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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-065**

Issue 03

Date 04/03/2026

#### TITLE

AUDITING OF QUALITY MANAGEMENT SYSTEMS BY THE NOBO

#### ORIGINATOR

NB RAIL STRATEGY SUBGROUP

#### SUBJECT RELATED TO

IOD 2016/797  
Modules Decision 2010/713/EU  
ERA Assessment Scheme  
All TSIs

#### AMENDMENT RECORD:

ISSUE 02, IOD REFERENCES UPDATE

ISSUE 03, FULL REVISION OF THE RFU AND MERGER WITH RFU-STR-036.

#### DESCRIPTION AND BACKGROUND EXPLANATION

### References

Reference documents used in this RFU (without TSI references):

- /D01/ IOD: Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union, amended by (EU) 2020/700.
- /D02/ Modules Decision 2010/713/EU: Commission decision of 9 November 2010 on modules for the procedures for assessment of conformity, suitability for use and EC verification to be used in the technical specifications for interoperability adopted under Directive 2008/57/EC of the European Parliament and of the Council.
- /D03/ ERA AS: Technical document; Requirements for conformity assessment bodies seeking notification, MNB – ERA Assessment Scheme 000MRA1044 2.0.
- /D04/ EN ISO/IEC 17021-1:2015: Conformity Assessment Requirements for bodies providing audit and certification of management systems-Part 1: Requirements (applicable sections of this standard according to ERA AS /D03/.
- /D05/ EN ISO/IEC 17065:2012: Conformity assessment – Requirements for bodies certifying products, processes and services.
- /D06/ EU Blue Guide: The ‘Blue Guide’ on the implementation of EU product rules 2022 (2022/C 247/01) of 29.06.2022.
- /D07/ EN ISO 9001:2015: Quality management systems – Requirements.
- /D08/ EN ISO 19011:2018: Guidelines for auditing management systems.



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- /D09/ RFU-STR-001 EC Certificates / QMS-approvals / ISVS, Issue 20 and following issues, unless changes that require the updating of this RFU.
- /D10/ RFU-STR-011 Content of the NoBo-File and of the NoBo-Conformity Assessment Report, Issue 15 and following issues, unless changes that require the updating of this RFU.
- /D11/ RFU-STR-059 APPLICATION OF H MODULES FOR DESIGN EXAMINATION and the ERA TO attached: ERA/OPI/2011-01/INT.
- /D12/ RFU-STR-60 Duration of Validity of Certificates and ISVs, Issue 15 and following issues.
- /D13/ RFU-STR- 88 Scope of Conformity Assessment Requirements for the Conformity Assessment by NoBos, Issue 02 and following issues, unless changes that require the updating of this RFU.
- /D14/ RFU-STR-092 Use and comparison of the different assessment modules for subsystems, Issue 03 and following issues, unless changes that require the updating of this RFU.
- /D15/ RFU-STR-700 Guidance for application of type examination (CB / SB) and conformity to type based on quality management system of the production process (CD/SD) by two different applicants, Issue 4 and following issues, unless changes that require the updating of this RFU.
- /D16/ Decision 768/2008/EC: Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC.
- /D17/ Decision (EU) 2023/2584: Commission Implementing Decision (EU) 2023/2584 of 15 November 2023 on harmonised standards for the interoperability of the rail systems drafted in support of Directive (EU) 2016/797 of the European Parliament and of the Council. Amended by Decision (EU) 2025/424: Commission Implementing Decision (EU) 2025/424 of 4 March 2025 amending Implementing Decision (EU) 2023/2584 as regards an update of the referenced standards and the addition of new referenced standards.
- /D18/ Regulation (EU) 2018/545: Commission Implementing Regulation (EU) 2018/545 of 4 April 2018 establishing practical arrangements for the railway vehicle authorisation and railway vehicle type authorisation process pursuant to Directive (EU) 2016/797 of the European Parliament and of the Council .
- /D19/ IAF MD 5: IAF MD 5:2023 Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems.
- /D20/ IAF MD 1: IAF MD 1:2023 IAF Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization.



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- /D21/ Opinion ERA/OPI/2025-6: Opinion ERA/OPI/2025-6 of the European Union agency for Railways for the European Commission regarding the combination of modules for assessment of conformity and suitability for use of interoperability constituents and EC verification of subsystems.
- /D22/ Railway Safety Directive 798/2016: Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety (recast)
- /D23/ EN ISO 22163: EN ISO 22163:2024 Railway applications - Railway quality management system - ISO 9001:2015 and specific requirements for application in the railway sector (ISO 22163:2023) (IRIS).

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## GENERAL BACKGROUND

Besides Inspection and Certification, Auditing is an essential conformity assessment method used by NoBos.

Only if these Audits have identified that the QMS activities within the Audit Scope complies with the Audit Criteria, the NoBo may issue a related 'QMS Approval' (this is a specific format of certification, refer to CLDs type 4 and 8.4 as defined in RFU-STR-001 /D09/).

To support the common application of the ERA AS /D03/ by all NoBos and in order to avoid diverging approaches which could undermine the trust into the whole NoBo Certification process, NB-Rail establishes in this RFU a uniform approach which shall be applied by all NoBos for the audit activities, regardless of the NoBo being Accredited or Recognised.

*Note: This document is intended to be applied by competent NoBo Managers, Technical Lead Evaluators (TLEs), Lead Auditors, Auditors and Technical Experts assigned to them. It may also be useful for Applicants, for Auditors in Training and for other interested parties (e.g. equivalent DeBo experts).*

*In order to avoid repeating those requirements which are defined in the ERA AS /D03/, this document employs references to its relevant content.*

## 'IOD QMS APPROVAL' WITHIN THE SCOPE OF IOD (EU) 2016/797

Some voices claim that 'IOD QMS Approval' by a NoBo is identical to an EN ISO 9001 /D07/QMS certification. **This is not the case.**

The '**Approval of the Quality Management System**' within the scope of IOD /D01/ and Modules Decision 2010/713/EU /D02/ has a distinctly different objective from an EN ISO 9001 /D07/ QMS certification:

The focus of the 'IOD QMS Approval' is related to the continuous **TSI CONFORMITY OF PRODUCTS** that are produced according to a **SPECIFIC TSI CONFORM DESIGN TYPE** by the Manufacturer using its **PRODUCTION-QMS**.

For certain Modules the Audit Scope covers additionally also the **DESIGNING-QMS** for the designing of that **SPECIFIC TSI CONFORM DESIGN TYPE**.

(The focus of an EN ISO 9001 /D07/ QMS certification is aiming for customer satisfaction and continuous improvement of the **QMS of a company in general** and is **not focussed on a specific product conformity or a specific design type conformity with the IOD /D01/ or with the TSIs.**)



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The presence of an EN ISO 9001 /D07/ QMS certification can in this regard be considered as supportive for an 'IOD QMS Approval', but not as equivalent.

Despite being supportive, it is not required by the IOD or by the TSIs that an EN ISO 9001 /D07/ QMS certification is present at an Auditee.

In short: The IOD QMS Approval shall provide confidence - based on audit and subsequent certification through an independent & competent NoBo (ERA AS /D03/, annex A) - that the Auditees have demonstrated their ability to design / produce (often in large quantity series production) TSI conform products which are in all their relevant aspects identical to that TSI conform design type on which they are based. (refer to "H.7.1- Audit objectives" and "H.7.2. Audit scope" of Annex H of the ERA AS /D03/ and the individual Modules of the Modules Decision 2010/713/EU /D02/).

### RFU PROPOSAL

The NoBo shall apply ERA AS /D03/ Annex H for auditing in combination with the following clarifications.

## **1 ESTABLISHMENT OF THE 'SET OF CONTRACTUAL DOCUMENTS' BETWEEN APPLICANT AND NOBO FOR AUDIT ACTIVITIES (APPLICATION, OFFER, OFFER REVIEW, ACCEPTANCE)**

It is mandatory that all NoBo activities are agreed by both sides in writing and in a legally binding format between

- a) NoBo and Applicant, or
- b) NoBo and the Applicant's Representative.

In relation to audit activities and subsequent certification of the Audit Scope, this agreement shall also include the duties and responsibilities for all sides during the audit and also after the certification has been issued. These duties and responsibilities are in detail defined in the ERA AS /D03/ and include elements as e.g. free and open access of the NoBo's teams to the Auditee's Locations during the auditing and also after(!) certification for unexpected visits. Such access shall also cover any Auditee's Locations (Auditees may be Design Organisations, Manufacturers and/or Significant Subcontractors to them).



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It is not the normal case that the Applicant provides an Application to the NoBo, which already includes all the information elements that are defined by IOD /D01/, the Modules Decision 2010/713/EU /D02/, the ERA AS /D03/ and the EN ISO/IEC 17021-1 /D04/.

Further, an application alone is not sufficient to establish a binding contract between Applicant and NoBo which fulfils the aforementioned requirements.

Therefore, the term “Application” is understood here in a general sense and includes already a potential or intending Applicant’s request for a NoBo to prepare an offer for performing the conformity assessment service.

It is the normal case that the application is only one aspect amongst others which shall be contained within the set of contractual documents.

This set of contractual documents is normally established step-by-step. This is typically starting with the Applicant providing initial basic information on the project, the NoBo in return making a service offer which includes assumptions for any missing information, the Applicant accepts (if the offer was acceptable) that offer and provides an Application together with the agreement to provide any outstanding information during the project progress.

This step-by-step completion of the set of contractual documents is acceptable as long as:

- all required information becomes available to the NoBo in good time during the project progress as necessary to proceed to the next conformity assessment step

and

- all information is completely available to the NoBo **at the end of the project evaluation activities AND in good time before any certification decision is taken by the NoBo.**

*Note: This step-by-step approach can also be used for the receipt by the NoBo of:*

- *the applicant’s technical documentation for the certified design type which is associated with the Audit Scope and*
- *a copy of the EC-type examination certificate (and its associated NoBo File/ NoBo Conformity Assessment Report)*



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*(both points are defined to be provided by the Applicant to the NoBo according to point 3.1 of Modules Decision 2010/713/EU /D02/ modules CD and SD).*

*Accordingly, under the conditions described under the following points 1.3.4 and 1.3.5, the activities for modules CB/SB and CD/SD can take place in parallel.*

*It is understood that such a parallel work is expected by IOD /D01/, point 3 of Art. 15: “Task of the notified body responsible for the ‘EC’ verification of a subsystem shall begin at the design stage [under modules CB/SB] and cover the entire manufacturing period [under modules CD/SD] through to the acceptance stage before the subsystem is placed on the market or in service. [...]”*

*However, the certification decision on CB/SB must have been taken BEFORE the certification decision module CD/SD can be taken. As long as this sequence is maintained, the certification decisions on CB/SB and CD/SD can be taken shortly after each other, even on the same date.*

*The word “date” in section 5.1.5 of the EU Blue Guide /D06/ should not be misunderstood to require the NoBo to wait 24h between these two certification decisions.*

*Further, it is frequently the case that during the Design Stage, the Applicant defines product-specific production methods and/or production related evaluation tests on the basis of e.g.:*

- *results of the requirement capture activities;*
- *lessons learned from Type Test results;*
- *lessons learned from Verification and Validation results.*

*It is important for the NoBo Audit Team to be fully aware on such product-specific production methods and/or production related evaluation tests to make a product specific audit of the designing and/or production QMS associated with the IC(s), respectively Subsystems(s) (=Object of Assessment as defined below in ‘section 1.1 Object of assessment’). This awareness can be only obtained by the NoBo Audit team in close cooperation with the Inspection Team of the same NoBo.*

For the audit activities the required information within the set of contractual documents that is established between Applicant and NoBo shall include at least the determination of:

- the identification of the **Applicant** for Certification,



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- (if applicable) the identification of the **Applicant's Representative**,
- the **Module(s)** that the NoBo shall apply during the auditing
- the **TSI(s)** that the NoBo shall apply during the auditing
- the **Audit Criteria** that the NoBo shall apply during the auditing
- the definition of the included **IC(s)**, respectively **Subsystem(s)**, (or part(s) thereof in case of ISV)
- the **Audit Scope associated with the designing and/or production QMS of the IC (s), respectively Subsystem (s) (=Object of Assessment as defined below in 'section 1.1 Object of assessment')**.

