Rules for the certification of Quality Management System

Certification scheme for the rail sector ISO/TS 22163

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Technical rules

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CERTIFICATION OF QUALITY MANAGEMENT SYSTEMS ACCORDING TO ISO/TS 22163:2017

CHAPTER 1
GENERAL

1.1

These Rules define the additional and/or substitutive procedures, applied by RINA for the certification of Quality Management Systems in the rail sector, with reference to what is set out in the

General Rules for the Certification of Management Systems

The paragraphs of these Rules refer to (and keep the same numbering of) the corresponding paragraphs of the General Rules for the Certification of Management Systems to which some changes and/or integrations have been made.

For any issues not covered in this document, reference should be made to:

- General contract conditions for the certification of systems, products and personnel
- IRIS Certification® Conformity assessment:2020
- Any FAQ issued by UNIFE

1.2

RINA issues the certification in accordance with the requirements of the ISO/IEC 17021-1:2015 standard to Organisations whose Management System has been recognised as fully conforming to all the requirements of the following standard:

ISO/TS 22163:2017

ISO/TS 22163: 2017 certificates can be issued both independently and as supplements to ISO 9001:2015 certificates.

In particular an Organisation that is already certified according to ISO 9001 requires the certification according to the ISO/TS 22163:2017 scheme, all processes must be totally evaluated on site and therefore it is not allowed to evaluate only the difference of the additional requirements with respect to the ISO 9001 standard.

1.3

All Organizations operating in the rail sector can gain access to certification, irrespective of whether they belong to an Association or Group or not; only the type of their activity is considered.

The "rail sector" (according to IRIS Certification® Conformity assessment:2020) refers to the entire supply chain whose scope is the design, manufacture and maintenance of products used in railway applications. This certification is also extended to the entire supply chain of rolling stock, products for signalling and for infrastructures.

1.6

The Organisation that guarantees the certifications issued by RINA (Accreditation Body) may request the participation of any of its observers to the audits carried out by RINA itself, aiming to verify that the evaluation methods adopted by RINA are compliant with the applicable standards. In addition to the

presence of these observers, the Organisation has to allow the presence, during the audits, of rail sector representatives appointed by IMC (IRIS Management Centre) along with RINA staff. Witness audits are directly planned by IMC and the dates of the audits are communicated to RINA 7 calendar days before the start of the audit. If the Organisation refuses to accept the above participation, RINA will start the certificate withdrawal process.

1.7

The terminology used in these Rules is the same used by standards ISO 9000, UNI CEI EN ISO/IEC 17000:2005 and IRIS Certification™ rules: 2017.

1.8

RINA is approved by UNIFE to conduct IRIS audit and certifications and such approval lapses in the event the contract between RINA and UNIFE terminates. In case of termination before Evaluation process has been carried out and the IRIS Certificate has been issued, the Organization is not entitled to claim the IRIS Certificate.

RINA is obliged and irrevocably authorized by the Organization to transmit the request for certification and Data to the IRIS Management Centre, independent of the result of the audit; the Data will be stored in the Database, will be administered by IRIS Management Centre and will be subject to restricted access right.

The Organization agrees that the IRIS Management Centre is irrevocably authorized to make Non-Detailed Data on passed audits available via the Database in accordance with its access rights.

The Organization itself decide to whom (e.g. customer) the Detailed Data (i.e. results of passed or failed audits) may be made available via Database by the IRIS Management Centre providing the access rights.

The Organization agrees to evaluate the RINA and its IRIS auditors. The Organization shall login to the Database and use the proper function to issue an evaluation for each IRIS auditor who was part of the audit team.

Any proprietary and/or confidential information, know how or other intellectual property of UNIFE/IRIS Management Centre, whether registered or unregistered, shall remain the exclusive property of UNIFE, that all intellectual property rights on the systems remain vested in UNIFE, and that no provisions of the agreement between RINA and the Organization shall give rise or shall be deemed to give rise to an assignment, transfer or licensing of the intellectual property right of UNIFE.

The Organization undertakes to use and shall cause ("se porte fort pour") its employees, directors, agents, and other representatives, as well as its shareholders and other companies or member of its group to use inly the original standard and Software and to refrain from using any document or copies of Software which might infringe the intellectual property right of UNIFE.

The Organization acknowledges and accepts that UNIFE and its representatives and employees cannot be held liability for any direct or indirect damages suffered by the Organization in relation to IRIS Certificate or the System, This limitation of liability shall only apply to extent permitted by mandatory applicable law. This exclusion of liability shall not apply in cases where an exclusion of liability is prohibited by mandatory applicable law.

