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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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TITLE	
QUALITY MANAGEMENT SYSTEMS APPROVAL: CORE ELEMENTS	
ORIGINATOR	**SUBJECT RELATED TO**
SG STRATEGY (WORKING PARTY: ARSENAL RACE BELGORAIL, LUXCONTROL, RINA)	IOD 2008/57 and IOD 2016/797 APPLIES TO MODULES D/CD, H1/CH, H2/CH1, SD, SH2/SH1
AMENDMENT RECORD: ISSUE 02, IOD REFERENCES UPDATE	

DESCRIPTION AND BACKGROUND EXPLANATION

General Background

Based on the various established ways for Accreditation (to either/or ISO 17020, 17021, 17025, 17065) or Recognition (often to comparable requirements) of NoBos, different approaches on the 'Approval of Quality Management Systems' have been developing. Stakeholders in Industry and NSAs have started to question this divergence. In order to avoid diverging approaches which could undermine the trust into the whole NoBo Certification process, NB-Rail establishes a uniform approach which shall be applied by all NoBos, regardless of being Accredited or Recognised.

This document describes the core elements for the Approval of Quality Management Systems to 2008/57/EC. It is intended to be applied by competent NoBo Quality Management Representatives and Audit Program Managers when managing those Lead Auditors, Auditors, Technical Experts assigned to them, but it may also be useful for Applicants, for Auditors in Training and for other interested parties. In order to avoid repeating those requirements which are defined in the relevant Standards, this documents employs references to the relevant content of these Standards.

References:

- 2008/57/EC : IOD (including all amendments as relevant at the time of auditing)
- 2010/713/EU: Modules decision
- ISI 17065 (2012) : Requirements for bodies certifying products, processes and services;
- ISO 17021 (2011) : Requirements for bodies providing audit and certification of management systems;
- ISO TS 17021-3 (2013) : Conformity assessment - Requirements for bodies providing audit and certification of management systems - Part 3: Competence

requirements for auditing and certification of quality management systems;

- ISO 19011 (2012) : Guidelines for auditing management systems;
- Guide ISO 53 (2006) : Guidance on the use of an organization's quality management system in product certification;
- IAF MD 5:2013 : Duration of QMS and EMS Audits
- The 'Blue Guide' (2014) on the implementation of EU product rules

RFU PROPOSAL

1. Approval of the Quality Management System within the scope of 2008/57/EC

The '**Approval of the Quality Management System**' within the scope of IOD (2008/57/EC, 2010/713/EU) as derived from the 'EU new approach' has a distinctly different core objective from an ISO9001 QMS certification. The dominating focus is related to the continuous **PRODUCT COMPLIANCE** against the TSIs, whereas the dominating focus of ISO9001 is to aim for **customer satisfaction** and **continuous improvement**. The requirements of ISO9001 shall therefore in this regard be seen as supportive, but not sufficient.

The IOD-QMS certification shall provide confidence - based on a certification statement of an independent & competent NoBo (ISO 17065 A.1 + ISO17021 4.1.2) - that the Manufacturer has demonstrated the ability to re-produce (often in large quantity series production) **TSI-COMPLIANT PRODUCTS** which are in all their relevant aspects identical to that TSI compliant designtype / prototype on which the series products are based.

'The essential objective is to ensure that each manufactured product placed on the market, is conform with the requirements expressed in the provisions of the relevant legislation.'(Blue Guide:2014 (5.1.1))

- **The 'Approval of the Quality Management System' is aiming at the product to be certified and its specific design and/or production process (as defined in the individual Modules (2010/713/EU)).**

2. Core Elements for Product Conformity Assessment Auditing

Independent of the form of notification (Akkreditation or Recognition) for NoBos, which may be different in the various Member States, the approach shall follow at minimum:

- the relevant Module Description
- in combination with the **Core Elements for product conformity assessment auditing** as defined by ISO17065
- in combination with the "applicable requirements" of ISO17021.
- ISO19011 may be considered to give further support.

