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-060	Issue 14 Date 19/06/2024

TITLE	
DURATION OF VALIDITY OF CERTIFICATES AND ISVS	
ORIGINATOR	**SUBJECT RELATED TO**
NB-RAIL SUB-GROUP STRATEGY	IOD (EU)2016/797 ALL TSIS SINCE 2010 DECISION 2010/713/EU

AMENDMENT RECORD:

Issue 10: amendment of some validity periods in annex tables

Issue 11: Minor changes to IC, end of section 3 of the proposal

Issue 12: Extension of section 'Required validity of CLDs covering IC'

Issue 13: Updating the validity due to TSI-Package 2023 ((EU) 2023/1694, (EU) 2023/1695)

Issue 14: How to manage modifications to ICs, new section 4 of this RFU. Administrative updates for the notes in the appendices.

DESCRIPTION AND BACKGROUND EXPLANATION

This RFU clarifies the starting point of the validity of 'Certification level documents' (CLDs) and their duration.

1) Validity of CLDs covering the product

The duration of validity for CLDs is listed below. Due to historical reasons (evolvement of TSIs) there are several different situations (depending on the publication date of the TSI):

1. For a TSI published before 31.12.2010 the duration of validity of the CLDs have been defined in the module descriptions in the annex of each TSI. This case is referred to as "old modules" and will no longer be treated by this RFU as number of projects applying these is very marginal.
2. In the TSIs published since 01.01.2011, reference is given to Decision 2010/713/EU. This case is referred to as "new modules". In the description of the modules an expiry date for the certificates and ISVs is required, but the duration of validity is not specified. Therefore, there are two possibilities:
    a. The TSI itself does not specify any duration of validity for the certificates. The same approach shall be applied *mutatis mutandis* to ISVs. So, only the requirements from the Decision 2010/713/EU on modules apply.
    b. The TSI specifies a duration of validity for certain certificates. The same approach shall be applied mutatis mutandis to ISVs. So, the requirements specified in the TSI are added to those from the Decision 2010/713/EU on modules.

The 'new' modules (cases 2a and 2b from above) with system approach assessment (Modules CD, SD, CH, CH1, SH1) described in the Decision 2010/713/EU require periodic audit at least every two years.

The CLDs should state that it remains valid as long as compliance of the subsystem/IC with the certification requirements is maintained.

Note: ISO 17065 4.1.2j & 7.10.2 shall be considered by NoBo for contractual requirements with the applicant.

According to ISO 17065 - 7.10.3; NoBo shall keep records of any case change which does not request any assessment and/or certification activities.

NOTE: the particularity of the modules CF/SF and SG is that in both cases, each individual product/installation is assessed by the NoBo. Therefore, there is no need to define a specific validity for the CLDs in such cases.

Note: ISV shall not be used for purpose of authorisation. See Application Guide PA VA §3.3.7.

2) Validity of CLDs covering product quality management system (Modules CD, SD, CH, CH1, SH1): date of start of the validity time frame of the certificate/ISV

There have been different interpretations about the date of start of validity of CLDs covering product QMS. This RFU clarifies a standard approach.

Note: as a specific scheme for NoBo conformity assessment has been defined, the basic 1 year surveillance with 3 year recertification cycle of ISO 17021 does not apply.

CLDs covering product QMS shall state that it remains valid as long as the subsystem/constituent is not modified and the approved QMS is maintained. Within the validity duration of the CLD covering product QMS 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 CLDs covering the type/design of the product. The validity of CLDs covering product QMS may be extended on the basis of future recertification auditing (see RFU-STR-001), leading to the issuing of a new CLD covering product QMS.

3) Required validity of CLDs covering IC

Sometimes CLDs for an IC are already expired when this IC is incorporated into a subsystem. The required validity of CLDs covering IC should be understood by all parties in the same way.

4) How to manage modifications to ICs

All modifications to an IC already certified imply new conformity assessment by the NoBo. The required action by the NoBo should be understood by all parties in the same way.

RFU PROPOSAL

1. Validity of CLDs

Case 1: “old modules”: No longer treated by this RFU. See issue 08 for additional information.

