified by the assessment bodies, and — documented in the technical file accompanying the EC declaration of verification .	>This is a requirement for the Applicant.
2014/897/EU 40	(VEHICLES) points (a), (b), and (c) of recommendation 39 ((a) safe integration between the elements composing a subsystem; (b) safe integration between subsystems that constitute a vehicle or a network project; and, for vehicles: (c) safe integration of a vehicle with the network characteristics;) should be carried out before authorisation for placing in service. Any condition and limits of use derived from them (e.g. any limitations for train composition including operation in multiple units or operation of the locomotives together with the vehicles forming the train) should be stated in the technical file accompanying the EC declaration of verification referred to in Article 18(3) of Directive 2008/57/EC in such a way that the user of the authorised subsystem or vehicle can apply these conditions and limits of use according to its SMS,	>This is a requirement for the Applicant.
2014/897/EU 40bis	(fixed installation Subsystems/ Network Projects) points (a), (b), (f) and (g) (a) safe integration between the elements composing a subsystem; (b) safe integration between subsystems that constitute a vehicle or a network project; (f) safe integration of a network project with the vehicle characteristics defined in TSIs and national rules; (g) safe integration with adjacent parts of the network (line sections);) of recommendation 39 should be carried out before authorisation for placing in service. Any condition and limits of use derived from them should be stated in the technical file accompanying the EC declaration of verification referred to in Article 18(3) of Directive 2008/57/EC in such a way that the user of the authorised subsystem or network project can apply these conditions and limits of use according to its SMS,	>This is a requirement for the Applicant.



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2014/897/EU 90-1	According to Article 18 and Annex VI to Directive 2008/57/EC, an 'EC' declaration of verification for a subsystem should be accompanied by a technical file	>This is a requirement for the Applicant.
2014/897/EU 90-2	including the documentation describing the subsystem,	>This is a requirement for the Applicant.
2014/897/EU 90-3	the documentation resulting from the verifications carried out by different assessment bodies	>This is a requirement for the Applicant.
2014/897/EU 90-4	and the documentation of the elements relating to the conditions and limits of use	>This is a requirement for the Applicant.
2014/897/EU 90-5	and to the instructions concerning servicing, constant or routine monitoring, adjustment and maintenance.	>This is a requirement for the Applicant.
2014/897/EU 90-6	the technical file accompanying the EC declaration of verification includes all supporting documents needed for the authorisation for placing in service.	>This is a requirement for the Applicant.
2014/897/EU 99	Each manufacturer, maintenance supplier, wagon keeper, service provider and procurement entity must ensure that rolling stock, installations, accessories and equipment and services supplied by them comply with the essential requirements and that the conditions for use are specified in the technical file accompanying the EC declaration of verification so that they can be safely put into operation by the railway undertaking and/or infrastructure manager.	>It is a requirement for the Applicant to agree these aspects with the relevant stakeholders.
2016/797 2(31)	design operating state' means 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 ;	>This is a requirement for the Applicant.
2016/797 15(4)	The applicant shall be responsible for compiling the technical file that is to accompany the 'EC' declaration of verification. That technical file shall contain all the necessary documents relating to the characteristics of the subsystem and, where appropriate, all the documents certifying conformity of the interoperability constituents . It shall also contain all the elements relating to the conditions and limits of use and to the instructions concerning servicing, constant or routine monitoring, adjustment and maintenance .	>This is a requirement for the Applicant.
2016/797 15(9)	The Commission may specify, by means of implementing acts: [...] (b) the templates for the 'EC' declaration of verification, including in the case of a modification of the subsystem or in the case of additional verifications, the intermediate statement of verification, and templates for documents of the technical file that is to accompany those declarations as well as templates for the certificate of verification.	>This is a requirement for the Applicant.
2016/797 Annex IV.2.4(a)	The technical file accompanying the 'EC' declaration of verification shall be assembled by the applicant and must contain the following: (a) technical characteristics linked to the design including general and detailed drawings with respect to execution, electrical and hydraulic diagrams, control-circuit diagrams, description of data-processing and automatic systems to the level of detail sufficient for documenting the verification of conformity carried out, documentation on operation and maintenance, etc., relevant for the subsystem concerned;	>This is a requirement for the Applicant.
2016/797 Annex IV.2.4(b)	The technical file accompanying the 'EC' declaration of verification shall be assembled by the applicant and must contain the	>This is a requirement for the Applicant.