Note: Any aspects of these standards outside of this 'core structure for product conformity assessment auditing', as e.g. training and evaluation of competence of Audit Team, level of independence of Audit Team and of NoBo, confidentiality, internal NoBo QMS provisions are only mandatory, if required by the individual national Accreditation or Recognition for NoBos. Their voluntary application is however recommended to all NoBos, as they represent good industry practice.

- **This document is limited to define the content elements of a minimum core structure for product conformity assessment auditing in the area of QMS Approval under 2008/57/EC.**

3. Core Elements

3.1 Core Elements relevant for Offer, Contract Review, Contract

These include aspects as Information on Product, Production process, manufacturer(s), availability of Audit Team, later use of Certification and related Certification Marks, duties and responsibilities for the Applicant, etc.

The NoBo shall apply ISO17065 7.3 (Application Review),

in combination with: ISO17065 7.2+4.1.2+4.1.3+6.1.1.1+6.1.1.2,

in combination with: ISO17021 4.3+5.1.2+7.1.1+7.1.2+7.1.4.2+7.2.2+7.2.3+7.2.6+

7.2.7+8.4+8.6.1.c-e+8.6.3.b-e+9.1.3+9.1.7+9.2,

in combination with: ISO17021-3: 6.2,

in combination with the following:

- The 'Certification Scheme' is in the framework of 2008/57/EC considered to be: 2008/57/EC(incl. all amendments) (Art.11+17+18+Annex VI, all other Articles to

provide supporting information) and the QMS related Module descriptions of 2010/713/EU. In case of applicability of TSI which in themselves contain Module descriptions, these Module descriptions form also part of the Certification Scheme.

- The NoBo should explain the framework of IOD and TSI if required to the Applicant.
- To prepare an offer, the NoBo must receive the following basic information:
  - name and address of the applicant and, if the application is lodged by the authorised representative, his name and address as well, project contact points,
  - name and address of the Manufacturer(s) and where relevant for H-type Modules of the designer(s)& Testing/V&V Body(ies), and where considered relevant by the NoBo also of significant sub-suppliers,
  - all relevant information for the Product (IC/ subsystem) (Type, definition, identification, configuration, version, borders, interfaces),
  - the Certificates and Technical Files, and in case of use of ISVs also Declarations of any preceding Modules or ISVs,
  - the project breakdown structure and the name and address of each involved entity for design, type testing, production, final inspection/ serial testing (to include all project related sites, main sub suppliers, where this is not otherwise known to the NoBo: number of staff involved in the project at the sites (Note: several sites processing the identical Product are possible, these may apply the same QMS or different QMS.)
  - generic QMS related documentation relevant for this product and as required by the NoBo to prepare an offer. In case of several QMS being related to the product, documentation related to all of them.
  - Language(s) of the Audit and of the Audit Report (Note: Language of the Audit Report must be aligned with Technical File)
  - Applicable TSIs, any available/ expected Derogations
  - Module(s) chosen by the Applicant for IC/ Subsystem Conformity Assessment,
  - If applicable, scope of ISV as defined by the Applicant

- Declaration to 2010/713/EU which requires the Applicant to declare, 'that the same Application has not been lodged with any other NoBo'.

- Based on this information the NoBo must check, if the request for Certification and the supplied information is conclusive and acceptable and if the NoBo has a competent Audit Program Manager and competent Audit Team available for this IC/ Subsystem. In these circumstances the NoBo may provide an offer, otherwise the NoBo must decline.

3.2 Core Elements for overall Conformity Assessment Planning/ Audit Programme

The NoBo shall apply ISO17065 7.4.1,

in combination with: ISO17021 8.6.1a-b+9.1.1+9.1.6

in combination with the following:

- The generic term 'plan' of EN17065 7.4.1 is for auditing activities more specifically defined as 'Audit Programme' in ISO17021.

- The Audit Programme may already be included within an overall Assessment Plan for the complete EC-Verification Process, if this Assessment Plan addresses all requirements for an Audit Programme as defined in the above references.