CHAPTER 2
REFERENCE STANDARD/CERTIFICATION REQUIREMENTS

2.1

In order to obtain RINA certification, a Quality Management System, as far as applicable in relation to the type of product or service in question, must meet, both initially and over time, the requirements of the reference scheme and those indicated in the following paragraphs of this chapter, together with the following provisions:

- IRIS Certification® Conformity assessment:2020
- any specific requirements requested by the customer

As far as accreditation is concerned, RINA must comply with specific reference documents issued by the Accreditation Bodies. These documents can be obtained from RINA or directly from the Accreditation Bodies (e.g. consulting their Internet sites).

2.2

In addition to the requirements of paragraph 2.2 of the General Rules for the Certification of Management Systems, to obtain the Management System certification according to the ISO/TS 22163:2017 Scheme, the Organisation must:

- Be a legal entity or belong to a company
- Have an independent Company Management System
- Perform at least one IRIS Certification™ activity: design, production and/or maintenance
- Be eligible for one of the certification scopes defined by annex 1 to IRIS Certification® Conformity assessment:2020
- Be located in a single site.

The Organisation must register to IRIS CertificationTM portal in order to:

- Obtain detailed information about IRIS Certification™
- Be able to acquire the Audit-Tool
- Select the Certification Body
- Start the certification process according to the ISO/TS 22163:2017 standard.

Before proceeding with the certification process according to ISO/TS 22163:2017, the Organisation has to complete the self-evaluation questionnaire which is aimed at understanding the conformity level of its own management system to the requirements of ISO/TS 22163:2017. Special attention must be paid to KO (Knock-out) questions.

2.3

Conformity of the Management System with the reference standard is verified through a set of audits including:

- an initial audit made up of two stages (the end date of the certification audit determines the "validity date", that will be the reference date for the surveillance and renewal audits)
- a surveillance audit in the first year (to be completed within 12 months from the "validity date")
- a surveillance audit in the second year (to be completed within 24 months from the "validity date")

- a certification renewal audit in the third year (to be completed within 36 months from the "validity date")

In particular, for the entire certification process and for the subsequent surveillance and recertification audits, RINA will use Lead Auditors and Auditors qualified by UNIFE.

CHAPTER 3
INITIAL CERTIFICATION

3.5

The initial audit consists of two stages:

- Readiness Review – carried out to the Organization's site
- Certification Audit – carried out to the Organization's site

During the initial audit the Organization must demonstrate that its Management System is fully operative and that the system is actually applied.

In the presence of any significant changes that may affect the management system, RINA can consider the need to repeat the Readiness Review. In this case, RINA will inform the Organisation if the outcomes of the Readiness Review may lead to a postponement or cancellation of the certification audit.

3.6

In addition to the requirements of the corresponding paragraph 3.6 of the General Rules for the Certification of Management Systems, in the presence of a non-conformity, a corrective action request (CAR) is generated, that it is recorded in a preliminary report using the IRIS Tool, that stores the actually obtained score. Any corrective action request will be closed within 90 calendar days from the end of the certification audit, according to the requirements of chapter 14 of IRIS Certification® Conformity assessment:2020.

In case of "insufficient" score, a re-audit to the company's site is foreseen within 90 days, whereas in case of "poor" score, the Lead Auditor may decide about the necessity of a re-audit or other appropriate methods to review the effectiveness of the corrective actions. When the CARs are closed, the total score will be adjusted consequently and the final result will be documented in a final audit Report. The IRIS Certificate will show only the total score obtained following the implementation of the corrective action. After the 90 days period has elapsed without a positive conclusion of the evaluation, RINA reserves the right to terminate the certification process and charge the time and the costs incurred up to that moment. In such cases, if the Organisation wishes to proceed with RINA certification, it must submit a new application and repeat the certification process.

In special cases, the above time limits may be modified at the request of the Organisation, if considered justified by Rina.

CHAPTER 4
MAINTENANCE OF CERTIFICATION

4.6

In addition to the requirements of the corresponding paragraph 4.6 of the General Rules for the Certification of Management Systems, in the presence of a non-conformity, a Corrective Action Request (CAR) is generated, that it is recorded in a preliminary report using the IRIS Tool, that stores the actually obtained score. Any corrective action request must be closed within 90 calendar days from the end of the surveillance audit and not after the "validity date", in accordance with what is set out in chapter 14 of IRIS Certification® Conformity assessment:2020.

A re-audit to the company's site is foreseen within 90 days in case of "insufficient" score or if the auditor reopens a CAR raised during the previous audit, whereas in case of "poor" score, the Lead

Auditor may decide about the necessity of a re-audit or other appropriate methods to review the effectiveness of the corrective actions. When the CARs are closed, the total score will be adjusted consequently and the final result will be documented in a final audit Report. The IRIS Certificate will show only the total score obtained following the implementation of the corrective action. After the 90 days period has elapsed without a positive conclusion of the evaluation, RINA reserves the right to start the withdrawal certification process.