Refer to the following sections for details on the topics Object of Assessment and Audit Scope associated to this Object of Assessment.

### 1.1 OBJECT OF ASSESSMENT



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The Object of Assessment (OoA) shall be the QMS for

- designing (in case of Modules CH1, SH1)
- production (in case of Modules CD, CH, CH1, SD, SH1)

associated either to:

- a) an **INTEROPERABILITY CONSTITUENT (IC)** or
- b) a **SUBSYSTEM (SubSys)**, or a part of it (in case of ISV).

*Examples are:*

*-the INF subsystem for the line 'abc' between km15.211 and km25.476,*

*-the CCT subsystem, part train protection of line 'abc' between km15.211 and km25.476,*

*-the CCO subsystem ETCS installation 'abc' on the trainset type 'efg',*

*-the RST IC freight waggon wheelset 'abc' of manufacturer 'edf'.*

It is not relevant for the NoBo audit if a specific Product-Design is intended for production of only one single Product or for a mass production of multiple identical products.

*Note: It is permitted, that the stakeholders use different vocabulary instead of 'product' (e.g. 'installation') or instead of Product-Design (e.g. 'vehicle type, version, variant, configuration'). To support the readability of this RFU, only the generic term 'Product-Design' is used.*

When the same Applicant demands the same NoBo to perform several parallel projects relating to different ICs or respectively Subsystem at the same time, it is a permitted and also a normal approach, that the NoBo combines these assessment activities. (E.g. where the same Applicant demands the same NoBo to conformity assess several similar Wagon Wheel -Designs in parallel.)

The NoBo shall take care to ensure that even in such a case all contractual documents/ checklists/ reports/ files/ CLDs/ etc. clearly identify all the different ICs or respectively Subsystem.

If a ICs or respectively Subsystem design is at the time of contracting not fully specified yet, at least the outline of the design must be defined at the time of contracting and there shall be an agreement that the design will become fully defined during the project progress and in good time before any NoBo certification decision can be taken.



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*Note: Examples for possible contractual text relating to this topic:*

*“the subsystem types of freight wagon ‘ABC1234’ and ‘ABC1235’ to be produced at the same location of Manufacturer ABC”*

*“the subsystem type locomotive ‘ABC4567’ to be produced at the Manufacturer’s Main Location ABC-X and also at the Manufacturers Further Location ABC-Y”*

*“several IC design-types of Concrete Sleeper – the exact design-type definitions will be agreed during the project progress - to be designed by Design Organisation ABC and to be produced inhouse at the Manufacturer ABC and also additionally at the second Manufacturer DEF”*

## 1.2 AUDIT SCOPE ASSOCIATED TO THE OBJECT OF ASSESSMENT

In addition to each Object of Assessment its associated AUDIT SCOPE shall be defined in the set of contractual documents and in the NoBo’s Audit Program/ NoBo Conformity Assessment Report / NoBo File / NoBo CLD types 4 or 8.4.

The Audit Scope shall identify as appropriate across all the Auditees that are involved in the project

- a) all the Activities to be audited,
- b) all the Auditees to be audited,
- c) all the Auditee’s Locations to be audited.

The Audit Scope is expected to be initially proposed by the Applicant. The NoBo shall check this information and, if it is not complete, the Applicant is expected to define the missing elements. The final Audit Scope shall cover all the above elements and it shall be acceptable to the NoBo.

### 1.2.1 ACTIVITIES TO BE AUDITED



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a) Under the **Modules CH\*, CH1, SH1** the Audit Scope shall include:

**All QMS activities for the designing of an IC, respectively Subsystem** (in conformity with the relevant & applicable TSI requirements for designing)

**AND**

**all QMS activities for the production of one or multiple Products in conformity with the design of the same IC, respectively Subsystem** (in conformity with the relevant & applicable TSI requirements for the production).

As the design activities include the performance of Evaluation Tests and the analysis of their results, at these modules the NoBo shall also audit how the Auditee implements the performance of these Evaluation Tests in their QMS according to the related requirements of the ERA AS /D03/, Annex F, which refers to the applicable requirements of EN ISO/IEC 17025.

In this regard, the NoBo Audit Team shall take the requirements of RFU-STR-022 for Evaluation Testing, mutatis mutandis, as Audit Criteria for the associated elements of the Auditee's QMS.

*Note: During the auditing, Evidence Tests and Evaluation Tests must be treated separately.*

*With these modules, the NoBo cannot directly control the performance of the Evaluation Tests but the NoBo has the duty to audit that the Auditee controls all the Evaluation Tests in an identical way how the NoBo would have done it. This approach ensures that Evaluation Tests performed under the control of the Auditee are performed according to one of the four permitted alternatives as indicated in section 3 of RFU-STR-022. Further, this ensures that the Auditee uses the requirements of Annex 2 of RFU-STR-022 as part of their QMS for the Evaluation Tests that are not performed in an accredited Test Laboratory. This applies irrespectively of whether the Evaluation Tests are performed: by internal resources of the Auditee or by outsourced resources.*

b) Under the **Modules CH\*, CD, SD** the Audit Scope shall include:

**All QMS activities for the production of one or multiple Products** in conformity with the **design of the same IC, respectively Subsystem** (in conformity with the relevant & applicable TSI requirements for the production of products).



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*Note: related to all Modules mentioned under b): As the Audit Scope does not include design activities, only Evidence Tests and no Evaluation Tests would be expected in the Audit Scope.*

*Note on CH\*: In the current TSIs module CH is only permitted to be applied when the associated product design was already established before the TSI became active. Therefore, for the current TSIs only case b) applies. However the definition of CH in the Modules Decision /D02/ is also compatible with case a), should a future TSI version include this.*

### 1.2.2 AUDITEES TO BE AUDITED

According to ERA AS, H.1 /D03/, the NoBo shall have received from the Applicant a 'project breakdown structure' determining each involved Design Organisation, each involved Manufacturer and each Significant Subcontractor (to any of the aforementioned organisations).

- a) Under the **Modules CH, CH1, SH1** the Audit Scope shall include as **Auditee** any involved '**Design Organisation**' (this can be the Applicant or a different organisation), **their legal Name/ Main Location/ Further Location(s)**.

*Note: 'Design Organisation' is the term used in RFU-STR-011 /D10/. This includes "name and address of the designer(s), Type-Testing body(ies) and verification and validation body(ies)" as defined in ERA AS, H.1 /D03/.*

- b) Under the **Modules CD, CH, CH1, SD, SH1** the Audit Scope shall include any **Auditee 'Manufacturer'** (this can be the Applicant or a different organisation), **legal Name/ Main Location/ Further Location(s)** for their production activities within the Audit Scope.

*Note: 'Manufacturer' is the term used in RFU-STR-001 /D09/ & 011 /D10/. This includes "name and address of the manufacturer(s); the project breakdown structure detailing the name and address of each involved entity for production, final product inspection and serial testing.*



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c) Under the **Modules CD, CH, CH1, SD, SH1** the Audit Scope shall include any **Auditee ‘Significant Subcontractor’ of a Design Organisation or a Manufacturer, its legal Name/ Main Locations/ Further Location(s)**. Significant Subcontractors may be involved in the project relating to:

- designing activities (under Modules CH, CH1, SH1)

and/ or

- production activities (under Modules CD, CH, CH1, SD, SH1)

within the Audit Scope.

*Note: According to the concepts included in the EU Blue Guide /D06/, the Applicant may design the Object of Assessment and manufacture conform Products internally or the Applicant may decide to have this done by a different Design-Organisation or a different Manufacturer. Additionally either of these may decide to subcontract any of these activities to subcontractors in part or fully. (In the EU Blue Guide /D06/ the term “Manufacturer” must be understood to be equivalent to the term “Applicant” as defined in the IOD /D01/)*

*Obviously not all subcontractors have a significant involvement within the project designing and/ or production activities (e.g. the production of a screw to be included in the Object of Assessment (=Product-Design) may not be a significant involvement).*

*The NoBo shall audit all those subcontractors that have a significant involvement in the designing and/ or production activities in this project.*

*‘Significant Subcontractor’ is the generic term taken from RFU-STR-011 /D10/. This includes “main sub-supplier” as defined in ERA AS, H.1 /D03/ and “relevant entities concerned” in “Audits are required to include an assessment visit to the premises of the relevant entities concerned” as defined in ERA AS, H.5 /D03/.*

*A Test-Lab performing Evaluation Testing may also be a Significant Subcontractor.*

Significant Subcontractors are those of the subcontractors which are performing a significant scope/ proportion/ part of the overall project designing and manufacturing activities. The Applicant is expected to identify all potentially Significant Subcontractors to the NoBo.



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*Note: This decision should be informed by the project breakdown structure and any additional information that the NoBo has obtained from the Applicant and other sources.*

*Typical Examples for a Significant Subcontractor are:*

- *The Product-Design of the IC(s), respectively Subsystem(s), is 60% designed by that subcontractor (and the remaining 40% by the Design Organisation),*
- *A product is 35% produced by that subcontractor (and 65% by the Manufacturer).*

*The decision of the NoBo to not determine a subcontractor as significant for NoBo auditing may in part be based on a demonstrated good ability of the Auditee 'Design-organisation' (under Modules CH, CH1, SH1) and/or the Auditee 'Manufacturer' (under Modules CD, CH, CH1, SD, SH1) to manage, control and audit that subcontractor.*

Each of the Auditees Design Organisation, Manufacturer, Significant Subcontractor shall always be an identifiable legal entity. It shall therefore NOT be acceptable to a NoBo that an Auditee is just defined as a 'group-of-companies ABC' or as a 'brand-name ABC' (which is not itself a legal entity).

*Note: The Applicant and the Design Organisation, Manufacturer may or may not be the same legal entity.*

The Applicant and the Design Organisation, Manufacturer, Significant Subcontractor may be within the same group of companies. In this case it is of importance to assign the correct legal Names and Audit Scope elements to these different legal entities.

Where within a group of companies one legal entity 'A' subcontracts to a different legal entity 'B', this is still subcontracting and not performing the activities internally (!).