- The Audit Programme (or Assessment Plan) may already be included within the Offer/Contract documents, if these documents address all requirements as defined for an Audit Programme in the above references.

- It is considered best practice, that the Audit Programme defines already the Audit Objectives, Scope and Criteria as defined in ISO17021 9.1.2.2 for the complete Project.

- The certification cycle (which defines the max. permitted validity duration of QMS-Certification) is in ISO17021 9.1.1.2 stated to be 3 Years. THIS IS NOT applicable, as the IOD Certification Scheme defines specific durations. These max. permitted validity durations of QMS-Certification are in summary described in RFU-STR-060.

- The Audit Programme must explain the full Certification cycle of:

  - initial Certification Audit and its expected validity duration,

  - any sheduled Surveillance Audit(s) during the validity duration,

- Re-Certification Audit(s) after the end of the validity duration.

3.3 Core Elements for defining Audit Criteria (Requirements for the Production Process, for H-type Modules also for Design & Testing/V&V Processes)

The NoBo shall apply ISO17065 7.4.4,

in combination with: ISO17021 8.6.1a-b+9.1.2.2

in combination with the following:

- The product and the process stages must satisfy the combination of all requirements for the PRODUCTION PROCESS including the FINAL INSPECTION, (for H-type Modules also design and type testing) as resulting from TSIs, Mandatory Standards, Voluntary Standards, Alternative Solutions as identified in the conformity assessment Modules preceding the QMS Authorisation. (Refer to RFU-STR-088 for further information on identification of these.)

- According to 2010/713/EU or the Module annexes of the 'older TSIs' and the Blue Guide:2014 5.1.6 the NoBo 'shall presume conformity' with those **requirements** in respect of the elements of the quality management system that:

  - R1: the Applicant implements regarding the relevant process stages in respect of the standards EN ISO 9000 & 9001:2008 which take into consideration the specificity of the product for which it is implemented, and comply with the corresponding specifications of the national standard that implements the relevant quality management standard [this means e.g. BS EN ISO/IEC, NF EN ISO/IEC, DIN EN ISO/IEC,…]

  - R2: comply with the corresponding specifications of the national standard that implements the relevant harmonised standard [this means e.g. BS EN, NF EN, DIN EN,…as relevant for the design, production, final testing/V&V]

  - R3: comply with the corresponding specifications of the national standard that implements the relevant technical specification [this means e.g. BS, NF, DIN,… as relevant for the design, production, final testing/V&V]

- The Applicant must demonstrate to the satisfaction of the NoBo, the correct application of the above requirements for each product and process stage. The NoBo must state in the Audit Report, those requirements it has accepted as presumption of conformity and applied during the auditing.

- For the sake of standardisation, it is considered that for this purpose the following gives presumption of conformity:
    - For level R1: Requirements of EN ISO 9001:2008 shall apply as general baseline.
    - For level R2: Production, Design and Testing requirements and QMS related requirements contained in those EN standards which have been applied at the Modules B, CB, SB or the design examination part of Modules H2/CH1, SH2/SH1. This shall be in line with the related Technical File/Documentation section 5.1. Typical examples are QMS provisions for design/ manufacturing/ testing contained in EN 15085 series for welding, EN 1326x series, EN50126/8/9, EN50215 for Typetesting/V&V.
    - For level R3: QMS related elements contained in those national standards which have been applied at the Modules B,CB,SB or the design examination part of Modules H2/CH1, SH2/SH1. This shall be in line with the related Technical File/Documentation section 5.1.
- It is highly recommended that the NoBo establishes a systematic and complete generic checklist of the level R1 requirements for use by the Auditors and Technical Experts and for the general information of Applicants, as these are of generic level and provide a systematic, basic and full coverage of all QMS elements.
- It is proposed that, if the aforementioned Checklist used, it includes the R1 requirements under following systematic headlines. (References to the related sections of ISO9001:2008 are given in brackets.) Alternative headlines are acceptable, if the NoBo ensures that the same overall content is contained.

