Supported by NB-Rail Association

RECOMMENDATION FOR USE

NB-RAIL COORDINATION GROUP

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

Co-funded by the European Union

RFU-STR-001	Issue 18 Date 09/11/2022

TITLE	
EC CERTIFICATES / QMS-APPROVALS / ISVS	
ORIGINATOR	**SUBJECT RELATED TO**
NB-RAIL SUB-GROUP STRATEGY	DIRECTIVE (EU) 2016/797 REGULATION (EU) 2019/250 DECISION 768/2008/EC

AMENDMENT RECORD:

ISSUE 16: USE OF THE TERM "ACCOMPANYING DOCUMENTATION" AND OTHER EDITORIAL IMPROVEMENTS

ISSUE 17: NANDO NUMBER IS ONLY FOR NOBO ACTIVITIES

ISSUE 18: CERTIFICATE TEMPLATES: CORRECTION OF REFERENCES TO NOBO-FILE SECTIONS, AMENDMENTS TO VALIDITY CONDITIONS.

DESCRIPTION AND BACKGROUND EXPLANATION

Harmonisation of the 'Certification level documents' (CLDs) issued by NoBos

CLDs issued by NoBos are:

- EC Certificates
- QMS-Approvals
- Intermediate Statements of Verification (ISVs)

The EU legislative documents 768/2008/EC, (EU) 2016/797, (EU) 2019/250 and 2010/713/EU establish a number of requirements on the content of CLDs. All these requirements have been taken into account and compiled in Annex 1 of this RFU. In Annexes 2 to 6 the minimum content (as well as a proposed layout) of the CLDs and their Annex are provided, taking into account all the provisions laid down in the legislative documents listed above

Note: in accordance with the spirit of (EU) 2016/797 whereas (64) and (EU) 2019/250 whereas (3) and (12): unless other (e.g. national) requirements apply, the DeBos are invited to use for their CLDs the same minimum content and proposed layout.

In any case 'EC' applies to those CLDs issued by a NoBo regarding solely the verification of conformity with relevant TSI and it is not possible for a NoBo to issue an 'EC' CLDs covering both Notified Body and Designated Body tasks, even if it is the same conformity assessment body to carry out the entire process of verification. NoBo CLDs and DeBo CLDs shall be issued as separated documents.

Furthermore, this RFU regulates the CLD ID and Version counter to be used by Notified Bodies. The combination of the CLD ID and the Version counter is the unique 'identification number' ensuring traceability of the CLD in accordance with (EU) 2019/250.

The EU legislative documents (EU) 2016/797 Annex IV (2.7) require NoBos to periodically publish relevant information on issued or refused CLDs in ERADIS. The responsibility for the population of ERADIS is defined in the "Line to take" of ERA document no ERA1209/003 V1.1.

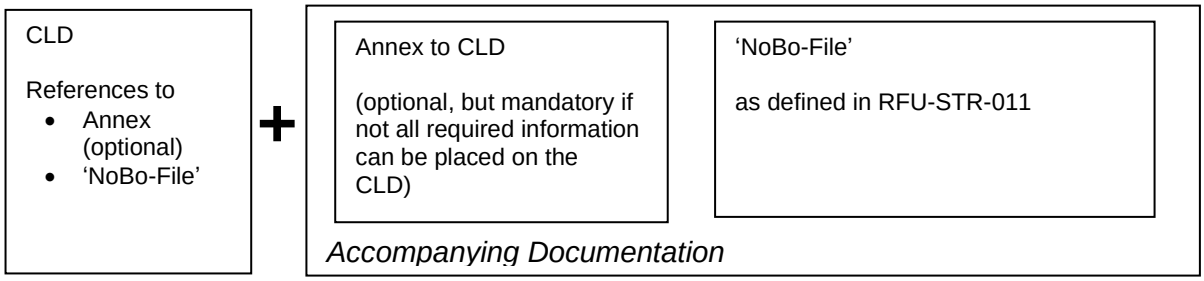
RFU PROPOSAL

A – Content of CLD and their Accompanying Documentation

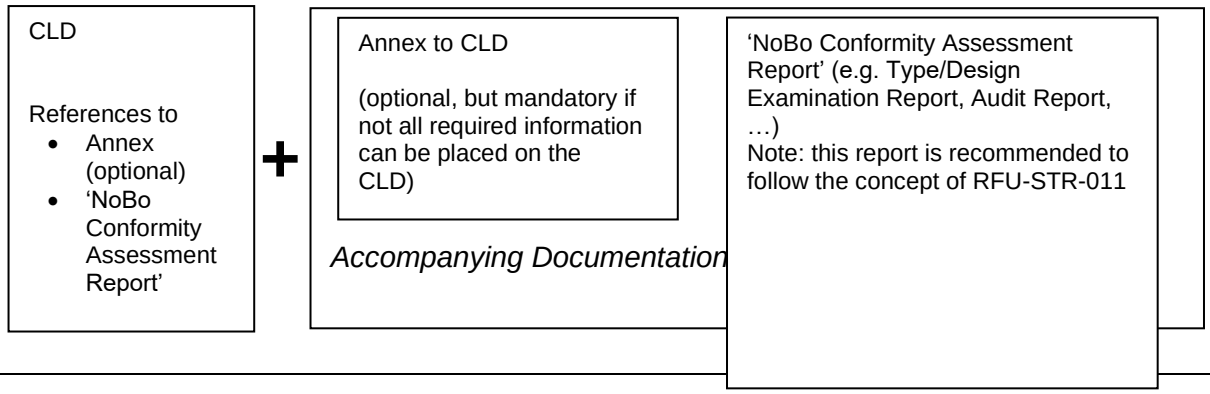
Due to the broad range of possible certification activities, NB-Rail cannot propose to fully standardise the content of the CLDs and their Accompanying Documentation. However, at least the following information shall be contained as minimum content on the CLD and their Accompanying Documentation.

A.1 General Overview

CLD of types 6 and 8.6 (for type numbers explanation see section C of this RFU) for Subsystems



Other CLDs



The use of the Annex to the CLD is optional. It is only required, if the related information could not be included on the cover page of the CLD.

It is highly recommended to apply the requirements on content of NoBo-File defined by RFU-STR-011 in a similar manner to the content of the 'NoBo-Conformity Assessment Report'. In the following only the term NoBo-File is used.