All Significant Subcontractors are expected to be identified by the Applicant to the NoBo. The NoBo shall check this information and, if it is not complete, the Applicant is expected to define the missing elements.. The final Audit Scope shall cover all Significant Subcontractors and it shall be acceptable to the NoBo.

The Auditees shall be identified in the section 1 of the NoBo File/NoBo Conformity Assessment Report according to RFU- STR-011.



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### 1.2.3 AUDITEE'S LOCATIONS

Every Auditee has one or several locations (sometimes in the industry called 'sites'), where it performs its parts of the activities to be audited.

The Auditee's Locations shall include "all project related sites" as defined in ERA AS, H.1 /D03/.

**Main Location:** This is that leading location where the Auditee established the QMS and from where the Auditee directs and controls all its activities including activities at other locations.

Normally an Auditee has one QMS defined from one Main Location, but it is possible, that an Auditee has decided to permit several locations to establish their own separate QMSs. In such a case the Auditee has several Main Locations.

**Any Main Location must be within the Audit Scope.**

**Further Locations:** This includes all further locations where the Auditee performs project related activities under direction and control by its Main Location. Any Further Location must use the same QMS as defined by its Main Location.

**Any such Further Location must be within the Audit Scope.**

The Main Location for each Auditee and, if present, any Further Locations of the same Auditee are expected to be identified by the Applicant to the NoBo. The NoBo shall check this information and, if it is not complete, the Applicant is expected to define the missing elements. The final Audit Scope shall cover all the above elements and it shall be acceptable to the NoBo.



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#### **1.2.3.1 AUDITEE'S MOBILE TEAMS**

Any Auditee's Main / Further Location may have mobile teams that are dispatched, directed and controlled from that location. These mobile teams may work for short time periods on locations that are neither a Main / Further Location (e.g. at one day only to perform work on a vehicle at its over-night stabling position).

Where such mobile teams are present in the project, the number of such teams and their range of activities are expected to be identified by the Applicant to the NoBo. The NoBo shall check this information and, if it is not complete, define which elements shall be added. The final Audit Scope shall cover all the above elements and it shall be acceptable to the NoBo.

Mobile Teams that work for a longer time at the same location – the NoBo may take a duration of >3Months as a 'longer time' - shall be considered as being an Auditee's Main or Further Location and no longer as a Mobile Team.

Mobile Teams that use a separate QMS from that of their leading Main / Further Location shall be treated as another Main Location (on the reason, that they have established their own QMS).

The NoBo shall determine based on the available information, whether the status Mobile Team, Further Location or Main Location applies.

#### **1.2.3.2 MULTIPLE SITE SAMPLING BETWEEN AUDIT LOCATIONS**

In accordance with Modules Decision /D02/ and Section "H.5. QMS-Multi-site sampling" of Annex H of the ERA AS /D03/, audits are required to *"include an assessment visit to the premises of the relevant entities concerned"*.

As result of this requirement, the on-site auditing shall be performed at any Main and Further Audit Locations.

The Main Location of each Auditee shall be always audited at any initial or re-certification audit (no multiple site sampling is permitted).

The multiple site sampling is permitted between "Further Locations" under the following conditions:



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- 1- An identified central function, located at the Main Location, shall have organizational authority to define, establish, direct, control, and maintain a single management system applicable also to all Further Locations.
- 2- The single management system shall be subject to centralized management review conducted under the responsibility of the Main Location.
- 3- All Further Locations shall be subject to the internal audit programme managed under the responsibility of the Main Location.
- 4- The sample of Further Locations shall be fully representative of any not-sampled Further Locations. Therefore, the sample shall include:
  - (i) Any activity of the Auditee within the Audit Scope at least at one Further Location.
  - (ii) Any team of the Auditee performing the afore mentioned activities.
  - (iii) A good proportion of all Further Locations. This shall consider: significant variations in the size of the locations; variations in shift patterns and work procedures; maturity of the quality management system and the NoBo's knowledge of the Auditee; differences in culture, language and regulatory requirements; whether the Further Locations are permanent or temporary.
- 5- The central function at the Main Location shall ensure the collection and analysis of data from all Further Locations and shall be able to demonstrate its authority and capability to initiate organizational change as required at these locations, including but not limited to:
  - (i) QMS documentation and QMS changes;
  - (ii) complaints;
  - (iii) evaluation of corrections, corrective actions and preventive actions;
  - (iv) internal QMS audit planning and evaluation of the internal audit results;
  - and
  - (v) any applicable statutory and regulatory requirements.
- 6- At the re-certification, the sample of Further Locations should be rotated by the NoBo, selecting in preference such Further Locations that were not audited in the previous cycles (the aim should be to eventually have covered all Further Locations within the first or second re-certification).



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7- The sample selection does not have to be made at the start of the audit process; it may be determined after completion of the audit of the central function at the Main Location or at a later point in time. In all the cases, the Auditee shall be kept informed, as soon as possible, about the sites selected by the NoBo for sampling.

For each audited Main and Further Location, the overall minimum Audit Time and Audit Duration shall be individually calculated.

Any planned and performed Multiple-Site Sampling and its justification shall be documented in the Audit Programme.

### 1.3 AUDIT CRITERIA

The Conformity Assessment Requirements for Auditing are called **Audit Criteria**.

The NoBo shall audit the various Auditee's activities within the Audit Scope and determine if these activities are conform with the Audit Criteria.

The selection of the Audit Criteria is expected to have been determined by the Applicant according to ERA AS, H.7.3 /D03/.

Only if this selection follows the requirements of ERA AS, H.7.3 /D03/ the NoBo may apply this selection for its auditing:

#### 1.3.1 AUDIT CRITERIA DEFINED IN THE MODULES DECISION 2010/713/EU (=GENERAL QMS AUDIT CRITERIA)

Modules Decision 2010/713/EU /D02/ states that the Applicant (and also the NoBo) may *“presume conformity with those requirements in respect of the elements of the quality management system that comply with the corresponding specifications of the national standard that implements the relevant quality management standard, harmonised standard and/or technical specification.”*



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*Note: Most Applicants select in this regard a 'national standard' version of EN ISO 9001 /D07/ or EN ISO 22163 /D23/ Both standards are also compatible with ERA AS, Annex I /D03/.*

To improve the readability of this RFU, in the following only EN ISO 9001 will be mentioned, but **all references to EN ISO 9001 will apply mutatis-mutandis also to EN ISO 22163 /D23/.**

*Note: For taking into account of ISO 9001 QMS certificates already granted to the applicants by other Certification Bodies, see the section ' 2.3 acceptance of qms Approvals and/or QMS certificates already granted to an Auditee' below.*

### 1.3.2 AUDIT CRITERIA DEFINED IN THE IOD /D01/ (= AUDIT CRITERIA DERIVED FROM THE 'ESSENTIAL REQUIREMENTS')

Article 3.1:

***"The Union rail system, subsystems and interoperability constituents including interfaces shall meet the relevant essential requirements."***

Article 2 (9):

***"essential requirements' means all the conditions set out in Annex III which must be met by the Union rail system, the subsystems, and the interoperability constituents, including interfaces;"***

The Essential Requirements are not sufficiently detailed to directly serve as Audit Criteria.

They need to be broken down into useable Audit Criteria. The IOD /D01/ defines two paths for this breaking down:

#### 1.3.2.1 AUDIT CRITERIA DEFINED IN THE TSIS

***IOD /D01/,article 4.3: "each TSI shall: [...] (b) lay down essential requirements for each subsystem concerned and its interfaces in relation to other subsystems; (c) establish the functional and technical specifications to be met by the subsystem and its interfaces in relation to other subsystems."***



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*IOD /D01/, article 2 (11): “technical specification for interoperability’ (TSI) means a specification adopted in accordance with this Directive by which each subsystem or part of a subsystem is covered in order to meet the essential requirements and ensure the interoperability of the Union rail system;”*

TSIs in this regard from case to case include directly Audit Criteria or references to standards that include such Audit Criteria.

*Note: Two examples in this regard are:*

- *Some TSIs define Audit Criteria for the designing of safety critical design elements included in EN 50126-1,*
- *Some TSIs define Audit Criteria for production of wheelsets by referencing the related criteria in EN 13260.*

### **1.3.2.2 AUDIT CRITERIA DEFINED IN STANDARDS WHICH PROVIDE PRESUMPTION OF CONFORMITY (PUBLISHED IN EU OFFICIAL JOURNAL)**

*IOD /D01/, article 17: “Presumption of conformity: Interoperability constituents and subsystems which are in conformity with harmonised standards or parts thereof, the references of which have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the essential requirements covered by those standards or parts thereof.”*

Current lists of such standards, which give this presumption of conformity, are published and updated from time to time in the EU Official Journal.

*Note: The list which is current at the time of drafting this RFU is: (EU) 2023/2584, amended by (EU) 2025/424 (/D17/).*

Such standards from case to case can include directly Audit Criteria and/or they can include references to other standards that in turn include such Audit Criteria.

*Note: Examples are:*

- *Audit Criteria for the designing of safety critical design elements are included in EN 50129,*



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- *Audit Criteria for manufacturing of rail butt-welds included EN 14587-2.*

### 1.3.3 COMBINED SET OF AUDIT CRITERIA

The Lead Auditor shall ensure that the Applicant has proposed a systematic combined set of all the Audit Criteria as defined in the previous subsections of this RFU.

*Note: Before NoBo auditing can take place, the NoBo must have progressed the NoBo inspection to a sufficient level.*

*The NoBo's inspection findings will very likely influence the selection of these Audit Criteria via section '1.3.2.1 Audit Criteria defined in the TSIs' and the Audit Criteria can therefore only be completely defined/ confirmed, when the Product-Design of the IC(s), respectively Subsystem(s), is completed or at least sufficiently mature to determine all associated Audit Criteria.*

Where this is not the case the Lead Auditor shall inform the Applicant and request improvement. If the situation persists, the Lead Auditor/ Auditors shall in the Audit Reporting propose to the certification team to either only issue an ISV for those QMS aspects that were so far suitably covered by Audit Criteria or to not issue a CLD due to the lack of a systematic combined set of all the Audit Criteria.

*Note: In any case it remains within the responsibility of the Applicant that a full combined set of Audit Criteria is available to the NoBo in good time.*

### 1.3.4 COMBINED SET OF AUDIT CRITERIA – PRACTICAL APPROACH IN CASE OF A SINGLE NOBO

In practice, a railway project normally lasts several years with designing and (at least initial) production proceeding in parallel.