Case 2: “new modules”:

2a) The validity of CLDs is described hereafter based on the module descriptions given in Decision 2010/713/EU for those cases where the TSI itself does not specify any duration or validity (e.g. for TSI CCS and partly for TSI WAG):

Interoperability constituents

- EC type examination certificate (CB) – unlimited
- EC design examination certificate (CH1) – unlimited
- EC certificate of suitability for use (CV) – unlimited
- EC certificate of conformity (CF) – unlimited
- Quality management system approval (CD, CH, CH1) – maximum of 2 years

Note: Use of ISV is not allowed at IC level.

Subsystems

- EC type examination certificate (SB) – unlimited
- EC design examination certificate (SH1) – unlimited
- Quality management system approval (SD, SH1) – maximum of 2 years
- EC certificate of verification (SD, SH1) – maximum of 2 years
- EC certificate of verification (SG, SF) – unlimited

Note: The same approach shall be applied mutatis mutandis to ISVs.

The NoBo shall evaluate how many surveillance audits are necessary within the interval of maximum two years , since NoBos are not required by module decision 2010/713/EU or by the TSIs or by the ERA Assessment Scheme to perform periodic audits for surveillance at intervals defined by ISO/IEC 17021-1:2015 (i.e., during the certification cycle: one surveillance audit once a year following the QMS approval decision, except in the last year prior to expiration of certification, when a recertification audit is required,

according to sections 9.1.3.2 and 9.1.3.3 of ISO/IEC 17021-1:2015). Therefore, according to module decision 2010/713/EU ("the frequency of the periodic audits shall be at least once every 2 years"), NoBos do not have to perform an annual surveillance audit, unless their evaluation concluded it was necessary. Where the NoBo evaluation has concluded that a 2 years surveillance interval is acceptable as set out above, the surveillance audit and the recertification audit will be coincident and only the recertification audit needs to be performed.

2b) The following TSIs define specific duration of validity for subsystems/ICs:

WAG 321/2013

INF 1299/2014

PRM 1300/2014

ENE 1301/2014

LOC&PAS 1302/2014

Amendment to several TSIs (EU) 2019/776

Please refer to the annex of this RFU for a complete overview about the duration of validity for case 2b.

2. Validity of CLDs covering product QMS: date of start of the validity of the time frame of the certificate

Following the instruction of the technical document MNB - Assessment scheme 000MRA1044 ver 1.1, section "7.4.QMS.C – Audit Programme", the date of the validity of a CLDs covering product QMS starts with the end of the preceding audit: "Each periodic time interval begins with the last day of the related preceding audit".

The requirements of 9.6 of ISO 17021-1:2015 (that is referred by section 7.4. "QMS.O - Maintaining approval" of Technical document MNB - Assessment scheme 000MRA1044 ver 1.1) apply with the following additional clarifications:

The term "periodic audit" of the module decision 2010/713/EU corresponds to the term "recertification audit" of the EN ISO/IEC 17021-1:2015.

The term "periodic audit" as used in the module decision 2010/713/EU is not defined in the 17021-series (version 2006, 2011 or 2015). NB-Rail Coordination Group has defined that the maximum period of 2 years corresponds to the recertification cycle as defined in the 17021-series.

As date of the end of the audit shall be taken the date of the closing meeting of the audit. In the case that several audits have to be carried out at different locations in order to assess the quality management, the date of the end of the closing meeting of the last audit shall be taken. All these audits must take place within six months.

To allow for a continuous extension of the certification, the validity of the new CLDs covering product QMS shall be linked to the date of the closing meeting of the first CLDs covering product QMS.

If a periodic audit is conducted within a period of six months prior to the expiry date of a CLD covering product QMS, the validity of the new CLD covering product QMS can start from the expiry date (the day after the end of the validity of the previous CLD) of the previous CLD covering product QMS and it is valid up to two years (this corresponds to item 9.6.3.2.3 of EN ISO/IEC 17021-1:2015).