It was noted that current legislation requires CLDs to be part of the NoBo-File as well as the Accompanying Documentation (which contains the NoBo-File) to be attached to the CLDs. To solve this circular reference, we propose that CLDs of type 6 and 8.6 shall have a NoBo-File (or an addendum and reference to an existing NoBo-File) attached to it. If a certificate is updated it will require at least section 2 of the NoBo-File to be updated.

Only the Content on the CLD Templates in the Annex to this RFU is binding as minimum content. The Format and Layout are presented only to propose and encourage a common layout to be used in order that CLDs across Europe might appear similar and contain the same information in the same places. The precise layout and any additional information given on the CLD, including any legal attestations, is the responsibility of the issuing Notified Body.

CABs are not allowed to use NoBo number (NANDO code) for other activities than NoBo activities (such as DeBo, AsBo, ECM-CB, etc.).

A.1.1 Concept of "Conditions and Limits of Use":

This terminology has been introduced with (EU) 2016/797 and replaces various similar terms (e.g. compatibility, restrictions, constraints) which have been used in 2010/713/EU and several TSIs to represent the same concept.

"Conditions and Limits of Use" define any information necessary to enable and ensure the intended use of a constituent or a subsystem in its surrounding only related to the fulfilment of the TSI requirements (related to the intended Placing in Service/Placing on the market). This information can e.g. be pre-defined minimum or maximum values, definitions of technical scope, technical interfaces or operational and maintenance requirements.

A limitation is a special kind of condition and both can be included under the same headline and no distinction between limitations and conditions is necessary or useful.

Conditions and Limits of Use may typically be a combination of those which were pre-defined by the applicant and those which resulted from the conformity assessment process.

Conditions and Limits of Use shall never be abused if the object of assessment does not comply with the relevant TSI requirements. This situation represents a nonconformity, in this case only an ISV can be issued to those remaining parts, which are conform.

NOTE: TSI CCS 2012/88/EU as amended and (EU) 2016/919 as amended follow a different approach described in Chapter 6.4 "Provisions in case of a partial fulfilment of TSI requirements". See also RFU-CCS-077.

The correction of nonconformities to TSI requirements shall be carried out by the applicant until conformity is reached (unless a non-application of TSI in accordance with Article 7 of Directive (EU) 2016/797 has been granted and demonstrated to the NoBo).

A.2 Information to be provided on the CLD and Accompanying Documentation:

Based on the requirements listed in Annex 1 of this RFU, the following information shall be included on the CLD and in the Accompanying Documentation [Text in square brackets indicates the requirements covered].

The Accompanying Documentation shall always be regarded as part of and delivered together with the CLD.

A.2.1 CLDs

1. **Type** and '**identification number'** of the CLD (see below Section C and D) [R25] The combination of the CLD ID and the Version counter is the unique 'identification number' ensuring traceability of the CLD in accordance with (EU) 2019/250.
2. Scope of Certification by reference to the **Certification Scheme** (). [R3.a,R34]
3. Scope of Certification by reference to **Object of Assessment**: Designation of the certified Interoperability Constituent/ Subsystem Type(s) and variant(s)/versions(s) included in the certification. Identified by industry-typical and un-ambiguous denomination. This may include a reference to a separate attached document which provides a more detailed definition (e.g. a Product Type Drawing, the NoBo-File/ Documentation, the EC Assessment Report.) [R4,R12,R28]
4. Name and address of **Applicant** (or of his authorized representative established within the Community.) [R9]
5. Name and address of the **Manufacturer** (or of his authorized representative established within the Community. If Applicant and Manufacturer are the same entity, it is sufficient to have a combined entry for "Applicant/Manufacturer".) [R1,R8,R33]
6. Scope of Certification by reference to **Location of manufacturer** (only if relevant (e.g. for all QMS approvals), only if different from address of Manufacturer. May also be a list of several locations.) [R3.a,R33]
7. Scope of Certification by reference to **Assessment Requirements**: TSIs and their identification number to which conformity was assessed, including any Amendments. (Format as given here: *[TSI CR L&P 2011/321/EU, amended by xxxxxx]*) For Harmonised Standards, Voluntary Standards and Alternative Solutions

(which include AMOC, Acceptable Means Of Compliance) reference to the relevant section of NoBo-File shall be made. [R3.a,R16,R35]

8. Scope of Certification by reference to **Exemptions from Assessment** [R17]
9. Scope of Certification by reference to Assessment **Module(s) applied** for Conformity Assessment. [R3.a,R34]
10. Statement about the **Assessment Results** (NoBo statement declaring the conformity of the Interoperability Constituent/ Subsystem or its phase/part, or quality management system with the appropriate Assessment Requirements. This is the central statement of the CLD.) [R2,R10,R16,R21,R30]
11. **Conditions and Limits of Use** (See section A.1.1 above). These are often partly contained in evidence documents supplied by the applicant and partly require documentation by the NoBo where identified during the assessment.

    The set of relevant Conditions and Limits of use must be contained in the NoBo-File section 3. On the CLD the following shall be provided:

    - the most relevant Conditions and Limits of Use in plain text and
    - a reference to the NoBo-File section 3 for the full set of relevant Conditions and Limits of Use related to the object of assessment. [R3.c, R11,R22]
12. (Where used) **Reference to Annex** of CLD [R5, R14]
13. **Reference to accompanying EC Assessment Report** [R5,R14,R22,R27,R31,R32]
14. **Reference to accompanying NoBo File** [R3.c,R5,R6,R7,R13,R14,R15,R18,R19,R35]
15. **Validity** of the Certification: any timeframes/conditions of validity shall be stated.[R3.b,R11,R36]
16. (Where applicable) **Reference to superseded CLD** in case of restricted or amendedEC Certificate. [R37]
17. Name and address of the **Notified Body** and its registration number at the European Commission. [R24]
18. **Date of issue, Signature** of the authorized signatory (usually the Certifier) of the Notified Body.[R20,R26,R29]

A.2.2 Annex of CLD

1. **Type** and **identification number** of the **related CLD** (see below Section B and C) [R25]
2. Scope of Certification by reference to **Object of Conformity Assessment**: Designation of the certified Interoperability Constituent/ Subsystem Type(s) and

variant(s)/versions(s) included in the certification. Identified by industry-typical and un-ambiguous denomination. This may include a reference to a separate attached document which provides a more detailed definition (e.g. a Product Type Drawing, the NoBo-File/ Documentation, the EC Assessment Report.) [R4,R12,R28]

3. **Conditions and Limits of use** (Follow on from the same topic on the Certificate Cover page).
4. Name and address of the **Notified Body** and its registration number at the European Commission.
5. **Date of issue, signature** of the authorized signatory of the Notified Body.