*Note: Further in some projects only one single product will be produced (e.g. a CCT fixed installation subsystem). As this one product will already be required for V&V, Evaluation Testing and design related Evidence Testing, a parallel proceeding of NoBo inspection*



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*and NoBo auditing is required (otherwise the CCT fixed installation had to be build one time for V&V, Evaluation Testing and design related Evidence Testing to enable the completion of NoBo inspection, broken down and build a second time to allow the required production audit as a second NoBo activity – this situation has to be avoided).*

*On the other side it will not be possible to claim that a NoBo production audit did confirm that the manufactured products conform to the specified Product-Design of the IC(s), respectively Subsystem(s), if a NoBo production audit was done before the design has been fully assessed through NoBo inspection and all the combined Audit Criteria became known. Therefore, certain conditions need to be followed in this practical approach case.*

**Where one single NoBo has been contracted to perform the assessment of both modules SB + SD or CB + CD in the same project,** parallel NoBo design-type inspection and NoBo auditing of designing and/or production shall only be permitted under following conditions, according to Opinion ERA/OPI/2025-6 /D21/:

**Condition 1) The Technical Lead Evaluator shall ensure that the NoBo inspection team,** which performs the Product-Design inspection of the assessed IC(s), respectively Subsystem(s), and the **QMS Lead Auditor shall be and remain in regular contact until this product design is certified** and exchange relevant information on the maturity of the product design and the associated combined Audit-Criteria for the Product-Design of the IC(s), respectively Subsystem(s).

*Note - Example for an Audit Criteria derived during the NoBo inspection: If Evaluation Testing for a bogie structure design-type has shown that the Evaluation Test can only be passed when this specific bogie design-type becomes subject to special post-weld treatments for certain structural welds. The necessity to perform these treatments becomes an Audit Criteria for the production audit.*

*The NoBo Audit Team shall audit if and how this special treatment is correctly implemented as part of the Production-QMS.*

**Condition 2)** During Stage 1 of the initial QMS audit, the Technical Lead Evaluator together with the Audit Team shall evaluate and justify if the combined set of Audit Criteria have reached a **sufficient level of completeness to commence the Stage 2 on-site audit.**

**Condition 3)** The Technical Lead Evaluator and the Lead Auditor shall ensure that coordination between NoBo inspection activities (Module CB/SB or Module CH1/SH1 design- examination activities) and NoBo auditing (Module CD/SD or Module CH1/SH1 QMS assessment activities) takes place.



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The end-result of the inspection activities and their final impact on the combined Set of Audit Criteria must be fully considered before the NoBo auditing can be fully concluded.

Approval of the QMS shall also depend on the satisfactory completion of the NoBo inspection activities.

Findings on already performed NoBo audit activities shall therefore be reviewed by the Audit Team verifying the consistency with the end-result of the NoBo inspection activities.

*Note: The result of the above shall, at the conclusion of the NoBo Inspection and NoBo Auditing activities, be documented in the sections 4.2.Reporting on performed Inspections and 4.3 Reporting on performed Auditing of the NoBo conformity assessment report / NoBo File: according to RFU-STR11 /D10/.*

**Condition 4)** The sequence of decision making for the CLDs of the types 1, 2, 4 and 6 shall always be as follows:

- First, CLD 1 or 2, 8.1 or 8.2;
- Second, CLD 4, 8.4;
- Third, CLD 6, 8.6.

Therefore, CLD type 1 or 2 (8.1 or 8.2) shall be considered as one of the mandatory inputs to be provided for the review and decision to grant CLD type 4 (8.4), and, if applicable, CLD type 6 (8.6).

*Note: This sequence fulfils the requirements for sequencing within the Modules Decision /D02/ considering the that the word “date” in section 5.1.5 of the EU Blue Guide /D06/ can be interpreted as meaning ‘date and time’. If the sequential CLDs are made on the same date, then the NoBo must provide information on the CD, SD CLDs about this sequence. E.g. :*

- *By providing date and time of issue on all project connected CLDs,*
- *Or, by ensuring that all connected CLD numbers follow the sequence.*
- *Or, by ensuring that the CD, SD CLDs quote the earlier connected CLDs.*

*These conditions are fully consistent with point 5.1.5 of the EU Blue Guide /D06/ that states: “The conformity assessment body involved under module B is not necessarily the same as the one involved in the module that is used together with module B. The date of issue of*



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*the certificate of the module issued together with module B must always be later as the date of the module B certificate. Both certificates must be available before the first placing of the product on the market.*

*Note: RFU-STR-700 /D15/ addresses scenarios involving two different applicants in the application of Modules B and D.*

### 1.3.5 COMBINED SET OF AUDIT CRITERIA – PRACTICAL APPROACH IN CASE OF MULTIPLE NOBOS

Any NoBo performing auditing activities is, according to the requirements of the Modules Decision /D02/, expected to be given full access to the project technical documentation as well as the NoBo conformity assessment report, NoBo Files and CLDs of any previously involved NoBo.

The TLE and Lead Auditor shall ensure, that the Audit Team has access to these documents and can on that basis investigate, if the Set of Audit Criteria is complete or not and ensure completion if required. The NoBo auditing shall only commence, when these documents are available and the complete Set of Audit Criteria is known to the Audit Team.

Where multiple NoBos have been contracted to perform in parallel the assessment of both modules SB + SD or CB + CD in the same project, the same conditions identified in section ' 1.3.4 Combined Set of Audit Criteria – practical approach in case of a single nobo' above shall be applied and documented mutatis-mutandis according to Opinion ERA/OPI/2025-6 /D21/.

## 2 ESTABLISHMENT OF THE AUDIT PROGRAMME

An Audit Programme according to the requirements of the ERA AS /D03/ shall be prepared by the NoBo.

The NoBo shall apply:

- regarding audit program: section "H.3. QMS - Audit programme" of Annex H of the ERA AS /D03/



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- regarding audit time & duration: Section “H.4. QMS-Determining audit time” of Annex H of the ERA AS /D03/
- regarding multiple-site sampling: Section “H.5. QMS-Multi-site sampling” of Annex H of the ERA AS /D03/

in combination with the following sections of this RFU.

The Audit Programme may already be included as a systematic sub-element within either:

- Offer/Contract documents,
- an overall Assessment Plan for the complete EC-Verification Process,

if these documents address all requirements defined for an Audit Programme.

As the information in the Audit Programme does require updating to be kept up-to date, it may however be more practical to keep it as a separate document.

## 2.1 DETERMINATION OF AUDIT TIME AND AUDIT DURATION

*Note: Based on international guidance document IAF MD 5 /D19/, the terms “audit time” and “audit duration” have different separate meanings.*

The determination of the overall **Audit Time** and of the minimum **On-site Audit Duration** (= the minimum on-site proportion of that overall Audit Time) is a critical step in planning and executing audits under the IOD framework. It shall be based on objective, project-specific factors that reflect the size of the Auditee and complexity and scope of the activities to be audited. In accordance with ERA AS /D03/ and EN ISO/IEC 17021-1 /D04/, the following elements shall be applied:

- a) For any Auditee, the starting point for determining overall Audit Time shall be based on the number of staff members which are working at the respective Auditee Activities (this information is the most relevant input):

According to Section “H.4. QMS-Determining audit time” of Annex H of the ERA AS /D03/, the determination of overall Audit Time shall follow EN ISO/IEC 17021-1 /D04/ 9.1.4 in combination with IAF MD 5 /D19/. In this context, the NoBo shall consider



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the number of staff involved in the processes related of the Audit Scope of this project, and **NOT** the overall staff-count of the Auditee.

- b) According to IAF MD 5 /D19/, the basic overall Audit Time initially calculated based on the number of staff members involved in the audited processes may be adjusted to reflect significant reduction or increase factors should these apply to the Auditee.

The Section “H.7.4-Audit Topics” of the ERA AS /D03/ identifies a possible reduction if an Auditee ‘actually applies’ a relevant QMS for their activities that is already certified by an accredited ISO 9001 Certification Body.

‘Actually applies’ means in this context, that the NoBo auditing must have demonstrated, that the Auditee does actually apply the ISO9001 certified QMS in this Audit Scope.

*Note: Due to the sampling nature of the certification audit it is possible that not all areas of the Auditee were audited and therefore non-audited areas may actively or inadvertently not apply the certified QMS.*

If the corresponding EN ISO 9001 /D07/ QMS certificate fulfils the conditions in ‘section 2.3 acceptance of qms Approvals and/or QMS certificates already granted to an Auditee’ below, the NoBo may take into account the following approach:

The NoBo should not completely re-audit the full QMS already audited by the accredited ISO9001 certification body. For that purpose, Annex I of the ERA AS /D03/ indicates which EN ISO 9001 /D07/ audit criteria already covered during the EN ISO 9001 /D07/ certification will not need to be re-audited by the NoBo.

**However, all reduction shall be justified by the NoBo and the total reduction shall not exceed 30% of the basic overall Audit Time.**

- c) After applying the relevant increase and/or reduction factors, where applicable, the resulting adjusted overall Audit Time shall be divided into
- on-site auditing (= on-site Audit Duration)

and



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- off-site auditing (preparation time, document review, remote auditing and reporting).

Section 4.1 of IAF MD 5 /D19/ establishes that a minimum proportion of 80% of the overall Audit Time should be allocated to on-site auditing. However, due to the product-oriented approach of the IOD-auditing, a greater proportion of off-site auditing is necessary in order to:

- Identify the requirements related to specific product design activities (where relevant, depending on the modules applied);
- Audit the planning and performance of production and serial testing (e.g. identify conditions for production process as defined in a preceding assessment step, any specific tolerances, any need for specific skills or equipment required, available V&V documentation, serial test instructions, samples of product serial testing records).
- Significant time is required for coordination and exchange of the product related knowledge between the NoBo's inspection and audit teams.

It is therefore considered that the appropriate minimum proportion of on-site auditing time (on-site Audit Duration) **may be reduced to a minimum of 50% of the total calculated and adjusted overall Audit Time** for IOD-auditing.

d) Regarding the established overall Audit Time and on-site Audit Duration, Section "H.4. QMS-Determining audit time" of Annex H of the ERA AS /D03/ amplifies point 9.1.4.4 of EN ISO/IEC 17021-1 /D04/ with requirements described below:

- When a QMS Lead Auditor / QMS Auditor is accompanied by one or more technical experts (e.g. to fulfil the requirements for technical competence), then:
  - The time accounted between all these Technical Experts taken together for their accompanying shall be at maximum 50% of the actual auditing time of the accompanied QMS Lead Auditor / QMS Auditor.
  - The auditing time accounted by the QMS Lead Auditor / QMS Auditor shall in this case also be limited to 50% of the actual auditing time.



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*Note: Simple interpretation of the above rule of the ERA AS /D03/: Even if an auditor is accompanied by technical experts, only the time of the auditor counts.*

- If overlapping activities for several products are audited at the same time and site, the total duration may be reduced accordingly.

## 2.2 REMOTE AUDITING

The concept of Remote Auditing (EN ISO/IEC 17021-1 /D04/ 9.4.1) may only be a supporting element of lesser significance and it may not replace any On-Site Audit. The minimum proportion of 50% audit time for on-site duration of Management System Audits must be respected.