If the periodic audit has not been completed or the notified body is unable to verify the implementation of corrections and corrective actions for any major nonconformity prior to the expiry date of the certification, but within 6 months after the expiration date, a renewed CLD covering product QMS can be issued. In this case the date of start of validity of the renewal is the renewal decision date. The expiry date shall be based on the prior certification cycle (this corresponds to items 9.6.3.2.4 and 9.6.3.2.5 of EN ISO/IEC 17021-1:2015).

After 6 months of the expiration date of the current CLD covering product QMS, a new certification process shall be started (this corresponds to item 9.6.3.2.5 of EN ISO/IEC 17021-1:2015).

3. Required validity of CLDs covering IC

Any interoperability constituent shall be:

- designed (for B or H type modules)
- produced (for D and H types modules)
- finally inspected and tested at the end of the production (for D and H types modules)
- type tested (for B or H types modules + V if required)

during the validity of its CLDs. According to the IOD, this fact shall be confirmed by the EC Declaration.

However, it is possible that such an IC is placed on the market and integrated into a subsystem at a later date. The applicant of the IC has full responsibility to ensure that the ICs placed on market are covered by valid CLDs. There is no obligation in IOD for the NoBo at subsystem level to check on the applicant's activities in this regard (e.g IC production under valid CLD period)

Products already placed on the market and covered by a declaration according to valid CLDs on the day of issuance of the declaration may be used (even if CLDs are expired at the time of authorisation of the subsystem) as long as technical requirements that apply to the subsystem are fulfilled. This concept applies to ICs when integrated:

- into a subsystem
- into a group of ICs (e.g. ETCS on-board and odometry),

- into a higher-level IC (e.g. a wheelset including wheels).

Note: If any inconsistencies are noticed, it is the obligation of the applicant to have this clarified.

4. How to manage all modifications to ICs

Where the applicant informs the NoBo that an already certified IC is modified (including minor modifications) the NoBo shall evaluate the modification.

For documentation of the NoBo's evaluation results of such a modification, a NoBo shall *not* issue any e-mail or letter or similar communication to accompany the original CLDs with the intention to extend the validity of the previous CLDs to cover also the modified IC.

A NoBo who assesses a subsystem into which a modified IC is incorporated, shall not accept any e-mail or letter or similar communication which accompanies the original CLDs for this purpose.

Note: evaluation results of NoBos for ICs may only be contained in CLDs and associated NoBo Conformity Assessment reports (see RFU-STR-001). Other kinds of documentation, such as e-mails or letters or similar communication to accompany the original CLDs cannot be entered in the ERADIS database.

These other kinds of documents are additionally not deemed acceptable under the existing IOD requirements to be used by the Applicant to draw up the declaration for placing the modified IC on the market.

In case of modifications to a certified type/design that may affect the conformity of the interoperability constituent with the requirements of the TSI or the conditions for validity of the certificate, the NoBo shall be informed by the applicant.

Such modifications shall require additional conformity assessment in the form of an "addition to the original EC type/design examination certificate" (wording from 2010/713/EU).

The NoBo who is contracted to assess the modifications to the IC shall issue a new NoBo-Conformity Assessment Report Nº 2 and a new Certificate Nº 2 (new CLD Identification Number) for the updated IC version V_{n+1}:

a) by assessing only the modifications from V_n to version V_{n+1} and incorporating existing NoBo-Conformity Assessment Report Nº 1 and Certificate Nº 1 into NoBo-Conformity Assessment Report Nº 2, or

b) by re-using and updating the original assessment documentation (only possible if it is the same NoBo that has issued NoBo-Conformity Assessment Report Nº 1 and Certificate Nº 1).

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In case of modifications without any impact on TSI compliance, NoBo-Conformity Assessment Report Nº 2 and Certificate Nº 2 can also state that the modifications made to the Object of Assessment do not have any impact on compliance with the applicable requirements, and therefore NoBo-Conformity Assessment Report Nº 1 and Certificate Nº 1 are equally applicable to the modified product.