A.2.3 Content which must be contained in the NoBo Conformity Assessment Report or NoBo-File

1. For detailed requirements and additional information see RFU-STR-011.

In addition to this minimum set of information, the Notified Body is free to complete the EC Certificate and its Accompanying Documentation with any additional information deemed to be appropriate for comprehensive information and to improve a mutual recognition.

B) Languages

CLDs including their annex can be issued in monolingual or bilingual version. At bilingual versions, English shall be the second language to enable information exchange between Notified Bodies as required by Decision 2010/713/EU and between other stakeholders.

For the other NoBo-File/Documentation a monolingual version is sufficient to avoid translation errors.

Any **Translations** of CLD shall bear the **original** '**identification number'** and be marked as a Translation.

NoBos shall ensure that the object of assessment is unambiguously identified on the CLD and in the Accompanying Documentation. If this information is not originally provided in Latin script (e.g. drawings codes in annexes of NoBo-File), NoBos shall place the translation in the Latin script, along with the original script in brackets (or vice versa if required), on the certificate and in the Accompanying Documentation.

C) Types of CLDs – EC Certificate/ QMS-Approval/ ISV

EC-Certificates: This term includes the types 1, 2, 5, 6 and 7 as defined below.

QMS-Approval: The Quality Management System Approval of CLD type 4 is not named EC-Certificate by the European legislation, even though it is a certification level document and according to ISO 17065 in combination with the relevant aspects of ISO 17021 all related requirements to a certificate shall apply also to this document.

ISVs: ISVs although having, as documents, a different scope, purpose and legal status, shall follow the same technical and administrative approach as for the other CLDs.

Each ISV shall clearly identify the stages and parts covered.

The second digit of the ISV type refers to the type of certificate/ QMS-Approval as described under section C.

Rail Notified Bodies may issue CLDs of the following types:

1 EC Type Examination Certificate (B,CB, SB)

2 EC Design Examination Certificate (CH1, H2, SH1, SH2)

4 Quality Management System Approval (CD, CH, CH1, D, SD, H1, H2, SH1, SH2)*

5 EC Certificate of Conformity (A1, CA1, CA2, CF, F)

6. EC Certificate of Verification (SD, SF, SG, SH1, SH2)

7 EC Certificate of Suitability for Use (CV, V)**

8.1. Intermediate Statement of Verification – EC Type Examination (SB)

8.2. Intermediate Statement of Verification – EC Design Examination (SH1, SH2)

8.4. Intermediate Statement of Verification – Quality Management System Approval (SD, SH1, SH2)

8.6. Intermediate Statement of Verification (SD, SF, SG, SH1, SH2)

(The Modules that lead to the indicated CLD types are given in brackets.)

Notes:

- *The previously used type 3, Design examination report, is now incorporated within type 2, Design Examination Certificate and is no longer supported. Certificates of type 3 that have been issued continue to remain valid until their normal expiry.*
- **This is not an approval for the overall Quality Management System of the designer/ manufacturer but of its specific suitability for the intended purpose to deliver the object of assessment in compliance with the IODs and TSIs*
- *** Suitability for use is defined in module CV or V to be equivalent with conformity by in-service experience*

D) CLD 'Identification number'

The CLD 'Identification number' shall consist of two parts:

- **CLD ID** (structured: NNNN/T/M/YEAR/SSS/C1C2/###/) and
- **CLD Version number** (structured: Vxx).

Note: ERA has advised NB-Rail that various different concepts for version/ issue/ etc. of CLD have been used in the past. Within the new ERADIS database and with the background of a clarified understanding of the amend activity, this requires now a standardised approach (please see explanations in Annex 7 in "Amend existing NoBo EC Certificate").

A CLD shall be structured as follows (no spaces to be used before or following a "/"):

NNNN/T/M/YEAR/SSS/C1C2/###/Vxx

With following elements:

NNNN: Notified Body Registration number at the European Commission

T: one digit for types 1, 2, 4, 5, 6 and 7; three digits for ISV – See section C) above

M: Module (SB, SH2 etc.) as appropriate 1, 2 or 3 characters

YEAR: Year of issue of the first version of the CLD (4 digits)

SSS: Subsystem concerned:

- INF Infrastructure (*INS has been used formerly according to previous TSI versions)*
- RST Rolling Stock
- ENE Energy
- CCO Control Command and Signalling (on-board)
- CCT Control Command and Signalling (trackside)

Note: CCS Control-Command and Signalling is no longer used since the subsystem has been split into a trackside and an on-board subsystem according to Directive 2011/18/EU

C1: Master Language of CLD and NoBo-File (use EU codes) e. g. DE = German, EN = English, FR = French etc.

C2: Second language of any CLD (where used) shall be English. If the certificate is monolingual, C2 is not used, so the language indication is C1 only (2 digits)

###: Unique number(s) as defined by each NoBo.

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Vxx: Version number of CLD, whereas xx is used for two digits starting with "01" for the first issue, and incremented at each amendment activity of the CLD.

Note: In order to manage refused CLDs the following Identification number may be used: NNNN/T/M/YEAR/SSS/C1C2/###/Vxx/Refused

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List of Annexes to this RFU

Annex 1 - Requirements for Content of CLDs
Annex 2 - Content of CLDs (other than QMS Approval)
Annex 3 - Content of QMS Approval
Annex 4 - Content of ISV (other than QMS Approval)
Annex 5 - Content of ISV (QMS Approval)
Annex 6 - Content of Annex to an EC Certificate
Annex 7 - Publication of issued or refused CLDs in ERADIS

THIS RFU WAS AGREED ON
PLENARY MEETING 66
THIS RFU ENTERS INTO FORCE ON
DATE OF PUBLICATION: 23/11/2022 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
PLENARY MEETING 66: NO COMMENTS

Annex 1 of RFU - Requirements for Content of EC Certificate

The Decision 768/2008/EC on a common framework for the marketing of products (which is repealing and replacing Decision 93/465/EC) defines general requirements for the content of EC Certificates provided by NoBos.