1. General Aspects & QMS Documentation (4.1+4.2.2+4.2.1)
2. Document Management (Availability/Control/Release of project QMS-Documents and QMS-Records) (4.2.3+4.2.4)
3. Management Responsibility (5.1 to 5.6)
4. Human Resources (6.1+6.2)
5. Infrastructural Resources (6.1+6.3+6.4)
6. Design - Planning, Inputs, Outputs (7.1+7.2+7.3.1+7.3.2+7.3.3)

7. Design - Evaluation, Verification& Validation (7.3.4+7.3.5+7.3.6)
8. Control of Design Changes (7.3.7)
9. Production/ Service provision - Planning, Performance (7.1+7.2+7.5.1 +7.5.3+7.5.4+7.5.5)
10. Production/ Service provision - Evaluation, Verification& Validation, Control of non-conforming products (7.5.2+8.3)
11. Control of Monitoring and Measurement Equipment (7.6)
12. Procurement and Control of purchased goods/services (7.4)
13. Continuous Monitoring, Measurment, Analysis (8.1+8.2+8.4)
14. Continuous Improvement – Corrective Actions, Preventive Actions (incl. project SMS) (8.5)

- Based on the diversity of level R2&3 requirements, it is considered, that in their combination the members of the competent Audit Team (consisting of Auditors and Technical Experts) shall possess a working knowledge of these requirements and shall during the Audit ensure that together with any level R1 requirement the related R2&3 requirements - as relevant for the given product and production stage - are audited as well. In complex conditions, it is however recommended that the Auditors and Technical Experts establish project specific additional checklists on level R2&3 requirements. This is compatible with the requirement in 2010/713/EU: “In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant subsystem field and product technology concerned, and knowledge of the requirements of the relevant TSI(s).”

- “Experience of evaluation in the relevant subsystem and product technology” shall mean, that the Audit Team has available between them:

    - competence on the general application of an QMS and relevant aspects of an SMS when applied to the railway technology production process,
    - competence on typical operation and maintenance of the product,
    - competence on typical design/production defects of this or similar products/technology and on previous defects of which have materialised in previous applications of this or similar products/technology – limited to those defects which could interfere with Safety, Health, the Environment

or any other Essential Requirement as defined by 2008/57/EC.

- In Case of **existing generic QMS-Certification of the Manufacturer**, 2010/713/EU defines: 'When the applicant operates a certified quality management system certified by an accredited certification body, for the manufacturing and final testing of the relevant subsystem, the notified body shall take this into account in the assessment. In this case, the notified body will make a detailed assessment of quality management system specific documents and records of the subsystem/ constituent only. The notified body shall not assess again the entire quality manual and all the procedures already assessed by the quality management system certification body.'

  In this regard it is considered, that if the Applicant provides a valid ISO9001:2008 Certificate from an Acccredited Certification Body for the site(s) and scope of activities and product(s) in question, the NoBo should discount from the systematic and complete generic checklist of the level R1 requirements the following ISO 9001:2008 Criteria, as these are of generic level and not significantly related to 'specific documents and records of the subsystem/ constituent':

  - 5.1b&c&d Management Commitment
  - 5.3 Quality Policy
  - 5.4 Planning
  - 5.5.3 Internal communication
  - 5.6 Management Review
  - 6.1b Customer Satisfaction
  - 7.2.3a&b Customer Communication
  - 8.2.1 Customer Satisfaction
  - 8.2.2 Internal Audit
  - 8.4 Analysis of Data

- The Requirements differ depending on the Module to which the Audit shall be performed:

	Process Stages (see below for detailed definition)		
Modules including QMS approval	Overall design process (including type tests)	Production process	Final testing process (series production)
D/CD/SD	n.a.	X	X
H2/CH1, SH2/SH1	X	X	X
H1/CH	X (limited to cont. improvement modifications of existing design)	X	X