*Note: Remote auditing can be useful for follow-up of corrective actions.*

## 2.3 ACCEPTANCE OF QMS APPROVALS AND/OR QMS CERTIFICATES ALREADY GRANTED TO AN AUDITEE

Section "H.3. QMS - Audit programme" of Annex H of the ERA AS /D03/ provides that point 9.1.3.4 of EN ISO/IEC 17021-1 /D04/ shall apply with the following amplified requirements: *"The CAB shall have a documented procedure on how certification(s) already granted to the applicant for the site(s) and scope of activities and product(s) in question by another CAB, is "taken into account". The Audit Programme shall determine the 'Audit-Objectives, Scope and Criteria' as defined in section H.7 of Annex H of this document."* This matter, i.e. certified quality management system of manufacturers and/or applicant, deserves an explanation for a common understanding:

- If the QMS Approval (= evidenced by a NoBo CLD) is a quality system approval issued by a NoBo on exactly the same Audit Scope, it must be integrated.
- If it's an EN ISO 9001 certificate, the conditions related to the certificate itself, and a method to take it into account are dealt with in section H.7.4 of Annex H (Normative) and Annex I (Informative) of the ERA AS /D03/, in combination with the following:



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The Notified Body may take into account the corresponding QMS certificate only if the following CONDITIONS RELATED TO THAT CERTIFICATE itself are satisfied:

- 1) The certificate is issued by a QMS certification body under accreditation by a signatory of the European co-operation for Accreditation (EA) or of the International Accreditation Forum (IAF) Multilateral Agreements of mutual Recognition (MLAs) for Quality Management System (the correspondent updated lists of signatories is available on the website: <https://european-accreditation.org/ea-members/directory-of-ea-members-and-mla-signatories/> and <https://iaf.nu/en/recognised-abs/>).
- 2) The Audit Scope for the NoBo audit is in the scope of that QMS certificate in terms of:
  - i. products included in that certificate,
  - ii. activities (design & associated testing + manufacturing/installation & associated testing) included in that certificate,
  - iii. Audit Locations included in that certificate,
  - iv. dates of validity of that certificate.

## 2.4 PLANNING OF THE AUDIT ACTIVITIES

The following graphic illustrates the permitted timing and structuring options for audit activities within the initial QMS approval cycle:

LCM = Last ON-SITE Closing meeting, Cert = date of certification decision, NC = Non-conformity



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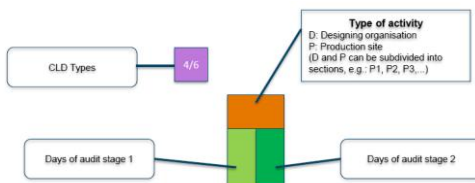
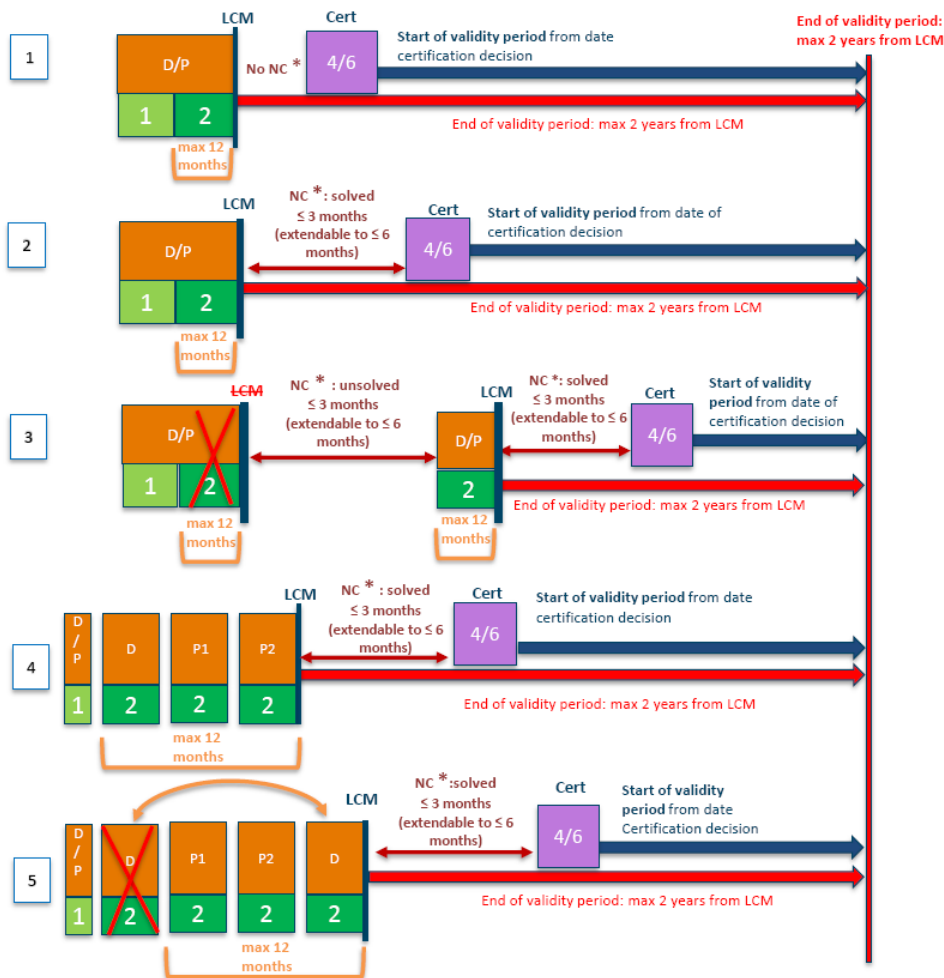


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\* NC: Major Non-Conformity (or Non-Conformity, where no distinction between Major- and Minor Non-Conformity is made)

*Note: This graphic reflects the validity period for the initial QMS approval cycle. The start date corresponds to the certification decision, and the end date is based on the closing meeting of the last on-site audit. See section '12 CERTIFICATION REVIEW AND CERTIFICATION DECISION & qms approval issue date + validity period' for further details'.*

*Note: The days of audit indicated above are set as an example.*



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Further, the Lead Auditor shall ensure that start of the on-site audit activities is not more than 12 Months prior to the intended date of the last on-site closing meeting. (Refer to section 12 of this RFU.)

## 2.5 PLANNING OF MULTIPLE COMBINED AUDIT ACTIVITIES AT THE SAME AUDITEE (“CLUSTER AUDIT”)

When the NoBo has been contracted to perform multiple audit activities for the same Auditee, it is possible to combine all of these activities into one single Audit Programme, if the following conditions are fulfilled. Otherwise separate Audit Programms shall be prepared.

Conditions:

- 1) Only the activities of one single Auditee may be included.
- 2) All activities within the Cluster Audit are performed by the same NoBo.
- 3) Multiple different Objects of Assessment may be included.

These Objects of Assessment may include:

- a) Objects of Assessment which have already been previously certified by a NoBo and require as next Audit activity a Surveillance Audit
  - b) Objects of Assessment which have already been previously certified by a NoBo and require as next Audit activity a Re-Certification Audit
  - c) Objects of Assessment which are not yet certified by a NoBo and require an initial Certification Audit
- 4) For each of the contained Objects of Assessment the NoBo shall individually identify (e.g. in a Matrix within the Audit Program) all its associated:
- a) Modules (as selected by the Applicant),
  - b) all the Auditee’s Activities to be audited,
  - c) all the Auditee’s Locations to be audited.



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In a Cluster Audit the minimum on-site audit duration is equal to the longest duration of any contained OaA.

*Note: Depending on the number of Objects of Assessment, Auditee's Activities, Auditee's locations the planning, performance and reporting for a Cluster Audit may be complex and requires precise planning and management, in order to not forget/skip any required audit activity.*

*The benefit is however, that, if carefully managed, one on-site audit activity at an Auditee's location can cover multiple Objects of Assessment simultaneously, where the same Auditee's teams, processes and equipment are employed for their design / production (e.g. for multiple wheel designs of different diameters, for several Concrete Sleeper designs, for several GSM-R radio designs).*

### 3 ESTABLISHMENT OF AUDIT PLANS

The NoBo shall apply:

- To audit plans: Section "H.9. QMS-Audit plan" of Annex H of the ERA AS /D03/.

in combination with the following:

- The Audit Plan shall define the specific application of the Audit Programme to each individual Audit contained in the overarching Audit Programme.
- For each on-site Audit an Audit Plan shall be prepared.
- The Audit Plan shall schedule an Opening Meeting, the proposed itinerary of the on-site Audit, including any breaks and internal meetings of the Audit Team and a Closing Meeting (applying Sections "H.9. QMS-Audit plan" and "H.11-QMS-Conducting audits" of Annex H of the ERA AS /D03/ and points 9.2.3.2, 9.4.2 and 9.4.7 of EN ISO/IEC 17021-1 /D04/)
- The Audit Plan shall cover at least any On-Site aspects of Stage1 and Stage 2.
- Should the Audit involve more than one Site, it is good practice to prepare a separate Audit Plan for each specific Site.



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- The Audit Stages 1 and 2 may be separately indicated in the Audit Plan to clarify the decision-making step at the end of Stage 1.

## 4 CLASSIFICATION OF AUDIT FINDINGS

The Audit Team shall judge if the QMS is able to achieve the **intended results**.

The **intended results** depend on the Module selected:

Module(s)	Intended Result
CD and SD	The Auditee has the ability to manufacture products that are conform with the associated certified product design in accordance with the applicable TSI(s).
CH	<i>Note: In the current TSIs, module CH is only permitted to be applied when the associated product design was established before the TSI became active. Therefore the intended result for the current TSIs is:</i> The Auditee has the ability to manufacture products that are conform with the associated product design in accordance with the applicable TSI(s).
CH1 and SH1	The Auditee has the ability to develop a TSI conform product design and also the ability to manufacture products that are conform with this product design in accordance with the applicable TSI(s).

Terms for classifying findings:

Finding Classification	Definition
Conform	The audited activity fully meets the applicable Audit Criteria and therefore supports also the intended results.
Conform with opportunity for improvement	The audited activity meets the Audit Criteria - but the Auditee's implementation of this activity is somewhat near to a non-conformity. In order to support the intended results, the Auditee is expected to maintain an effective control of this activity to ensure that it is not deteriorating towards a non-conformity or (as preferred action) to generally improve the implementation of this activity.



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	Any such findings shall become an interest point at the next surveillance or re-certification audit.
Minor Non-Conformity	<p>The audited activity does not fully meet the applicable Audit Criteria, but this does not affect the capability of the Auditee's management system to achieve the intended results.</p> <p><i>Note: Refer to notes below this table and point H.12. QMS of ERA AS and referenced point 9.5.2 of EN ISO/IEC 17021-1.</i></p> <p>The Auditee is expected to improve the implementation of this activity in order to establish conformity with the audit criteria within a defined timeframe.</p> <p>The Lead Auditor shall only accept such a timeframe if it is <b>12 months or less</b>, counting from the closing meeting following the identification of the Minor Non-Conformity.</p> <p><i>Note: This timeframe is twice the timeframe established for a major non-conformity.</i></p>
Major Non-Conformity	<p>The audited activity does not meet the applicable Audit Criteria, and this affects the capability of the Auditee's management system to achieve the intended results.</p> <p><i>Note: Refer to notes below this table and point H.12. QMS of ERA AS and referenced point 9.5.2 of EN ISO/IEC 17021-1.</i></p> <p>The Auditee is expected to improve the implementation of this activity in order to establish conformity with the audit criteria within a defined timeframe.</p> <p>The Lead Auditor shall only accept such a timeframe if it is <b>3 months or less</b>, counting from the closing meeting following the identification of the Major Non-Conformity.</p> <p>Where the Lead Auditor considers that it is beneficial for the effectiveness of the improvement, this time frame may be extended to a maximum of 6 months.</p> <p><i>Note: Refer to notes below this table and point H.12. QMS of ERA AS and referenced point 9.5.3.2 of EN ISO/IEC 17021-1.</i></p> <p><b>Additionally:</b></p> <p>A significant number of Minor Non-Conformities (typically more than 5) associated with the same Audit Scope shall by the Audit Team be</p>



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	<p>considered as a systemic failure of the QMS capability and it thus becomes a major non-conformity.</p> <p>A Minor Non-Conformity which is not brought to Conform (or to Conform with opportunity for improvement) within the maximum permitted timeframe shall be considered as a systemic failure of the Auditees capability to continuously improve the QMS and it thus becomes a major non-conformity.</p>
Not Applicable	Where an audit criterion is outside the Audit Scope.
Conform via ISV	Where an audit criterion was already in the Audit Scope of an ISV.
Non-application of TSI	Where the Applicant has informed the NoBo that a defined part of the Audit Scope is subject to a Non-Application of a TSI. Details on this are included in section 2.2 of the NoBo Conformity Assessment Report / NoBo-File.