These general requirements for an EC Certificate are (Summary of relevant requirements from 768/2008 Annex II):

R1. **The certificate shall contain the name and address of the manufacturer,**

R2. **the conclusions of the examination,**

R3. **the conditions (if any) for its validity** (Validity is considered to cover 3 Aspects:

a. **The Scope of certification,**

b. **the term or expiry date of certification,**

c. **the Conditions for the Use of the Subsystem.**

It is proposed that the Requirement R3.c may be covered by reference to the NoBo-File (i.e. Section 3 as defined by RFU-STR-011).)

R4. **and the necessary data for identification of the approved type.**

R5. **The certificate may have one or more annexes attached.** (This is considered to mean BOTH: either an “Annex to the EC Certificate” OR other documentation attached to the Certificate such as a NoBo Conformity Assessment Report or the NoBo-File.)

R6. **The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured products with the examined type to be evaluated.** (Note: Due to the significant number of assessment requirements relating to an IC/Subsystem, it is not considered reasonable to provide this information directly on the Certificate. This information is provided on the annex to certificates and/or the NoBo-File and/or the conformity assessment report (see A.1 General Overview).

R7. **The certificate and its annexes shall contain all relevant information to allow for in-service control.** (Note: “In service control” is considered to cover:

a. **the provisions for operation and maintenance** (these may be required by TSIs, 2004/49/EC and other regulations derived from the EU Treaty)

b. and the Conditions for use of the subsystem. (Already covered under R3 above.)

For reasons similar to those stated at R6 above, this requirement shall be satisfied by inclusion of the relevant information in the NoBo-File/Documentation (i.e. Section 3, 5.5 and 5.6 as defined by RFU-STR-011) and referencing the NoBo-File/ Documentation on the Certificate.)

Within the scope of the Interoperability Directive (IOD) (EU) 2016/797 (which is repealing and replacing the earlier Interoperability Directives) specific assessment Modules for IOD have been defined.

Initially these Modules were defined in the Annexes of TSIs. For TSIs published after 2010, these Modules are defined in the separate Decision 2010/713/EU and no longer inside the Annexes of the TSIs. At the same time new or updated definitions of assessment Modules for IOD were introduced. These new/updated Modules for IOD are incorporated in this RFU.

Note: The previous Modules for IOD will remain applicable according to the applicability of that TSI in which they are defined. Certificates must adhere in content and validity to that assessment Module for IOD which was used in the project.

The IOD and the definitions of the Modules for IOD contain a number of specific requirements (i.e. (EU) 2016/797 Annex IV, 2010/713/EU (description of modules) CB, CH1, CV, SB, SD, SF, SG, SH1) for EC Certificates:

R8. The certificate shall contain the name and address of the manufacturer (same as R1),

R9. the certificate shall contain the name and address of the Applicant,

R10. the conclusions of the examination (same as R2),

R11. the conditions (if any) for its validity (variant of R3) and

R12. the necessary data for identification of the **approved type/design** (variation of R4) and

R13. **if relevant, a description of the product's functioning.** (Note: It is not considered reasonable to provide this information directly on the Certificate. This requirement shall therefore be satisfied by inclusion of the required information in the NoBo-File (i.e. Section 5.2 as defined by RFU-STR-011) and referencing the NoBo-File on the Certificate.)

R14. The certificate may have one or more annexes attached (same as R5).

R15. The certificate and its annexes shall contain all relevant information to allow the conformity of **Interoperability Constituents/Subsystems with the examined type/ design** to be evaluated. (variation of R6) (Note: Due to the significant number of assessment requirements relating to an IC/Subsystem, it is not considered reasonable to provide this information

directly on the Certificate. Further (EU) 2016/797and 2010/713/EU specifically require this information be included in the NoBo-File/Documentation. This requirement shall therefore be satisfied by inclusion of the information in the NoBo-File/Documentation (i.e. Section 5.2 as defined by RFU-STR-011) and referencing the NoBo-File/Documentation on the Certificate.)

R16. The 'EC' verification certificate must provide reference to the TSIs with which the conformity has been assessed.

In case of TSI with additional optional technical requirements to quote whether it is inclusive of the optional requirements or not.

R17. Where a subsystem has not been assessed for its conformity with all relevant TSI(s) (e.g. in the case of a derogation, partial application of TSIs for upgrade or renewal, transitional period in a TSI or specific case)**, the 'EC' certificate shall give the precise reference to the TSI(s) or their parts whose conformity has not been examined by the Notified Body during the 'EC' certification procedure**

R18. A list of the relevant parts of the Technical Documentation shall be annexed to the EC certificate of suitability for use. (This supports the argument given in R5.)

R19. 'EC' certificate of Verification, accompanied by corresponding calculation notes (Note: It is not considered reasonable to provide this information directly on the Certificate. This requirement shall therefore be satisfied by inclusion of the required information in the NoBo-File (i.e. Section 5.2 as defined by RFU-STR-011) and referencing the NoBo-File on the Certificate.)

R20. and signed by the Notified Body responsible for the 'EC' verification,

R21. stating that the subsystem complies with the requirements of the relevant TSI(s) (Core Statement of the Certificate.)

R22. and mentioning any reservations recorded during performance of the activities and not withdrawn;

R23. **the 'EC' certificate of verification should also be accompanied by the inspection and audit reports drawn up by the same body** (This supports the argumentation provided at R5.)

Further NoBos must adhere to requirements based on their Accreditation or Recognition or are voluntary following the same requirements as good industry practice. These are contained in the ISO standards for Conformity Assessment Bodies (ISO 17020, 17021, 17065).

Any CLD shall include all of the following:

R24. **Identification of the issuing body;**

R25. **unique identification and**

R26. **date of issue;**

R27. **date of inspection** (Note: Due to the significant number of inspections relating to an IC/Subsystem, it is not considered reasonable to provide this information directly on the Certificate. This requirement shall therefore be satisfied by inclusion of the information in the NoBo Conformity Assessment Report and by referring to this Report on the Certificate.)

R28. identification of the item(s) inspected (variation of R4+R12);

R29. signature or other indication of approval, by authorized personnel (variation of R20);

R30. a statement of conformity where applicable (variation of R21);

R31. **the inspection results, except where detailed in a separate report.** (Note: Due to the significant number of inspections relating to an IC/Subsystem, it is not considered reasonable to provide this information directly on the Certificate. This requirement shall therefore be satisfied by inclusion of the information in the NoBo Conformity Assessment Report and by referring to this Report on the Certificate.)