- For **those H-type Modules where the product is based on an "existing design"** and for **any B-type Modules**, from the generic list of the level R1 requirements the following ISO 9001:2008 Audit Criteria shall be removed, as they are relating to design and type-testing activities which are out of scope for "existing design":
    - 7.3.1 Design and development planning
    - 7.3.2 Design and development inputs
    - 7.3.3 Design and development outputs
    - 7.3.4 Design and development review
    - 7.3.5 Design and development verification
    - 7.3.6 Design and development validation
    - Only excluded for B-type Modules: 7.3.7 Control of design and development changes
- Note: 7.3.7 Control of design and development changes remains explicitly included for those H-type Modules where a product is based on an "existing design", as the continuous improvement process may require small design improvements to be managed.

3.4 Core Elements for preparing an individual Audit Plan (confirmation of Audit Team with client on Sites, Times &Duration, Multiple Site Sampling)

The NoBo shall apply ISO17065 7.4.3,

in combination with: ISO17021 9.1.2+9.1.3+9.1.4+9.1.5+9.1.7+9.1.8.

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. Should the Audit involve more than one Site, it is good practice to prepare a separate Audit Plan for each specific Site.

- For each on-site Audit an Audit Plan shall be prepared which defines Audit Objectives, Scope and Criteria and refers to the Audit Programme. The Audit Plan shall cover at least the On-Site aspects of Stage1 and all Stage 2 aspects.

- The Audit Stages 1 and 2 may be separately indicated to make the decision-making step at the end of Stage 1 more visible to the Applicant (see section 4.5 below).

- The Audit Plan shall schedule an Opening Meeting to ISOI17021 9.1.9.2, the proposed literary of the on-site Audit, including any breaks and internal meetings of the Audit Team and a Closing Meeting to ISO17021 9.1.9.8.

- The determination of the Audit Duration per site for Stage1&2 shall follow ISO17021 9.1.4 in combination with IAF MD 5:2015. In this context, the NoBo shall consider the number of staff related to the Production Process of the Product in question, and NOT to the overall staff-count of the Manufacturer. The duration can be divided into on-site and off-site auditing. IAF MD 5:2015 indicates for this case in section 4.1 a minimum proportion of 80% on-site auditing for Management System Audits. Due to the product oriented approach of the IOD-QMS certification a larger proportion of off-site time may be required to:

  – identify the requirements relating to the specific product design activities (where relevant, based on the modules used);

  – 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).

It is therefore considered, that the appropriate minimum proportion of on-site auditing may be reduced to a minimum of 50% of the calculated audit time for IOD-QMS certification audits."

- Remote Auditing: According to 2010/713/EU, Audits are required to “include an

assessment visit to the premises of the relevant entities concerned". Insofar, the concept of Remote Auditing ISO17021 9.1.9.1 may only be a supporting element of lesser significance, but may not replace the On-Site Audit. It can be useful for the audit of subcontractors, or for follow up of corrective actions.

- Multiple Site sampling: According to 2010/713/EU, Audits are required to "include an assessment visit to the premises of the relevant entities concerned". Insofar, the concept of Multiple Site Sampling ISO17021 9.1.5 may only permit a reduction of audit activities at a Remote Site where the same processes are applied as on the Main Site, but it may not fully replace an On-Site Audit at the remote site.

3.5 Core Elements for performing Audit Stage1 (Pre-evaluation by Review of QMS documentation and supporting Interviews)

The NoBo shall apply ISO17065 7.4.2 to 7.4.9+6.1.1.1+6.1.1.2,

in combination with: ISO17021 9.1.5+9.1.6+9.1.7+9.1.9+9.2.3.1,

in combination with the following:

- It is considered good practice, that the Stage1 Audit is largely performed as desk top Audit involving Review of QMS documentation and supporting remote Interviews. According to ISO17021 9.2.3.1.1 it is recommended, that at least parts of Stage1 are 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 to confirm the Audit Team's understanding of the QMS and permit the closure of open questions from the previous Stage1 desk top Audit.

- The Lead Auditor must make a decision, 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.