#### Option:

It is permitted that a NoBo decides to use instead of the two classifications “Major Non-Conformity” and “Minor Non-Conformity” only a single classification “Non-Conformity”:

Non-Conformity	<p>The audited activity does not meet the applicable Audit Criteria, and this affects the capability of the Auditee’s management system to achieve the intended results.</p> <p><i>Note: Refer to notes below this table and point H.12. QMS of ERA AS and referenced point 9.5.2 of EN ISO/IEC 17021-1.</i></p> <p>The Auditee is expected to improve the implementation of this activity in order to establish conformity with the audit criteria within a defined timeframe.</p> <p>The Lead Auditor shall only accept such a timeframe if it is <b>3 months or less</b> counting from the identification of the Non-Conformity.</p> <p>Where the Lead Auditor considers that it is beneficial for the effectiveness of the improvement, this time frame may be extended to a maximum of 6 months.</p>
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*Note: Refer to notes below this table and point H.12. QMS of ERA AS and referenced point 9.5.3.2 of EN ISO/IEC 17021-1.*

## 5 PERFORMANCE OF AUDIT STAGE 1 (PRE-EVALUATION OF THE QMS DOCUMENTATION AND SUPPORTING INTERVIEWS)

The NoBo shall apply section “H.10 – QMS-Initial certification” audit of Annex H of the ERA AS /D03/. This section requires application of point 9.3 - including all its subsections - of EN ISO/IEC 17021-1 /D04/ and describes amplified requirements for this point.

*Note: It is considered good practice, that the Stage1 Audit is largely performed as desk top Audit involving Review of QMS documentation and may include supporting remote audit interviews. According to the note in point 9.3.1.2.2 of EN ISO/IEC 17021-1 /D04/, it is recommended, that at least a part of Stage1 is performed on site. This can be done directly preceding the Stage2 audit in the form of an Introductory Presentation by the Manufacturer on the QMS and its main documentation as applied for this Product and an Interview by the Audit Team to confirm the Audit Team’s understanding of that QMS and to permit the closure of open questions from the previous Stage1 desk top audit (should these exist).*

Audit Stage 1 is dealt with in point 9.3.1.2. of EN ISO/IEC 17021-1 /D04/ in combination with the following:

It is recommended to perform the final part of stage 1 on site. If a small scope of the audit criteria could not be concluded yet, it is permitted for the lead auditor to decide to have them audited during stage 2.

The Lead Auditor shall decide whether the Stage1 Audit has sufficiently concluded that the Manufacturer operates a systematic and stable QMS so that a meaningful Stage2 Audit may commence.

Any remaining open issues from Stage1 must be covered by follow-up actions which are acceptable to the NoBo. See section ‘1.3.4 Combined Set of Audit Criteria – practical approach in case of a single nobo’ and ‘1.3.5 Combined Set of Audit Criteria – practical approach in case of multiple nobos’ above for further details on parallel design-type inspection and auditing of designing and production.



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It is not required, that a Stage1 Audit is performed as one audit section “on-block”. It is permitted that the Audit Team performs a Stage1 Audit in multiple audit sections.

The Audit Team shall inform the Auditee in writing or in verbal communication when the objectives of Stage 1 have been fulfilled or not:

- STAGE 1 completed and management system ready for STAGE 2 audit.
- STAGE 1 completed and management system ready for STAGE 2 audit with a small number of identified issues which require follow up during the STAGE 2 audit.
- STAGE 1 completed and management system NOT ready for STAGE 2 audit.

*Note: This is a mandatory requirement of EN ISO/IEC 17021-1 /D04/, point 9.3.1.2.*

## 6 PERFORMANCE OF AUDIT STAGE2 (CONDUCTING AUDITS: AUDIT FINDINGS IDENTIFICATION AND THEIR RECORDING)

The NoBo shall apply:

- section “H.10 – QMS-Initial certification audit “of Annex H of the ERA AS /D03/. This section requires application of point 9.3, including all the subsections, of EN EN ISO/IEC 17021-1 /D04/ and describes amplified requirements besides this point. Audit Stage 2 is dealt with in point 9.3.1.3. of EN ISO/IEC 17021-1 /D04/.
- section “H.11 – QMS-Conducting audits” of Annex H of the ERA AS /D03/. This section requires application of point 9.4 including all the subsections of EN ISO/IEC 17021-1 /D04/ and describes amplified requirements besides this point.

in combination with the following:

- Only after the Lead Auditor has decided that the Stage1 Audit has sufficiently concluded that the Manufacturer operates a systematic and stable QMS the Stage2 Audit may commence, through on-site and remote auditing (i.e. assessment visit/s to the premises of the relevant entities concerned), interview, observation of processes and activities, review of documentation and records. For the minimum proportion of on-site auditing, multiple-site sampling and remote auditing, see section ‘2 ESTABLISHMENT OF THE AUDIT PROGRAMME’
- The Audit Findings to individual Requirements shall be documented. It is good industry practice to maintain the large quantity of very detailed information within



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the internal NoBo Records on the Audit and only forward following Audit Findings into the formal Audit Report:

- 1) Summary of the positive audit findings. For exemplary topics this shall include reference to the related evidence (such as Product ID, QMS Procedural Documents, QMS Records, etc.).
- 2) Complete itemisation of all non-conformities (major and minor). For any non-conformity a detailed argument on topic, related audit criteria and evidence shall be provided.
- 3) Summary of Good Practices identified. This section of reporting is optional. It is however recommended to highlight these elements within the report as confirmation for the Auditee(s).
- 4) Conform with Opportunities for improvement: For each of these findings, a detailed argument of topic - and related audit criteria and evidence - shall be provided. A note shall inform the Auditee, that all these findings will be topics to be considered by the Audit Team at future Audits.
- 5) Audit Conclusion: this is a summarising statement of the Audit Team across all Audit Findings, which shall include a statement of "recommendation to issue a QMS-CLD" or not for the NoBos Certification staff.

It is not required, that a Stage 2 Audit is performed as one audit section "on-block". It is permitted that the Audit Team performs a Stage 2 Audit in multiple audit sections, if all such sections are performed within a timeframe of 12 Months at maximum between first on-site audit day and last on-site closing meeting. Any audit section that falls out of this timeframe shall be repeated in a way, that in the end all audit sections have been performed within 12 Months.

### 6.1 REPETITION OF STAGE2

If during the initial certification auditing an Auditee does not provide for a Major Non-Conformity (or for a Non-Conformity, where no distinction between Major- and Minor Non-Conformity is made) a root cause analysis and evidence on correction, corrective / preventive action to the satisfaction of the NoBo audit team within the defined timeline, at least the audit stage2 shall be completely repeated.



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*Note: Refer to point H.12. QMS of ERA AS in connection with point 9.5.3.2 of EN ISO/IEC 17021-1.*

If it is not possible to perform all ON-SITE and REMOTE Audit Sections within consecutive 12 Months, all the audit Sections that have fallen out of this timeframe shall be repeated so that in the end all ON-SITE and REMOTE Audit Sections fall into the 12 Months timeframe.

## 7 ON SITE CLOSING MEETING

The NoBo shall apply points 9.3 and 9.4 including all the subsections of EN ISO/IEC 17021-1.

The audit team shall analyse all information and audit evidence gathered during stage 1 and stage 2 collected so far in ON-SITE and REMOTE auditing, discuss and agree internally on the audit findings.

A formal closing meeting shall be held with the client to present the audit findings in summary and any non-conformities (major and minor) in detail at the end of each on-site audit section in this closing meeting. Non-conformities shall be presented in that meeting in such a manner that they are understandable to the Auditee, and the Auditee is expected to propose a timeframe for correction, corrective action and preventive action in order to establish conformity with the audit criteria.

The Lead Auditor shall only accept such a timeframe if it conforms with the definitions in section '4 Classification of audit findings' of this RFU.

*Note: "Understood" does not necessarily mean that the non-conformities have been accepted by the Auditee.*

The closing meeting shall also include the following elements:

- a. the method and timeframe of reporting, including any grading of audit findings;
- b. the NoBos post audit activities.

The certification body shall require the Auditee to analyse the (root)cause and describe the specific correction, corrective actions / preventive actions taken, or planned to be taken, to eliminate the nonconformities, within the defined timeframe.

The date of the last On-Site closing meeting defines the end of all the on-site audit activities and it is also the start date for calculating the end-of-validity of the initial QMS Approval CLD (refer to sections '2.4 planning of the audit activities' and '12 CERTIFICATION



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## 8 ADDITIONAL REMOTE CLOSING MEETING

If Remote Audit segments are performed after the last On-Site closing meeting, the NoBo shall apply the definitions of section '7 On site closing meeting' of this RFU in analogy and perform a Remote Closing Meeting for such remote audit activities.

## 9 FOLLOW-UP INCLUDING CLOSING OF ANY NCS

The NoBo shall apply point 9.4 and 9.5 (including all their subsections) of EN ISO/IEC 17021-1/D04/.

**The audit team shall review**

- **for Non-conformities / Major Non-Conformities:**

The Auditee's answer containing (root) cause, the planning and evidence on performance of corrections, corrective actions and preventive actions and evaluate their effectiveness.

- **for Minor Non-Conformities:**

The Auditee's answer containing at least the (root) cause and the planning for the performance of corrections, corrective actions and preventive actions. When evidence on corrections, corrective actions and preventive actions becomes available, the Audit Team shall evaluate their effectiveness.

The associated evidence obtained by the NoBo Audit Team shall be recorded.

The Auditee shall be informed, if a repeat full audit, an additional limited on-site audit or an additional remote audit is planned in conjunction with the above.



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*Note: Review of effectiveness of the action(s) taken by the Auditee can be carried out based on a review of documented information provided by the client, or where necessary, through on-site and /or remote auditing.*

The Auditee shall be informed on the result of the review and of the closure of any NC.