THIS RFU WAS AGREED ON

PLENARY MEETING 071

THIS RFU ENTERS INTO FORCE ON

03/07/2024 (DATE OF PUBLICATION)

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

RFU APPLICATION IS MANDATORY STARTING FROM

03/07/2024

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 071 – 19/06/2024: NO COMMENTS

ANNEX 1 – TABLE OF DURATION OF VALIDITY PER SUBSYSTEM/CONSTITUENT

SUBSYSTEM ROLLING STOCK – FREIGHT WAGONS

TSI WAG (EU) 321/2013 AMENDED BY (EU) NO 1236/2013, (EU) 2015/924, (EU) 2019/776, (EU) 2020/387 AND (EU) 2023/1694

INCLUDING TSI NOISE (EU) NO 1304/2014, AMENDED BY (EU) 2019/774 AND (EU) 2023/1694

INCLUDING TSI NOISE 2011/229/EU, AMENDED BY 2012/464/EU

			TSI WAG (EU) 321/2013	
			Amendments (EU) 1236/2013 (EU) 2015/924, (EU) 2019/776, (EU) 2020/387	Amendments (EU) 1236/2013 (EU) 2015/924, (EU) 2019/776, (EU) 2020/387 (EU) 2023/1694
	ITEM	TYPE	VALIDITY	
Constituents	EC Type Examination Certificate	1/CB	10 years	unlimited [1)]
	Quality Management System Approval	4/CD	2 years	
	EC Certificate of Conformity	5/CF	unlimited	
	EC Design Examination Certificate	2/CH1	10 years	unlimited [1)]
	Quality Management System Approval	4/CH 4/CH1	2 years	
	EC Certificate of Suitability for Use	7/CV	10 years	unlimited [1)]
Subsystems	EC Type Examination Certificate	1/SB	10 years	unlimited [2)]
	Quality Management System Approval	4/SD	2 years	
	EC Certificate of Verification	6/SD	2 years	
	EC Certificate of Verification	6/SF	unlimited	
	EC Design Examination Certificate	2/SH1	10 years	unlimited [2)]
	Quality Management System Approval	4/SH1	2 years	
	EC Certificate of Verification	6/SH1	2 years	

[1)] Even if the end of validity in the NoBo CLD is unlimited Chapter 7.2.3.2. Annex I (EU) 2023/1694 **applies for Constituents**

(1) This point concerns interoperability constituents which are subject to type examination or design examination or to suitability for use.

(2) The type or design examination or suitability for use remains valid even if a revision of this TSI or of the TSI NOI comes into force, unless explicitly otherwise specified in the revision of those TSIs.
During this time, new constituents of the same type are permitted to be placed on the market without a new type assessment.

Note: The NoBo CLD is valid for the Object of Assessment as mentioned in the CLD and as long as compliance of the Object of Assessment with certification requirements, as stated in the CLD, is maintained by the Applicant. The validity may become limited by future versions of the certification requirements.

[2)] Even if the end of validity in the NoBo CLD is unlimited Chapter 7.2.3.1.3. Annex I (EU) 2023/1694: **applies for Subsystems**

(1) When a revision of this TSI or of the TSI NOI comes into force, the EC type or design examination certificate for the subsystem remains valid unless it is required to be revised in accordance with the specific transition regime of a TSI change.

(2) Only the changes to the TSIs with a specific transition regime can apply to units in production phase or to units in operation.

Note 1: The NoBo CLD is valid for the Object of Assessment as mentioned in the CLD and as long as compliance of the Object of Assessment with certification requirements, as stated in the CLD, is maintained by the Applicant. The validity may become limited by future versions of the certification requirements.

Note 2: TSI WAG point 7.2.2.2 may apply.

Note 3: The same validity as defined for each certificate for subsystems shall be applied mutatis mutandis to ISV. Please refer to RFU-STR-001 for exact numbering and denomination of ISVs.

Note 4: Validity of CLDs covering product QMS are based on the definition as stated in part 2) of the RFU.