R32. **An inspection body shall issue an inspection certificate that does not include the inspection results only when the inspection body can also produce an inspection report containing the inspection results, and when both the inspection certificate and inspection report are traceable to each other.** (This supports the argumentation provided at R31.)

R33. **The scope of certification relating to the** product(s), **process(es) or service(s) for which the certification is granted** (in relation to products same as R4+R12). It is considered that scope of certification relating process or service is only relevant for modules including Quality Management System Assessment. Due to the large number processes/services relating to a QMS, it is not considered reasonable to include this information directly on the Certificate. This requirement shall therefore be covered by stating the Manufacturer and the Location(s) of manufacture on the Certificate, as this is considered to identify suitably the related QMS.

R34. **The scope of certification relating to the applicable certification scheme.** The Certification Scheme is considered to be defined by 768/2008, (EU) 2016/797and 2010/713/EU, in each case including amendments. The Modules for IOD are part of the Scheme. For clarity, it

is considered that the reference to (EU) 2016/797including amendments and to the Module(s) used at this Certification shall suffice.

R35. The scope of certification relating to the standard(s) and other normative document(s), including their date of publication, to which it is judged that the product(s), process(es) or service(s) comply. (Note: This covers

a. standards or other documents referred to in the TSI's (and hence mandatory),

b. where applicable other Standards or other documents not referred to in the TSI's which give presumption of conformity with the TSI Requirements (Harmonised Standards and Voluntary Standards),

c. Alternative Solutions to b. if proposed by the Applicant. (see 2010/713/EU)

Due to the significant number of assessment requirements relating to an IC/Subsystem, it is not considered reasonable to provide this information directly on the Certificate, other than the references to TSIs. As (EU) 2016/797and 2013/713/EU specifically require this information be included in the NoBo-File/ Documentation, this requirement shall be satisfied by inclusion of the information in the NoBo-File/ Documentation (Section 5.1 as defined by RFU-STR-011) and by referencing the NoBo-File/ Documentation on the Certificate.

R36. The term or expiry date of certification, if certification expires after an established period (variation of R3.c);

R37. An amended certificate shall identify the replaced certificate.

R38. Any other information required by the certification scheme (covered by R1 to R23 above).

Annex 2 of RFU *(only for CLD types 1, 2, 5, 6, 7)*

EC *[Type Examination Certificate][Design Examination Certificate][Certificate of Conformity][Certificate of Verification] [Suitability for Use Certificate]*

Identification Number: NNNN/T/M/YEAR/SSS/C1C2/###/Vxx

In accordance with Directive (EU) 2016/797 of 11 May 2016 (as amended)
Assessment according to the Technical Document of ERA 000MRA1044 version 1.1 of June 2017

Object of Assessment	[Interoperability Constituent][Subsystem] (DESIGNATION) (and for A1, CA1, CF, F, SF, SG UNIQUE SERIAL NUMBERS –) (where required reference to Annex)
[Applicant] [Applicant/ Manufacturer]	(NAME, ADDRESS)
Manufacturer	(NAME, ADDRESS)
Manufacturing Location(s)	(NAME, ADDRESS) (only where different from Manufacturer, only relevant for CH1, H2, SD, SH1, SH2)
Assessment Requirements	(TSI INF CR 2011/275/EU, amended by xxxx) in combination with those Harmonised Standards, Voluntary Standards (or parts thereof), other European or national rules authorized by TSI's and Alternative Solutions as identified in the [NoBo-File/Accompanying Documentation] (Section 2)
[Scope of /Exemptions from Assessment]	(*optional*) Where a subsystem has not been assessed for its conformity with all relevant TSI(s) (e.g. in the case of a derogation, partial application for upgrade/ renewal, transitional period or specific case). This section contains precise reference to the TSI(s)/parts assessed or not assessed, part of Subsystem (according to CCS TSI). May be done by reference to Accompanying Documentation. This section shall be used for specifying optional requirements of subsystems or interoperability constituents.
Module applied	[A1, B, CA1, CA2, CB, CF, CH1, CV, F, H2, V, SB, SD, SF, SG, SH1, SH2] of the relevant decision adopted pursuant to the Directive
Assessment Result	The Object of Assessment as identified above was shown to comply with the Assessment Requirements, subject to any Conditions and Limits of use as listed below. The Assessment Results are provided in detail within the accompanying [EC Assessment Report or NoBo-File/ Accompanying Documentation section 4]. The Essential Requirements have been assessed as being met through compliance with the requirements of the relevant TSI only.
Conditions and Limits of use	Text and/or reference to detailed information on Conditions and Limits of use (these may also be referred to as Limitations, Restrictions, Constraints, etc.) of the Object of Assessment. Where defined in a TSI this shall include the 'Area of Use' information as far as this is to be evaluated by the NoBo. Make reference to Annex of Certificate or to the Assessment Report or to the NoBo-File section 5.2.

Annex of EC Certificate	(Only if used at issue of Certificate) (identifier, revision (if used), date)
Accompanying Documentation	(either NoBo File or NoBo Conformity Assessment Report, with identifier, revision, date). This documentation is an integral part of this Certificate.
Validity	Start: dd/mm/yyyy End: dd/mm/yyyy (*or "unlimited" as applicable, duration according to relevant TSI/Module/RFU-STR-060, based on the shortest validity period of the related certificates/QMS approval*) This certificate is valid for the Object of Assessment as mentioned above as long as compliance of the Object of Assessment with certification requirements is maintained by the Applicant. *[(only for SD, SH1 modules) Within the validity duration of this Certificate the Applicant can perform production/installation and final product/installation inspection of the Object of Assessment as long as the product/installation conforms to the EC Type/Design Examination Certificate. This validity duration may be extended on the basis of future updating of related Certificates/QMS approvals.]*
	(Where applicable:) This certificate amends / restricts (chose as applicable) certificate number xxxxx (*and, if needed*: dated xx/xx/xx) *(Where applicable:)* This certificate follows certificate number xxxxx (and, if needed: dated xx/xx/xx)
DATE of Issue:_____	Signature:_____ Name: (printed) Title: (printed) On behalf of [NAME/ ADDRESS/ EC-Identification No. of Notified Body]

Annex 3 of RFU *(only for CLD type 4)*

Quality Management System Approval

Identification Number: NNNN/T/M/YEAR/SSS/C1C2/###/Vxx

In accordance with Directive (EU) 2016/797 of 11 May 2016 (as amended)
Assessment according to the Technical Document of ERA 000MRA1044 version 1.1 of June 2017