## 10 AUDIT REPORT AND NOBo FILE / NOBo CONFORMITY ASSESSMENT REPORT

The NoBo shall apply:

- a) section "H.11 – QMS-Conducting audits" of Annex H of the ERA AS /D03/. This section requires application of point 9.4 including subsection 9.4.8.2 of EN ISO/IEC 17021-1 /D04/,

in combination with:

- b) The Audit Report may be a standalone document (and referred to in the QMS Approval CLD as accompanying documentation) or it may be embedded within the certification accompanying documentation NoBo File / NoBo Conformity Assessment Report according to section 4.3 of RFU STR 011 /D10/.
- c) It is highly recommended that the Audit Report provides all findings in relation to the structured Subject-Headlines as per section "H.7.4 Audit topics" of Annex H of the ERA AS /D03/ (in this sense, please, see section '1.3 **Audit Criteria**' above).

## 11 FINAL INTERNAL NOBo (OR NOBo-NOBo) COORDINATION MEETING (SEE 3.1 OF CD MODULES DECISION 2010/713/EU)

Where NoBo design-type inspection and NoBo auditing of designing and/or production have been performed in parallel by one single NoBo, the approval of the QMS shall depend on a final internal NoBo coordination meeting by the NoBo Audit Team together with the



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NoBo Inspection Team (coordinated by the QMS Lead Auditor and the Technical Lead Evaluator, respectively) to confirm:

- 1) The satisfactory completion of all design-type inspection activities.
- 2) At the conclusion between NoBo Inspection and NoBo Audit teams that all audit criteria have been identified and included in the auditing. Where this is not the case, further auditing shall be performed until all audit criteria are included.

The decision to grant initial QMS approval shall only be made in sequence **AFTER** the decision to issue the associated type/design examination certificate.

In case of multiple NoBos have been contracted to perform in parallel the NoBo design-type inspection and NoBo auditing of designing and/or production using the modules SB + SD or CB + CD in the same project, the above mentioned approach and conditions shall be applied in analogy (refer to ERA Technical Opinion ERA/OPI/2025-6 /D21/). In this case the internal NoBo coordination meeting becomes an NoBo-NoBo coordination meeting.

See sections '1.3.4 Combined Set of Audit Criteria – practical approach in case of a single nobo' and '1.3.5 Combined Set of Audit Criteria – practical approach in case of multiple nobos' of this RFU for further details.

## 12 CERTIFICATION REVIEW AND CERTIFICATION DECISION & QMS APPROVAL ISSUE DATE + VALIDITY PERIOD

A positive certification decision shall only be made:

- a) where any major non-conformities (non-conformities, when no distinction between major and minor non-conformity is done by the NoBo) were identified, **AFTER** the NoBo audit team has reviewed and accepted the Auditee's corrections, corrective actions, preventive actions.
- b) where any minor non-conformities (when distinction between major and minor non-conformity is done by the NoBo) were identified, **AFTER** the NoBo audit team has reviewed and accepted at least the Auditee's **planning** and timeline for corrections, corrective actions / preventive actions.
- c) where all connected Stage 2 Audit Activities up to the last on-site closing meeting have been performed within 12 Months



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d) all other requirements applicable to the Audit Scope of ERA Assessment Scheme /D03/ and of this RFU are fulfilled.

A negative certification decision shall be made in any other situation, e.g. where a Major Non-Conformity was not closed in the defined timeline.

According to section '4 Classification of audit findings' of this RFU, failure to close an Minor Non-Conformity in the defined timeframe or a large number of Minor Non-Conformities are present, this becomes a Major Non-Conformity.

To document the certification decision, the NoBo shall apply:

- EN ISO/IEC 17065 /D05/ 7.5 + 7.6 + 7.7,
- section "H.12 – QMS-Approval decision" of Annex H of the ERA Assessment Scheme 000MRA1044 ver 2.0. /D03/,
- RFU-STR-001 /D09/
- RFU-STR-011 /D10/

in combination with the following:

The Audit Report shall be one of the inputs to the NoBo Certification Review (EN ISO/IEC 17065 /D05/ 7.5).

All decisions to issue/ suspend/ restrict/ withdraw/ refuse QMS related CLDs shall be published on the ERADIS ERA database. This addresses section 7.8 of EN ISO/IEC 17065 /D05/.

The **ISSUE DATE AND VALIDITY PERIOD** on the QMS related CLDs shall be based on the section "H3 QMS – Audit Programme" of the ERA Assessment scheme 000MRA1044 ver 2.0 /D03/ and RFU-STR-060 /D12/.

- The **QMS APPROVAL ISSUE DATE** shall be on or after the date of the decision to grant the initial or a re-certification for QMS Approval (this corresponds to points 9.1.3.2 and 9.6.3.2.3 of EN ISO/IEC 17021-1 /D04/). This decision shall be made in sequence **AFTER** the decision to issue the associated



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CLD type 1 or 2 (8.1 or 8.2). (Refer also to ERA Technical Opinion ERA/OPI/2025-6 /D21/).

• The **VALIDITY PERIOD** for an **INITIAL QMS Approval**:

- The earliest ‘validity **start date**’ on a CLD can be the date of the decision to grant the initial QMS approval (this corresponds to point 9.1.3.2 of EN ISO/IEC 17021-1 /D04/) by the NoBo’s certifier (decision maker). *Note: Where the NoBo internal processes between the date of a positive decision and the date of issue of the associated CLDs require some time, this should not be reducing the validity period to the disbenefit of the Applicant and Auditees. It is therefore permitted, that the validity start date can be before the related CLD issue date but never shall precede the date of the decision.*
- The latest ‘validity **end date**’ (expiration date) on a CLD shall be calculated from the LAST ON-SITE closing meeting date (see section ‘7 On site closing meeting’ of this RFU). *Note: This corresponds to section “H3 QMS – Audit Programme” of the ERA Assessment scheme 000MRA1044 ver 2.0 /D03/: “Each periodic time interval begins with the last day of the related preceding audit” and to the Modules Decision 2010/713/EU /D02/ sections 4.3 of Modules CD and CH, section 5.3 of Module CH1, section 7.3 of Module SD and section 5.3 of Module H1).* The latest ‘validity end date’ shall be 2 years after the date of the LAST ON-SITE CLOSING MEETING.

• **VALIDITY PERIOD** for QMS Approval in case of **on-time RE-CERTIFICATION**:

- If the re-certification audit (i.e. the “periodic audit” under Modules Decision 2010/713/EU /D02/) has been successfully completed within the six months prior to the ‘validity end date’ of the previous QMS approval, the validity period of the following QMS approval may begin from the day following ‘validity end date’ of the previous QMS approval (this corresponds to point 9.6.3.2.3 of EN ISO/IEC 17021-1 /D04/ and RFU-STR-001/D09/). Only in this case, the latest ‘validity end date’ shall be 2 years after the ‘validity start date’.

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• **VALIDITY PERIOD** for QMS Approval in case of **up to 6 months delayed RE-CERTIFICATION**:



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- If the re-certification audit (named “periodic audit” in Modules Decision 2010/713/EU /D02/) has not been completed, or if the Audit Team cannot come to a positive evaluation result for a major non-conformity (or non-conformity, when no distinction between major and minor non conformity is done by the NoBo) prior to the ‘validity end date’ of the previous QMS approval CLD, then:

- The re-certification must not be recommended.
- The validity of the previous associated CLDs shall in this case not be extended, neither for the type 4 / 8.4 CLDs nor for the related type 6 / 8.6 CLDs.
- The Applicant shall be informed of this situation.

*Note: This corresponds to point 9.6.3.2.4 of EN ISO/IEC 17021-1 /D04/.*

- However, in such a case, the type 4 / 8.4 CLDs (and related type 6 / 8.6 CLD) may still be followed within six months after the ‘validity end date’ with re-certification CLDs, provided that:

- The pending re-certification activities have been completed within this timeframe, and
- The closure of any major non-conformity (non-conformities, when no distinction between major and minor non-conformity is done by the NoBo) has been evaluated by the Audit Team.
- In this case, the ‘validity start date’ of the following QMS approval shall be the date of the re-certification decision, and the expiration date shall be at the latest 2 years after the ‘validity end date’ of the previous QMS approval CLD.

(This corresponds to point 9.6.3.2.5 of EN ISO/IEC 17021-1 /D04/)

• **VALIDITY PERIOD for QMS Approval in case of re-instating after a more than 6 Months delayed RE-CERTIFICATION:**

- In this case the certification has been lost for more than 6 months after the ‘validity end date’ of the previous CLDs. The entire QMS approval process must be restarted. This means undergoing a new initial QMS approval cycle (this corresponds to point



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9.6.3.2.5 of EN ISO/IEC 17021-1 /D04/). In this case stage 1 may be abbreviated, where the Auditee's QMS remains without changes.

## 12.1 SHORTENING OF THE VALIDITY END DATE

Where a NoBo Audit Team finds, that a shorter validity end date (shorter than the maximum permitted validity end date according to RFU-STR-060 /D12/) should be taken for the QMS approval CLD to be issued, they shall propose this and the related reasons to the NoBo certification team.

*Note: This may be relevant, where a large number of Further Locations could otherwise not become sampled before the final products are manufactured.*

## 13 MAINTAINING QMS APPROVAL

The NoBo shall apply section "H.13 – QMS-Maintaining approval" of Annex H of the ERA AS /D03/. This section requires application of point 9.6 including all the subsections of EN ISO/IEC 17021-1 /D04/. Surveillance audits and recertification are dealt with in points 9.6.2.2. and 9.6.3. of EN ISO/IEC 17021-1 /D04/, respectively.

in combination with:

- section "H.3. QMS - Audit programme" of Annex H of the ERA AS /D03/,
- RFU-STR-001 /D09/
- RFU-STR-060 /D12/

in combination with the following:

It is permitted to perform a combined Surveillance/Recertification Audit for several products at the same time.

*Note: The term "periodic audit" of the Modules Decision 2010/713/EU /D02/ corresponds to the term "re-certification audit" of the EN ISO/IEC 17021-1:2015 /D04/.*

*The term "periodic audit" as used in the Modules Decision 2010/713/EU /D02/ 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 re-certification cycle as defined in the 17021-series.*



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### 13.1 SURVEILLANCE AUDITS

The NoBo's audit team shall evaluate based on the Auditees performance and on the maturity of the audited QMS, if and how many surveillance audits are necessary within the planned validity duration of the QMS CLD.

When a Surveillance Audit shall be performed, the NoBo shall apply section H.13 of the ERA Assessment Scheme /D03/ in combination with section 9.6 (in particular 9.6.2) of ISO/IEC 17021-1:2015 /D04/.

*Note: NoBos are not required by Modules Decision 2010/713/EU /D02/ or by the TSIs or by the ERA Assessment Scheme to always perform periodic annual audits for surveillance (as e.g. defined by EN ISO/IEC 17021-1:2015 /D04/).*

### 13.2 RE-CERTIFICATION

When a Re-Certification Audit shall be performed, the NoBo shall apply section H.13 of the ERA Assessment Scheme /D03/ in combination with section 9.6 (in particular 9.6.3) of ISO/IEC 17021-1:2015 /D04/.