3.6 Core Elements for performing Audit Stage2 (On site Auditing through Interview, Observation of Processes and Activities, Review of Documentation and Records);

The NoBo shall apply ISO17065 7.4.2 to 7.4.9+6.1.1.1+6.1.1.2,

in combination with: ISO17021 9.1.5+9.1.6+9.1.7+9.1.9+9.2.3.2+9.2.4,

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.

3.7 Core Elements for Reporting of Audit Findings and Management of Non-Conformities

The NoBo shall apply EN17065 7.4.2+7.4.6+7.4.9,

in combination with: EN17021 9.1.9.6+9.1.10+9.1.11+9.1.12+9.1.13.

in combination with the following:

- The Audit Findings to individual Requirements must be documented. It is good industry practice to maintain large quantity of very detailed information within the internal NoBo Records on the Audit and only forward following Audit Findings into the formal Audit Report:
    - Summary of positive audit findings. For exemplary topics this shall include reference to the related evidence (such as Product ID, QMS Procedural Documents, QMS Records, etc.).
    - Complete itemisation of all Non-Conformities. For each NC a detailed argument of topic and related evidence shall be provided.
    - Summary of Good Practice identified. This section of reporting is optional. It is however recommended to highlight these elements within the report as confirmation for the Applicant.
    - Recommendations for improvement: For each Recommendation a detailed argument of topic - and if applicable related evidence - shall be provided. A note shall inform the Applicant, that all recommendations for improvement will be followed up at future Audits.
    - Audit Conclusion: This is a summarising Statement of the Audit Team, which shall include a statement of “recommendation to issue a QMS-Certificate” or not to the NoBo’s Certification Commitee.
- The formal report may be a standalone document (and referred to in the Technical File under Section 6.2) or is may be embedded within the Technical File section 6.2.

- It is highly recommended that the Report provides all findings in relation to the structured Subject-Headlines as per section 4.3 above:

1. General Aspects & QMS Documentation (4.1+4.2.2+4.2.1)
2. Document Management (Availability/ Control/ Release of project QMS-Documents and QMS-Records) (4.2.3+4.2.4)
3. Management Responsibility (5.1to 5.6)
4. Human Resources (6.1+6.2)
5. Infrastructural Resources (6.1+6.3+6.4)
6. Design - Planning, Inputs, Outputs (7.1+7.2+7.3.1+7.3.2+7.3.3)
7. Design - Evaluation, Verification& Validation (7.3.4+7.3.5+7.3.6)
8. Control of Design Changes (7.3.7)
9. Production/Service provision - Planning, Performance (7.1+7.2+7.5.1+7.5.3+7.5.4+7.5.5)
10. Production/ Service provision - Evaluation, Verification& Validation, Control of non-conforming products (7.5.2+8.3)
11. Control of Monitoring and Measurement Equipment (7.6)
12. Procurement and Control of purchased goods/services (7.4)
13. Continuous Monitoring, Measurment, Analysis (8.1+8.2+8.4)
14. Continous Improvement – Corrective Actions, Preventive Actions (incl. project SMS) (8.5)

3.8 Core Elements for Certification Review and Certification Decision

The NoBo shall apply EN17065 7.5 + 7.6.2 + 7.6.6 + 7.7,

in combination with: EN17065 6.1.1.1+6.1.1.2,

in combination with: EN17021 7.2.9+7.5.2+8.2+9.1.15+9.2.5,

in combination with: EN17021-3: 6.3

in combination with: RFU-STR-001

in combination with the following:

- The Audit Report will be an input to the Certification Review (EN17065 7.5).
- All issued/ withdrawn/ rejected Certificates must be published by each NoBo on CIRCABC. This covers EN17065 7.8+ISO17021 8.1.3.