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	following: (b) a list of interoperability constituents, referred to in point (d) of Article 4(3), incorporated into the subsystem;	
2016/797 Annex IV.2.4(c)	The technical file accompanying the 'EC' declaration of verification shall be assembled by the applicant and must contain the following: (c) the files referred to in Article 15(4), compiled by each of the notified bodies involved in the verification of the subsystem, which shall include: — copies of the 'EC' declarations of verification and, where applicable, 'EC' declarations of suitability for use established for interoperability constituents referred to in point (d) of Article 4(3) and accompanied, where appropriate, by the corresponding calculation notes and a copy of the records of the tests and examinations carried out by the notified bodies on the basis of the common technical specifications, — where available, the ISV that accompany the certificate of verification, including the result of verification by the notified body of the ISV validity, — the certificate of verification, accompanied by corresponding calculation notes and signed by the notified body responsible for the verification, stating that the subsystem complies with the requirements of the relevant TSI(s) and mentioning any reservations recorded during performance of the activities and not withdrawn; the certificate of verification should also be accompanied by the inspection and audit reports drawn up by the same body in connection with its task, as specified in points 2.5.2 and 2.5.3;	>This is a requirement for the Applicant.
2016/797 Annex IV.2.4(d)	The technical file accompanying the 'EC' declaration of verification shall be assembled by the applicant and must contain the following: (d) certificates of verification issued in accordance with other legal acts of the Union;	>This is a requirement for the Applicant.
2016/797 Annex IV.2.4(e)	The technical file accompanying the 'EC' declaration of verification shall be assembled by the applicant and must contain the following: (e) when verification of safe integration is required pursuant to in point (c) of Article 18(4) and in point (c) of Article 21(3), the relevant technical file shall include the assessors' report(s) on the CSMs on risk assessment referred to in Article 6(3) of Directive 2004/49/EC.	>This is a requirement for the Applicant.
2016/797 Annex IV.2.6	A copy of the technical file accompanying the 'EC' declaration of verification must be kept by the applicant) throughout the service life of the subsystem. It must be sent to any Member State or the Agency, upon request.	>This is a requirement for the Applicant.
2016/797 Annex IV.2.8	Language The files and correspondence relating to the 'EC' verification procedure must be written in a Union official language of the Member State in which the applicant is established or in a Union official language accepted by the applicant	>It is a requirement for the Applicant to agree on the primary and any secondary languages/ translations with the ERA and/or NSA(s) as applicable. >The NoBo may accept and will prepare documents in any languages they have contractually agreed upon with the Applicant.
2016/797 Annex IV.3.3	The file compiled by the designated body and accompanying the certificate of verification in the case of national rules must be	>This is a requirement for the Applicant.



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	included in the technical file accompanying the 'EC' declaration of verification referred to in point 2.4 and shall contain the technical data relevant for the assessment of the conformity of the subsystem with those national rules.	
2018/545 Art.15(2)	(3) '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: (b)changes are controlled and documented either in the technical files or in the file accompanying the issued authorisation;	>This is a requirement for the Applicant. It must be considered together with the additional requirements of Art15 and Art 16. This may require the Applicant to update the ECDV-TF.
2018/545 Art.15(2)	When a change falls under point (b) or (c) of paragraph 1, the technical files accompanying the EC declarations for verification for the subsystems shall be updated and the holder of the vehicle type authorisation shall keep available the relevant information upon request of the authorising entity and/or the NSAs for the area of use. Note: (b) = a change that introduces a deviation from the technical files accompanying the EC declarations for verification for the subsystems which may require new checks and therefore require verification according to the applicable conformity assessment modules but which do not have any impact on the basic design characteristics of the vehicle type and do not require a new authorisation according to the criteria set out in Article 21(12) of Directive (EU) 2016/797; (c) = a change in the basic design characteristics of the vehicle type that does not require a new authorisation according to the criteria set out in Article 21(12) of Directive (EU) 2016/797;	>This is a requirement for the Applicant.
2018/545 Art16(4.c)	If the entity managing changes categorised in accordance with Article 15(1)(b) and (c) to an already authorised vehicle is not the vehicle type authorisation holder it shall: (a) assess the deviations from the technical files accompanying the EC declarations for verification for the subsystems (c) update the technical files accompanying the EC declarations for verification for the subsystems;	>Requirement for the entity managing changes of types (b) and (c).
2018/545 Art28(a)	The applicant for a vehicle type authorisation and/or a vehicle authorisation for placing on the market shall establish the evidence for the application by: (a) putting together the EC declarations of verification for the subsystems composing the vehicle and providing the evidence, in the technical file accompanying the EC declarations, of the conclusions of the conformity assessments done following the identification carried out pursuant to Article 21;	>This is a requirement for the Applicant.