Object of Assessment	Quality Management System for the [design of and] (only for CH1, H2, SH1, SH2) production of the [Interoperability Constituent][Subsystem] (DESIGNATION) (where required reference to Annex)
[Applicant] [Applicant/ Manufacturer])	(NAME, ADDRESS)
Manufacturer	(NAME, ADDRESS)
Manufacturing Location(s)	(NAME, ADDRESS) (only where different from Manufacturer
Assessment Requirements	(TSI INF CR 2011/275/EU, amended by xxxx) in combination with the Harmonised Standards, Voluntary Standards (or parts thereof) and Alternative Solutions as identified in the [NoBo-File/Accompanying Documentation] (Section 2)
[Scope of /Exemptions from Assessment]	(*optional*) (Where a subsystem has not been assessed for its conformity with all relevant TSI(s) (e.g. in the case of a derogation, partial application for upgrade/renewal, transitional period or specific case), precise reference to the TSI(s)/parts not assessed, part of Subsystem (according to CCS TSI)) (May be done by reference to Accompanying Documentation). This section shall be used for specifying optional requirements of subsystems or interoperability constituents.
Module applied	[CD, CH, CH1, D, H1, H2, SD, SH1, SH2] of the relevant decision adopted pursuant to the Directive.
Assessment Result	The Quality Management System of the aforementioned Manufacturer [at the indicated Location(s)] has been audited and was shown to comply with the Assessment Requirements, subject to any Conditions and Limits of use as listed below. The Assessment Results are provided in detail within the accompanying [EC Audit Report or NoBo-File/Accompanying Documentation section 4]. The Essential Requirements have been assessed as being met through compliance with the requirements of the relevant TSI only.
Conditions and Limits of use	Text and/or reference to detailed information on Conditions and Limits of use (these may also be referred to as Limitations, Restrictions, Constraints, etc.) of the Object of Assessment. Where defined in a TSI this shall include the 'Area of Use' information as far as this is to be evaluated by the NoBo. Make reference to Annex of the QMS Approval or to the Assessment Report or to the NoBo-File section 5.2.
Annex of QMS Approval	(Only if used at issue of QMS Approval) (identifier, revision (if used), date)

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Accompanying Documentation	(e.g. NoBo Conformity Assessment Report, Audit Report, with identifier, revision , date). This documentation is an integral part of this QMS Approval.
Validity	Start: dd/mm/yyyy End: dd/mm/yyyy (*or "unlimited" as applicable, duration according to relevant TSI/Module/RFU-STR-060, based on the shortest validity period of the related certificates/QMS approval*) The validity of this QMS Approval is subject to [continued compliance with the [Design][Type] Examination Certificate(s) as listed above/on the attached annex and] (not applicable for CH, H1) the continued maintenance of the Quality Management System in accordance with the requirements of the above Directive. This QMS Approval is valid as long as compliance of the Quality Management System with certification requirements is maintained. If certification requirements are affected, then the NoBo must be informed. Within the validity duration of this QMS Approval the Applicant can perform production/installation and final product/installation inspection of the object of the assessment. This validity duration may be extended on the basis of future auditing.
	(Where applicable:) This QMS Approval amends / restricts (chose as applicable) QMS Approval number xxxxx (and, if needed: dated xx/xx/xx) *(Where applicable:)* This QMS Approval follows QMS Approval number xxxxx (and, if needed: dated xx/xx/xx)
DATE of Issue:_____	Signature:_____ Name: (printed) Title: (printed) On behalf of [NAME/ ADDRESS/ EC-Identification No. of Notified Body]

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Annex 4 of RFU *(only for CLD types 8.1, 8.2 and 8.6)*

[Intermediate Statement of Verification]
[Intermediate Statement of Verification - EC Type Examination]
[Intermediate Statement of Verification - EC Design Examination]

Identification Number: NNNN/T/M/YEAR/SSS/C1C2/###/Vxx

In accordance with Directive (EU) 2016/797 of 11 May 2016 (as amended)
Assessment according to the Technical Document of ERA 000MRA1044 version 1.1 of June 2017

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Object of Assessment	[Subsystem] (DESIGNATION) (and for SF, SG UNIQUE SERIAL NUMBERS) (where required reference to Annex)
[Applicant] [Applicant/ Manufacturer]	(NAME, ADDRESS)
Manufacturer	(NAME, ADDRESS)
Manufacturing Location(s)	(NAME, ADDRESS) (only where different from Manufacturer, only relevant for CH1, H2, SD, SH1, SH2)
Assessment Requirements	(TSI INF CR 2011/275/EU, amended by xxxx) in combination with those Harmonised Standards, Voluntary Standards (or parts thereof), other European or national rules authorized by TSI's and Alternative Solutions as identified in the [NoBo-File/Accompanying Documentation] (Section 2)
[Scope of /Exemptions from Assessment]	(*optional*) Where a subsystem has not been assessed for its conformity with all relevant TSI(s) (e.g. in the case of a derogation, partial application for upgrade/ renewal, transitional period or specific case). This section contains precise reference to the TSI(s)/parts assessed or not assessed, part of Subsystem (according to CCS TSI). May be done by reference to Accompanying Documentation. This section shall be used for specifying optional requirements of subsystems
[Stages]	Only applicable for ISVs, it is used to clearly define which project stage(s) are covered by this ISV.
Module applied	[SB, SD, SF, SG, SH1, SH2] of the relevant decision adopted pursuant to the Directive
Assessment Result	The Object of Assessment as identified above was shown to comply with the Assessment Requirements, subject to any Conditions and Limits of use as listed below. The Assessment Results are provided in detail within the accompanying [EC Assessment Report or NoBo- File/Accompanying Documentation section 4]. The Essential Requirements have been assessed as being met through compliance with the requirements of the relevant TSI only.
Conditions and Limits of use	Text and/or reference to detailed information on Conditions and Limits of use (these may also be referred to as Limitations, Restrictions, Constraints, etc.) of the Object of Assessment.