## 14 MODIFICATION OF THE IC'S, RESPECTIVELY SUBSYSTEM'S, DESIGN AND/OR OF THE AUDIT SCOPE

*Note: A NoBo is required to react on any relevant information from any party that relates to a QMS Approval CLD during its validity period. That means that design modification reported after*

- *the expiry of the validity period of the QMS Approval CLD,*
- *a QMS Approval CLD withdrawal*

*fall outside the NoBo's duty to react. (The NoBo may voluntarily still react, as far as actually possible, as there may be no longer a contractual relationship between NoBo and Applicant after the end of the validity.)*



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The NoBo shall apply

- EN ISO/IEC 17065 /D05/ (clause 7.10 – Changes affecting certification), as referenced in Part 2 of the ERA AS /D03/,

together with

- EN ISO/IEC 17021-1 /D04/ clauses 9.6.4 (Changes to the scope of certification) and 9.6.5 (Suspending, withdrawing or reducing the scope of certification), as referenced by ERA AS /D03/ Annex H – H.13 ‘QMS – Maintaining approval’.

While the IC’s, respectively Subsystem’s, remains covered by a valid QMS Approval CLD, the Applicant and the Auditees within the Audit Scope shall inform the NoBo without undue delay of intended modifications that may affect either:

- Their part of the QMS activities;
- The design of the IC, respectively Subsystem,
- The list of Auditees and Locations or Mobile Teams included in the Audit Scope (e.g. a new Significant Subcontractor, an additional Main or Further Location).

*Note: This obligation stems from the railway Modules Decision 2010/713/EU /D02/ (section 3.5 of modules CD, CH, CH1, SD and SH1) and from ERA AS /D03/ and EN ISO/IEC 17065 /D05/, “section 4.1.2 Certification agreement” and shall be part of the Set of Contractual Documents. Refer also to section 1 of this RFU.*

*Typical cases of modification may be:*

- *Changes in QMS activities within the Audit Scope, for example:*
  - *Changes to process controls, Evidence Tests, process steps, or competence/qualification requirements of staff;*
  - *New or modified Main/Further Locations or Mobile Teams, Significant Subcontractors or in the allocation of tasks among the Auditees.*
- *Changes in the IC, respectively Subsystem (design type / product design), for example:*
  - *Design updates impacting essential characteristics or product specific production methods or Evidence-Testing mandated during the type/design examination;*



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- *Introduction of new materials, suppliers or equipment with potential impact on conformity;*
- *New design type/variants/versions/configurations of the IC, respectively Subsystem.*

The NoBo shall also consider relevant public information, complaints, incidents and regulatory feedback indicating possible non-systematic application of the certified QMS during the QMS Approval CLD validity period.

The NoBo shall based on such relevant information make notes or updates in the Audit Programme and may perform additional Auditing and/or Unexpected Visits.

Upon receipt of such relevant information, a NoBo Lead Auditor shall classify its impact on the existing certification (i.e. on the IC, respectively Subsystem design, the Audit Scope, the Audit Criteria and the CLD documentation) and shall determine the appropriate NoBo action (see below).

Where the specified IC, respectively Subsystem design is involved, the NoBo shall also apply sections '1.3.4 Combined Set of Audit Criteria – practical approach in case of a single nobo' or '1.3.5 Combined Set of Audit Criteria – practical approach in case of multiple nobos' of this RFU in relation to additional inspection activities, depending on whether a single NoBo or multiple NoBos are involved.

In all cases, the NoBo shall keep records of the classification of impact, even in the case when no additional auditing (and/or inspection) activities are required. These records shall include justifications for excluding any of the below mentioned activities and shall be consistent with EN ISO/IEC 17065 /D05/(7.10.3), RFU-STR-001/D09/(CLD/File content and ERADIS publication rules) and RFU-STR-060 /D12/.

*Note: Article 15 of Regulation (EU) 2018/545 /D18/ provides, in the context of vehicle/type authorisations, a categorisation of modifications to an already authorised type (e.g. no deviation; deviations without changes to basic design characteristics; changes to basic design characteristics leading to new version/variant; changes requiring a new authorisation). While that regulation addresses authorisations, these categories can be used by analogy to classify the degree of design modification and the proportionality of the NoBo's reaction under the IOD /D01/ and Modules Decision 2010/713/EU /D02/ framework.*

### 14.1 NOBO ACTIONS WHILE THE QMS APPROVAL IS LIVE



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Depending on the classification of the modification affecting certification and while the QMS Approval is valid, the NoBo shall, as appropriate, perform one or more of the following actions and update the Audit Programme accordingly:

- Coordinate with the inspection activities (type/design inspection) to ensure that the Audit Criteria remain complete and up to date;
- Perform a targeted Stage 1 delta audit focused on the modified aspects ;
- Plan and perform a targeted Stage 2 delta on site audit of the modified aspects;
- Update and/or issue a new NoBo File/Conformity Assessment Report and corresponding CLD to reference the modification and its evidence, maintaining full traceability in line with EN ISO/IEC 17065 /D05/, RFU-STR-001 /D09/ and RFU-STR-060 /D12/ (e.g. identification of version /variant/configuration of the assessed IC(s), respectively Subsystem(s) or part(s) thereof, where applicable);
- Inform the Applicant when the change cannot be covered under an existing valid QMS approval CLD; in such cases a new initial audit process shall be initiated under the relevant modules for the modified aspects.

All these actions shall be performed in accordance with the applicable parts of ERA AS /D03/, EN ISO/IEC 17065 /D05/ and EN ISO/IEC 17021-1 /D04/.

## 15 TERMINATION, REDUCTION OF SCOPE, SUSPENSION OR WITHDRAWAL OF CERTIFICATION

The NoBo shall apply EN ISO/IEC 17065 /D05/ 7.11 according to section “7.11-Termination, reduction, suspension or withdrawal” of Part 2 of the ERA AS /D03/.

in combination with

- EN ISO/IEC 17021-1 /D04/ 9.6.5. according to section “H.13 – QMS-Maintaining approval” of Annex H of the ERA AS /D03/ requires application of point 9.6 (including all the subsections) of EN ISO/IEC 17021-1 /D04/.

*Note: “Suspending, withdrawing or reducing scope of recertification” are dealt with in point 9.6.5. of EN ISO/IEC 17021-1 /D04/.*

- RFU-STR-001 /D09/
- RFU-STR-060 /D12/



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in combination with the following:

- a) In case of impossibility to perform a surveillance audit (where such an audit had been required by the NoBo), e.g. because the product in question is not in production, it is possible to issue a decision of (temporary) Suspension by the NoBo, based on a request of an Applicant in good time (at least 4 weeks) in advance of the planned surveillance audit.
- b) If a Minor Non-Conformity is not solved within the defined timeframe, it becomes a Major Non-Conformity and the issued QMS Approval CLD may not remain 'life'. The NoBo shall therefore suspend the QMS Approval CLD and any other CLD depending on these.

The NoBo shall in these cases **suspend** all affected CLDs and declare this in ERADIS database.

*Note: ERADIS suspensions are reversible, once a positive surveillance audit was performed by the NoBo.*

*A suspended CLD entry in ERADIS hinders the Applicant to declare the conformity on the basis of the suspended CLDs of any product which was produced after the date of suspension. The suspended CLD also hinders an authorising entity to authorise any product which was produced or incorrectly declared to be conform after the suspension date.*

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 suspension.

The direct communication to the Applicant shall clarify:

- a. that no production is permitted, until the suspended Supervision Audit is performed with a positive outcome.
- b. that the Applicant is expected to notify the NoBo in good time (at least 4 weeks) in advance of the production re-start to enable the NoBo to arrange for the Surveillance Audit to take place together with the re-start of production.

If a surveillance audit **cannot be performed** and **no Suspension by the NoBo is present** (e.g. when the Applicant simply does not invite/permit the NoBo to perform the surveillance auditing or if production has been finally terminated, the QMS-Approval CLD shall be suspended. Please, refer to RFU-STR 001 /D09/ and to RFU-STR-060 /D12/



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Generally, where a NoBo finds that an Auditee no longer complies with the Audit criteria and/or requirements of the relevant TSI(s), the NoBo shall take actions as defined in RFU-STR-001 /D09/ on the issued CLDs.

Also where a NoBo finds retrospectively that an Auditee has at times in the past while the QMS Approval was valid not complied with Audit Criteria and/or the requirements of relevant TSI(s), the NoBo shall take actions as defined in RFU-STR 001 /D09/ on the issued CLDs. *Note in such a case the NoBo needs to consider a Withdrawal of CLDs.*

## 16 UNEXPECTED VISITS (DURING QMS APPROVAL VALIDITY PERIOD)

Modules Decision 2010/713/EU /D02/ defines: *“In addition, the notified body may pay unexpected visits to the applicant. During such visits the notified body may, if necessary, carry out subsystem tests, or have them carried out, in order to verify that the quality management system is functioning correctly. The notified body shall provide the applicant with a visit report and, if tests have been carried out, with a test report.”*

*Note: The concept of “Unexpected Visits” is not defined within either EN ISO/IEC 17065 /D05/, EN ISO/IEC 17021-1 /D04/ 9.6.4.2 or EN ISO 19011 /D07/. Section “H.13 – QMS-Maintaining approval” of Annex H of the ERA AS /D03/ requires application of point 9.6.4.2 of EN ISO/IEC 17021-1 /D04/ on “Short-notice Audits” that also mentions “unannounced audits” but these terms are not identical to “Unexpected Visits”.*

*IOD /D01/ clarifies, that through its EC-Declaration, the Applicant as Manufacturer or on behalf of the Manufacturer declares under its sole responsibility, that it has applied – amongst many other considerations – also the QMS as it was certified by the NoBo.*

*Under Railway Safety Directive 798/2016 /D22/ article 4.5, the RUs/IMs operating the product are in combination with the actors indicated in 4.4 (these include suppliers of services and railway equipment), responsible to identify and remedy any safety concerns relating to the product post placing in service.*

*The element of NoBo Unexpected Visit can never replace the above-mentioned powerful provisions and may in practice only serve as a very marginal supplement to them. This is due to the fact that product related problems which establish themselves during operation are very seldom becoming known to the NoBo as neither RUs/IMs/NSAs/ Manufacturers*



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*are required to report those risks to the relevant parties involved and NoBos are not explicitly cited in art. 4.5 of Railway Safety Directive 798/2016 /D22/, and if this is done at all, there is usually a significant time delay.*

Therefore the following shall apply:

- a) As long as a product is covered by a valid QMS Approval CLD, the issuing NoBo shall remain generally vigilant on information in the public domain or information received from its Applicant on incidents and accidents relating to the product or similar products of the Applicant and/or Manufacturer. In this regard, the NoBo shall discount such information, which can be identified to be based on misuse of the product.
- b) If such information gives rise to a concern that the QMS of an Auditee may have been not systematically applied, the NoBo shall consider to pay that Auditee an Unexpected Visit.
- c) Based on the findings during such a visit, the NoBo may suspend, restrict, withdraw the status of the related CLDs.

#### THIS RFU WAS AGREED ON

PLENARY MEETING 076

#### THIS RFU ENTERS INTO FORCE ON

04/03/2026 (DATE OF PUBLICATION)

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

#### RFU APPLICATION IS MANDATORY STARTING FROM

04/09/2026

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 076 04-03-2026 – NO COMMENT FROM ERA