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SUBSYSTEM INFRASTRUCTURE

TSI INF 2011/275/EU, AMENDED BY 2012/464/EU
TSI INF (EU) NO 1299/2014, AMENDED BY (EU) 2019/776 AND (EU) 2023/1694
TSI SRT (EU) NO 1303/2014, AMENDED BY (EU) 2016/912 AND (EU) 2019/776
TSI PRM (EU) NO 1300/2014, AMENDED BY (EU) 2019/772 AND (EU) 2023/1694

	ITEM	TYPE	VALIDITY			
			TSI INF 2011/275/EU	TSI INF (EU) No 1299/2014	TSI SRT (EU) No 1303/2014	TSI PRM (EU) No 1300/2014
Constituents	EC Type Examination Certificate	1/CB	unlimited	7 years	-	5 years
	Quality Management System Approval	4/CD	2 years	2 years	-	2 years
	EC Certificate of Conformity	5/CF	unlimited	unlimited	-	unlimited
	EC Design Examination Certificate	2/CH1	-	-	-	5 years
	Quality Management System Approval	4/CH	2 years	2 years	-	2 years
	EC Certificate of Suitability for Use	-				
Subsystems	EC Certificate of Verification	6/SG	unlimited	unlimited		
	EC Design Examination Certificate	2/SH1	unlimited	unlimited		
	Quality Management System Approval	4/SH1	2 years	2 years		
	EC Certificate of Verification	6/SH1	2 years	2 years		

Note 1: The same validity as defined for each certificate for subsystems shall be applied mutatis mutandis to ISV. Please refer to RFU-STR-001 for exact numbering and denomination of ISVs.

Note 2: Validity of CLDs covering product QMS are based on the definition as stated in part 2) of the RFU.

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SUBSYSTEM ENERGY

TSI ENE 2011/274/EU, AMENDED BY 2012/464/EU

TSI ENE (EU) NO 1301/2014, AMENDED BY (EU) 2018/868,(EU) 2019/776 AND (EU) 2023/1694

INCLUDING TSI SRT (EU) NO 1303/2014, AMENDED BY (EU) 2016/912 AND (EU) 2019/776

			TSI ENE 2011/275/EU	TSI ENE (EU) No 1301/2014
	ITEM	TYPE	VALIDITY	
Constituents	EC Type Examination Certificate	1/CB	unlimited	7 years
	EC Design Examination Certificate	2/CH1	unlimited	7 years
	Quality Management System Approval	4/CH 4/CH1	2 years	2 years
Subsystems	EC Certificate of Verification	6/SG	unlimited	unlimited
	EC Design Examination Certificate	2/SH1	unlimited	unlimited
	Quality Management System Approval	4/SH1	2 years	2 years
	EC Certificate of Verification	6/SH1	2 years	2 years

Note 1: The same validity as defined for each certificate for subsystems shall be applied mutatis mutandis to ISV. Please refer to RFU-STR-001 for exact numbering and denomination of ISVs.

Note 2: Validity of CLDs covering product QMS are based on the definition as stated in part 2) of the RFU.