	Where defined in a TSI this shall include the 'Area of Use' information as far as this is to be evaluated by the NoBo. Make reference to Annex of ISV or to the Assessment Report or to the NoBo-File section 5.2.
Annex of ISV	(Only if used at issue of Certificate) (identifier, revision (if used), date)
Accompanying Documentation	(either NoBo File or NoBo Conformity Assessment Report, with identifier, revision, date). This documentation is an integral part of this ISV.
Validity	Start: dd/mm/yyyy End: dd/mm/yyyy (*or "unlimited" as applicable, duration according to relevant TSI/Module/RFU-STR-060, based on the shortest validity period of the related certificates/QMS approval*)
	This ISV is valid for the Object of Assessment as mentioned above and as long as compliance of the Object of Assessment with the certification requirements is maintained by the applicant. [(*only for SD, SH1 modules*) Within the validity duration of this ISV the Applicant can perform production/installation and final product/installation inspection of the object of the assessment as long as the product/installation conforms to the EC Type/Design Examination ISV. This validity duration may be extended on the basis of future auditing.]
	(Where applicable:) This ISV amends / restricts (chose as applicable) ISV number xxxxx (and, if needed: dated xx/xx/xx) *(Where applicable:)* This ISV follows ISV number xxxxx (and, if needed: dated xx/xx/xx)
DATE of Issue:_____	Signature:_____ Name: (printed) Title: (printed) On behalf of [NAME/ ADDRESS/ EC-Identification No. of Notified Body]

RFU-STR-001	Issue 18 Date 09/11/2022

Annex 5 of RFU *(only for CLD type 8.4)*

Intermediate Statement of Verification - *Quality Management System Approval*

Identification Number: NNNN/T/M/YEAR/SSS/C1C2/###/Vxx

In accordance with Directive (EU) 2016/797 of 11 May 2016 (as amended)
Assessment according to the Technical Document of ERA 000MRA1044 version 1.1 of June 2017
(depending on NoBo notification)

Object of Assessment	Quality Management System for the [design of and] (only for SH1, SH2) production of the [Subsystem] (DESIGNATION) (where required reference to Annex)
[Applicant] [Applicant/ Manufacturer])	(NAME, ADDRESS)
Manufacturer	(NAME, ADDRESS)
Manufacturing Location(s)	(NAME, ADDRESS) (only where different from Manufacturer)
Assessment Requirements	(TSI INF CR 2011/275/EU, amended by xxxx) in combination with the Harmonised Standards, Voluntary Standards (or parts thereof) and Alternative Solutions as identified in the [NoBo-File/Accompanying Documentation] (Section 2)
[Scope of /Exemptions from Assessment]	(*optional*) (Where a subsystem has not been assessed for its conformity with all relevant TSI(s) (e.g. in the case of a derogation, partial application for upgrade/renewal, transitional period or specific case), precise reference to the TSI(s)/parts not assessed, part of Subsystem (according to CCS TSI).) (May be done by reference to Accompanying Documentation). This section shall be used for specifying optional requirements of subsystems
[Stages]	Only applicable for ISVs, it is used to clearly define which project stage(s) are covered by this ISV.
Module(s) applied	[SD, SH1, SH2] of the relevant decision adopted pursuant to the Directive.
Assessment/ Audit Result	The Quality Management System of the aforementioned Manufacturer [at the indicated Location(s)] has been audited and was shown to comply with the Assessment Requirements, subject to any Conditions and Limits of use as listed below. The Assessment Results are provided in detail within the accompanying [EC Audit Report or NoBo-File/ Accompanying Documentation section 4]. The Essential Requirements have been assessed as being met through compliance with the requirements of the relevant TSI only.
Conditions and Limits of use	Text and/or reference to detailed information on Conditions and Limits of use (these may also be referred to as Limitations, Restrictions, Constraints, etc.) of the Object of Assessment. Where defined in a TSI this shall include the 'Area of Use' information as far as this is to be evaluated by the NoBo. Make reference to Annex of ISV or to the Assessment Report or to the NoBo-File section 5.2.
Annex of ISV	(Only if used at issue of ISV) (identifier, revision (if used), date)
Accompanying Documentation	(e.g. NoBo Conformity Assessment Report, Audit Report, with identifier, revision, date). This documentation is an integral part of this ISV

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Validity

Start: dd/mm/yyyy

End: dd/mm/yyyy (*or "unlimited" as applicable, duration according to relevant TSI/Module/RFU-STR-060, based on the shortest validity period of the related certificates/QMS approval*)

The validity of this ISV - QMS Approval is subject to [continued compliance with the [Design][Type] Examination Certificate(s) as listed above/on the attached annex and] the continued maintenance of the Quality Management System in accordance with the requirements of the above Directive. This ISV - QMS Approval is valid as long as compliance of the Object of Assessment with certification requirements is maintained. If certification requirements are affected, then the NoBo must be informed.

Within the validity duration of this ISV - QMS Approval the Applicant can perform production/installation and final product/installation inspection of the object of the assessment. This validity duration may be extended on the basis of future auditing.

(*Where applicable*:) This ISV amends / restricts (chose as applicable) ISV number xxxxx (and, if needed: dated xx/xx/xx)

(Where applicable:) This ISV follows ISV number xxxxx (and, if needed: dated xx/xx/xx)

DATE of Issue:_____

Signature:_____

Name: (printed) Title: (printed)

On behalf of [NAME/ ADDRESS/ EC-Identification No. of Notified Body]

Annex 6 of RFU

Annex to (precise reference to related certification level document)

Identification Number: NNNN/T/M/YEAR/SSS/C1C2/###/Vxx

Object of Conformity Assessment	[Interoperability Constituent][Subsystem] (DESIGNATION) (and for A1, CA1, CF, F, SF, SG UNIQUE SERIAL NUMBERS) (where required reference to Annex)

Conditions and Limits of use	(follow up from related EC-Certificate/ QMS-Approval/ ISV)
[any other information which could not be placed on the EC Certificate]	(text or reference to detailed information)

DATE of Issue: _____ Signature:_____

Name: (printed) Title: (printed)

On behalf of [NAME/ ADDRESS/ EC-Identification No. of Notified Body]

Annex 7 Publication of issued or refused CLDs in ERADIS

Note: ERADIS uses currently the term 'EC Certificate' instead of the generic term 'CLD'. ERA has confirmed to NB-Rail, that this shall be understood to represent any type of CLD.