3.9 Core Elements for Surveillance (Surveillance Note and Suspension Note)

The NoBo shall apply EN17065 7.9,

in combination with: EN17065 7.11.3 to 7.11.6 (suspension),

in combination with: EN17021 9.3+9.6

in combination with the following:

- Maximum permitted duration until Surveillance is defined either within a TSI or 2010/713/EU. If required by previous Audit Findings, a NoBo shall reduce this max. duration accordingly.
- In many cases, initial or previous Certification may have been issued a significant time after the last Audit day to permit follow up actions to conclude. It is therefore generally defined, that the Surveillance Audit must commence before or at the last day of the previous audit plus the validity period of the Certificate.
- It is permitted to perform a combined Surveillance Audit for several products at the same time.
- Upon positive Surveillance, the NoBo shall serve the Applicant with a Surveillance Note. This shall carry a validity duration.
- If the product in question is not in production, but re-start of production is intended at a later stage, it is possible to Suspend a Surveillance based on a request of an Applicant. The NoBo must in this case serve the Applicant a Suspension Note. This shall be valid as long as the production itself is suspended, however at maximum until next Surveillance or Recertification date, whatever is earlier. The Note must clarifiy that no production is permitted, until the suspended Supervision Audit is performed. The notice should require the Applicant to notify the NoBo at least 4weeks in advance of intended production re-start to arrange for the Audit to take place at start of production.

- If Surveillance cannot be performed (e.g. when the Applicant does not invite the NoBo for auditing or if production has been terminated), the QMS-Certification must be withdrawn.

3.10 Core Elements for Re-Certification (Certification Review and Decision)

The NoBo shall apply: EN17021 9.4,

in combination with the following:

- Maximum permitted duration until Recertification is defined either within a TSI or 2010/713/EU. If required by Audit Findings, a NoBo shall reduce this duration accordingly.
- In many cases, initial or previous Certification/ Surveillance Notes may have been issued a significant time after the last Audit day to permit follow up actions to conclude. It is therefore generally defined, that the Recertification Audit must commence before or at the last day of the previous audit plus the duration period of previous Certification/Surveillance Notes.
- The NoBo shall apply the same approach as given above for the Certification, but taking into account, that the Product, Production Process are already known to the NoBo and that the Manufacturer is operating an already established QMS.

3.11 Core Elements relating to Modification of Product, Production Process, Manufacturer (Amendment, Modification, Withdrawal of Certification)

The NoBo shall apply EN17065 7.10,

in combination with: EN17065 6.1.1.1+6.1.1.2+7.6.6.

in combination with: EN17021 8.6.2+8.6.3+9.5

in combination with the following:

- Changes introduced by the Certification Scheme (ISO17065 7.10.1) can often be avoided by the Applicant based on Transition Provisions in new TSIs (typically in section 7 of a TSI) or based on claiming a derogation under 2008/57/EC Art9.1(a).
- The change of Product, Production Process and Manufacturer includes also

Sub-suppliers if these may have an influence on the conformity of any individual product. The NoBo must be informed about any change and must be satisfied that there is no such portential. Otherwise, a Delta-Audit shall be performed on the modified aspects.

- Depending on the scope of the change, the NoBo will serve the Applicant with a

    - ‘Supplementary Note’ amending the initial Certificate which documents the modification and states, that the modified product retains the performance parameters and properties as defined by initial Certification. This Note will typically be accompanied by an updated Technical File. (Typical Examples: The Applicant has improved a weld geometry based on received operational feedback. A second source supplier for a printed circuit board has been chosen for a signalling equipment. A second source of raw-material supply for axles is introduced.)

    - replacement Certificate which documents the alternative design or alternative production process, if these remain still within the TSI tolerances. This will be accompanied in all cases by an updated technical file. (Typical Examples: The Applicant has installed a second production site. The Applicant has modified the interior layout of a vehicle to accommodate more seats. The Applicant has modified the geometry of a wheel-web.)

3.12 Core Elements relating to Termination, extension of scope, reduction of scope, suspension or withdrawal of certification

The NoBo shall apply EN17065 7.11,

in combination with: EN17021 9.5.2+9.6.

3.13 Core Elements relating to Unexpected Visits (within the Supervision period)

2010/713/EU 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.”