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SUBSYSTEM ROLLING STOCK – LOCOMOTIVES AND PASSENGER ROLLING STOCK

TSI LOC&PAS 2011/291/EU, AMENDED BY 2012/88/EU AND 2012/464/EU

TSI LOC&PAS (EU) NO 1302/2014, AMENDED BY (EU) 2016/919, (EU) 2018/868, (EU) 2019/776, (EU) 2020/387 AND (EU) 2023/1694

INCLUDING TSI NOISE (EU) NO 1304/2014, AMENDED BY (EU) 2019/774 AND (EU) 2023/1694

INCLUDING TSI PRM (EU) NO 1300/2014, AMENDED BY (EU) 2019/772 AND (EU) 2023/1694

INCLUDING TSI SRT (EU) NO 1303/2014, AMENDED BY (EU) 2016/912 AND (EU) 2019/776

			TSI Loc&Pas 2011/291/EU	TSI Loc&Pas (EU) No 1302/2014	
			Amendments 2012/88/EU 2012/464/EU	Amendments (EU) 2016/919 (EU) 2018/868 (EU) 2019/776 (EU) 2020/387	Amendments (EU) 2016/919 (EU) 2018/868 (EU) 2019/776 (EU) 2020/387 (EU) 2023/1694
	ITEM	TYPE	VALIDITY		
Constituents	EC Type Examination Certificate	1/CB	5 years	5 years	unlimited [1)]
	Quality Management System Approval	4/CD	2 years	2 years	
	EC Certificate of Conformity	5/CF	unlimited	unlimited	
	EC Design Examination Certificate	2/CH1	5 years	5 years	unlimited [1)]
	Quality Management System Approval	4/CH 4/CH1	2 years	2 years	
	EC Certificate of Suitability for Use	7/CV	5 years	5 years	unlimited [1)]
Subsystems	EC Type Examination Certificate	1/SB	7 years	7 years	unlimited [2)]
	Quality Management System Approval	4/SD	2 years	2 years	
	EC Certificate of Verification	6/SD	2 years	2 years	
	EC Certificate of Verification	6/SF	unlimited	unlimited	
	EC Design Examination Certificate	2/SH1	unlimited	7 years	unlimited [2)]
	Quality Management System Approval	4/SH1	2 years	2 years	
	EC Certificate of Verification	6/SH1	2 years	2 years	

[1)] Even if the end of validity in the NoBo CLD is unlimited Chapter 7.1.3.2. Annex V (EU) 2023/1694 applies for **Constituents**

(1) This point concerns an interoperability constituent which is subject to type or design examination or to suitability for use.

*(2) Unless otherwise explicitly specified in the **revision** of this TSI or of the TSI NOI or the TSI PRM, the type or design examination or suitability for use remains valid even if a revision of these TSIs enters into force. During this time, new constituents of the same type are permitted to be placed on the market without a new type assessment.*

Note:The NoBo CLD is valid for the Object of Assessment as mentioned in the CLD and as long as compliance of the Object of Assessment with certification requirements, as stated in the CLD, is maintained by the Applicant. The validity may become limited by future versions of the certification requirements.

2) Even if the end of validity in the NoBo CLD is unlimited Chapter 7.1.3.1.3 Annex V (EU) 2023/1694 applies for: **Subsystems**

*(1) When a revision of this TSI or of the TSI NOI or the TSI PRM comes into force, the EC type or design examination certificate for the subsystem remains valid unless it is required to be revised according to the **specific transition regime** of a TSI change.*

(2) Only the changes to the TSIs with a specific transition regime can apply to Rolling Stock in production phase or to Rolling Stock in operation.

Note 1: The NoBo CLD is valid for the Object of Assessment as mentioned in the CLD and as long as compliance of the Object of Assessment with certification requirements, as stated in the CLD, is maintained by the Applicant. The validity may become limited by future versions of the certification requirements.

Note 2: TSI LOC&PAS point 7.1.2.2 (11) may apply.

Note 3: The same validity as defined for each certificate for subsystems shall be applied mutatis mutandis to ISV. Please refer to RFU-STR-001 for exact numbering and denomination of ISVs.

Note 4: Validity of CLDs covering product QMS are based on the definition as stated in part 2) of the RFU.

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SUBSYSTEM CONTROL COMMAND AND SIGNALLING

TSI CCS 2012/88EU, AMENDED BY 2012/696/EU AND (EU) 2015/14
TSI CCS (EU) 2016/919, AMENDED BY (EU) 2019/776, (EU) 2020/387 AND (EU) 2020/420
TSI CCS (EU) 2023/1695

	ITEM	TYPE	VALIDITY
Constituents	EC Type Examination Certificate	1/CB	unlimited
	Quality Management System Approval	4/CD	2 years
	EC Certificate of Conformity	5/CF	unlimited
	EC Design Examination Certificate	2/CH1	unlimited
	Quality Management System Approval	4/CH1	2 years
Subsystems	EC Type Examination Certificate	1/SB	unlimited
	Quality Management System Approval	4/SD	2 years
	EC Certificate of Verification	6/SD	2 years
	EC Certificate of Verification	6/SF	unlimited
	EC Certificate of Verification	6/SG	unlimited
	EC Design Examination Certificate	2/SH1	unlimited
	Quality Management System Approval	4/SH1	2 years
	EC Certificate of Verification	6/SH1	2 years

Note 1: The same validity as defined for each certificate for subsystems shall be applied mutatis mutandis to ISV. Please refer to RFU-STR-001 for exact numbering and denomination of ISVs.

Note 2: Validity of CLDs covering product QS are based on the definition as stated in part 2) of the RFU.