Operations in ERADIS	Definition (OA= Object of Assessment)	Status attribute of the CLD
"Submit new NoBo EC Certificate"	**Either**: Where a NoBo finds that all applicable requirements of the relevant TSI(s) have been met by an applicant for a new, upgraded or renewed OA the NoBo can issue a new CLD. 'New' includes also the case where an already certified OA is modified and has also been certified in this new configuration. 'New' includes further the case where an already certified OA became associated with a different applicant or manufacturer and has also been certified in this new configuration.	A new CLD becomes "issued".
	Or: Where a NoBo finds that all applicable requirements of the relevant TSI(s) have been met by an applicant during the re-certification of an already certified OA the NoBo can issue a new NoBo CLD.	A new CLD becomes "issued".
	Or: Where a notified body finds that requirements of the relevant TSI(s) have not been met by an applicant for a new, upgraded or renewed OA and the applicant stops the improvement of the OA, the NoBo has to stop the evaluation and certification which leads to refuse a new NoBo CLD for the OA. *Note: NoBos are obliged to publish this information.*	Refused (only an entry in ERADIS, no actual CLD is issued)
"Suspend existing NoBo EC Certificate"	Where, in the course of the Monitoring of Conformity, a NoBo finds that an OA no longer complies with the Requirements of the relevant TSI(s), the NoBo shall require the applicant to take appropriate corrective measures within a limited time period. *Note: The limited time period has to be defined by the NoBo taking into account the extent of the deficiency.* If the corrective measures are not taken or do not have the required effect, the NoBo shall suspend all affected CLDs after expiration of this limited time period. The suspension status shall be kept until the OA has become compliant again. Where the applicant fails to improve the OA, the suspension status may become indefinite. A suspended CLD entry in ERADIS hinders the applicant to declare the conformity on the basis of the suspended CLD of any OA which was produced after the date of suspension. The suspended CLD also hinders an authorising entity to authorise any OA which was produced or declared to be conform after the suspension date. *Note: NoBos are obliged to inform the applicant (by direct communication), the notifying authority and the related authorising entities (via the ERADIS database entry) of the suspension.*	The previously "Issued" CLD changes its status attribute to "Suspended"
Restrict an existing CLD by	Where, in the course of the Monitoring of Conformity, a NoBo finds that an OA no longer complies with the Requirements of relevant	A previously "Issued (or already "Suspended") CLD

a) "Suspend existing NoBo EC Certificate" and b) "Submit new NoBo EC Certificate"	TSI(s), the NoBo shall require the applicant to take appropriate corrective measures within a limited time period. *Note: The time period has to be defined by the NoBo taking into account the extent of the deficiency.* If corrective measures are not taken or do not have the required effect, but the OA still meets the TSI related requirements, but in a restricted way when compared to the original CLD, the notified body shall suspend the existing certificate and may issue a new (restricted) CLD for the same OA. The new (restricted) CLD shall reference the previous CLD identification number and state the nature of the restriction. Any declarations or authorisations based on the original CLD shall remain valid. Future declarations or authorisations shall be made on basis of the new (restricted) CLD, not on the basis of the suspended CLD. *Note: NoBos are obliged to inform the applicant (by direct communication), the notifying authority and the competent national safety authorities (both via the ERADIS database entry) of the restriction.*	changes (retains) its status attribute in "Suspended". A new (restricted) CLD becomes "issued".
"Restore an existing suspended CLD" *Note: This function is not yet active for NoBos in ERADIS and requires a super-user intervention by ERA.*	When the OA has become compliant again, the NoBo shall restore the "suspended" NoBo Certificate. This can also be performed where the suspension was caused by a restriction.	The previously "Suspended" CLD "changes its status back to "Issued".
"Withdraw existing NoBo EC Certificate"	Where, in the course of the Monitoring of Conformity, a NoBo finds retrospectively that an OA has never complied with the Requirements of relevant TSI(s), the NoBo shall require the applicant to take appropriate corrective measures within a limited time period. If corrective measures are not taken or do not have the required effect, the notified body shall withdraw the certificate. The withdrawal has the effect, that the CLD is invalidated back to its start of validity. This means that any previous or intended future declarations and authorisations performed on its basis become/ are invalid. *Note: NoBos are obliged to inform the applicant (by direct communication), the notifying authority and the competent national safety authorities (via the ERADIS database entry) of the withdrawal.*	The previously "Issued or Suspended" NoBo certificate" changes its status to "Withdrawn NoBo Certificate"
Amend existing NoBo EC Certificate by two steps:	This case is used when a certificate must be amended. The "amend" activity shall only be used in case of small and strictly administrative amendments to an already issued CLD in order to correct an error. Such an amendment may be, for example, the correction of a spelling mistake in the address of the applicant, a typographical error	An existing CLD changes its status to "suspended". A new CLD with the same Document ID but with an updated

a) "Suspend existing NoBo EC Certificate" and b) "Submit new NoBo EC Certificate" which amends with corrected information the previous CLD	in the description of the product, a mismatch in the month/day in the validity dates, etc. The *amend* function shall never be used to change the scope of a CLD that has already been issued. The *amend* function may only be used to correct an administrative error. The list below gives examples that are considered to be a change in scope. These examples are not considered to be administrative changes, and shall not be changed using the *amend* function: - extending the validity of a CLD following a new audit result - introducing an additional Manufacturer on a CLD - modifying the OA stated on a CLD - changing the Conditions and Limits of Use on a CLD. Where a CLD is required to certify a change of scope, the NoBo shall issue a completely new CLD for the new scope of work according to the workflow for new CLDs as indicated above in this table. Where the administrative error to be corrected is in the CLD identification number (this is expected to be a rare case), the NoBo shall seek the support of an ERA super-user, as this cannot be managed by the NoBo alone. For the new (amended) CLD to be issued the CLD Version number shall be incremented. The CLD ID shall remain identical. The new (amended) CLD shall reference the full previous CLD identification number and state the nature of the amendment. All not amended information shall remain identical on the new (amended) CLD. Any declarations or authorisations based on the original non-amended CLD shall remain valid as the amendment relates by the definition provided in this RFU strictly only to the correction of an administrative error and never to any change of the scope of the CLD. Future declarations or authorisations shall be made on basis of the new (amended) CLD, not on the basis of the suspended previous CLD.	Version counter is issued.

Note: A CLD which

- *is in the status "issued" and*
- *is valid (according to the validity start and end dates)*

is required to be present at least throughout the production process of the OA.
The aforementioned is required as basis for an EC Declaration to be prepared by the applicant and also for any subsequent authorisations (APIS for Fixed Installations, APOM for Vehicles, Conformity to Type Authorisation for Vehicles), which could take place at a later stage.