The concept of Unexpected Visits is not further defined within either ISO17065, Blue Guide:2014, ISO 17021 9.5.2 or ISO19011.

Note that 9.5.2 on “short notice Audits/Visits” is not identical to “unexpected visit”.

The Blue Guide:2014 further 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 certified by the NoBo.

Under Railway Safety Directive 2004/49/EC 4.3, the RUs/IMs operating the product are in combination with their Suppliers responsible to identify and remedy any safety concerns relating to the product post placing in service. This is further detailed in CSM Monitoring 1078/2012.

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 are not required to publicise them, and if this is done at all, there is usually a significant time delay.

The following shall apply:

- As long as a product is covered by a QMS Certification, the issuing NoBo shall remain generally vigilant on information in the public domain or information received from the Applicant on incidents and accidents relating to the product or similar products of the Manufacturer. In this regard, the NoBo shall discount such information, which can be identified to be based on mis-use of the product.

- If such information gives rise to a concern that the QMS of the Manufacturer as previously certified and surveilled may have been not systematically applied, the NoBo shall consider to pay the Manufacturer an Unexpected Visit.

- Based on the findings of such a visit, the NoBo may retain the status of certification, reduce, suspend or withdraw it.

3.14 Audit Records on the Audit

The NoBo shall apply EN17065 7.12,

In combination with EN17021 9.9.

3.15 Compatibility between 2010/713/EU&ISO19011

Cross-reference table between audit process (ISO 19011) and modules including QMS approval (2010/713/EU)

Modules defined in 2010/ 713/EU / ***Typical audit activities*** [1]	*Module D / CD QMS for Production & Final testing*	*Module H1 / CH QMS for Design, Production & Final testing*	*Module H2 / CH1 QMS for Design, Production & Final testing*	*Module SD QMS for Production & Final testing*	*Module SH2 / SH1 QMS for Design, Production & Final testing*
6.2 Initiating the audit	§ 3.1 – Bullet 1 § 3.1 – Bullet 2 § 3.1 – Bullet 3	§ 3.1 – Bullet 1 § 3.1 – Bullet 4	§ 3.1 – Bullet 1 § 3.1 – Bullet 2 § 3.1 – Bullet 4	§ 3.1 – Bullet 1 § 3.1 – Bullet 2 § 3.1 – Bullet 3 § 3.1 – Bullet 4	§ 3.1 – Bullet 1 § 3.1 – Bullet 2 § 3.1 – Bullet 3 § 3.1 – Bullet 6
6.3 Preparing audit activities	§ 3.1 – Bullet 4	§ 3.1 – Bullet 3	§ 3.1 – Bullet 3	§ 3.1 – Bullet 5	§ 3.1 – Bullet 4
6.4 Conducting the audit activities	§ 3.1 – Bullet 5 § 3.2 § 3.3	§ 3.1 – Bullet 2 § 3.2 § 3.3	§ 3.2 § 3.3	§ 3.1 – Bullet 6 § 3.1 – Bullet 7 § 3.2 § 3.3	§ 3.1 – Bullet 5 § 3.2 § 3.3
6.5 Preparing and distributing the audit report	§ 3.3	§ 3.3	§ 3.3	§ 3.3	§ 3.3
6.6 Completing the audit					
6.7 Conducting audit follow-up	§ 3.5 § 4	§ 3.5 § 4	§ 3.5 § 5	§ 3.5 § 7	§ 3.5 § 5

[1] Typical audit activities defined in §6 of ISO 19011:2011

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THIS RFU WAS AGREED ON
PLENARY MEETING 059
THIS RFU ENTERS INTO FORCE ON
23/06/2020 (DATE OF PUBLICATION) FROM THIS DATE ON THIS RFU CAN BE APPLIED INSTEAD OF THE PREVIOUS MANDATORY VERSION.
RFU APPLICATION IS MANDATORY STARTING FROM
23/06/2020 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 059 – 17/06/2020: NO COMMENTS