All costs relating to any supplementary audits deriving from any deficiencies of the Quality Management System will be charged to the Organisation.

CHAPTER 5
RECERTIFICATION

5.4

In addition to the requirements of the corresponding paragraph 5.4 of the General Rules for the Certification of Management Systems, in the presence of a non-conformity, a Corrective Action Request (CAR) is generated, that it is recorded in a preliminary report using the IRIS Tool, that stores the actually obtained score. Any Corrective Action Request must be closed within 90 calendar days from the end of the surveillance audit and not after the "validity date", in accordance with chapter 14 of the IRIS Certification® Conformity assessment:2020.

A re-audit to the company's site is foreseen within 90 days in case of "insufficient" score or if the auditor reopens a CAR raised during the previous audit, whereas in case of "poor" score, the Lead Auditor may decide about the necessity of a re-audit or other appropriate methods to review the effectiveness of the corrective actions. When the CARs are closed, the total score will be adjusted consequently and the final result will be documented in a final audit Report. The IRIS Certificate will show only the total score obtained following the implementation of the corrective action. After the 90 days period has elapsed without a positive conclusion of the evaluation, RINA reserves the right to start the withdrawal certification process.

All costs relating to any supplementary audits deriving from any deficiencies of the Quality Management System will be charged to the Organisation.

CHAPTER 6
CONDUCTION OF AUDITS

6.1.3

Instead of the corresponding paragraph 6.1.3 of the General Rules for the Certification of Management Systems, a written report is prepared for each audit using the IRIS Audit-Tool, indicating any Non Conformities (CAR) and recommendations (IAR) for improvement purposes.

6.1.4

After analysing the reasons for any non-conformities indicated in the above report, the Organisation must, within the date specified in the report, inform RINA of its proposals for handling the non-conformities, as well as the corrective actions required and the dates expected for their implementation.

Within 90 days from the closing date of the audit, the Organisation must provide evidence of the implementation of the proposed corrective actions.

6.1.5

In the presence of any non-conformities (CAR) the certification process is suspended.

The audit team can decide to carry out the supplementary audit either on site or by a documental review, depending on the type of corrective actions to be checked.

All costs relating to any supplementary audits deriving from any deficiencies of the Quality Management System will be charged to the Organisation.

6.2 INITIAL CERTIFICATION AUDIT

The initial certification audit consists of two stages.

6.2.1 – Readiness Review

The Readiness Review is aimed at verifying the conformity level to the pre-requisites of ISO/TS 22163:2017. In particular, the following aspects will be verified:

- Verification of the presence of mandatory processes/KPIs;
- Level of customer satisfaction;
- Conformity check to the requirements related to Knock-Out aspects;
- Check of the site, evaluating its suitability to the type of activity carried out;
- Check of certification scope;
- Resource allocation for the audit and acceptance by the Client in relation to the audit details;
- Audit planning.

No Non conformities will be issued during the Readiness Review.

The Readiness Review report is compiled using the IRIS Audit-Tool and will indicate the outcome (Pass/Fail).

6.2.2 – Certification audit

In addition to the requirements of the corresponding paragraph 6.2.2 of the General Rules for the Certification of Management Systems, in the presence of a non-conformity a Corrective Action Request (CAR) is generated, that it is recorded in a preliminary report using the IRIS Tool that stores the actually obtained score. Any Corrective Action Request must be closed within 90 calendar days from the end of the recertification audit and not after the "validity date", in accordance with chapter 14 of the IRIS Certification® Conformity assessment:2020.

A re-audit to the company's site is foreseen within 90 days in case of "insufficient" score or if the auditor reopens a CAR raised during the previous audit, whereas in case of "poor" score, the Lead Auditor may decide about the necessity of a re-audit or other appropriate methods to review the effectiveness of the corrective actions. When the CARs are closed, the total score will be adjusted consequently and the final result will be documented in a final audit Report. The IRIS Certificate will show only the total score obtained following the implementation of the corrective action.

After the 90 days period has elapsed without a positive conclusion of the evaluation, RINA will start the certificate withdrawal process.

In such cases, if the Organisation wishes to proceed with RINA certification, it must submit a new application and repeat the certification process.

In particular cases, the above time limits may be modified at the request of the Organisation, if considered justified by Rina.

6.3 SURVEILLANCE AUDITS

6.3.1

RINA performs periodic audits to the Management System in order to evaluate whether it remains compliant with the requirements of the reference standard, at least once every 12 months.

The date within which the audits must be performed is indicated in the three-year audit plan provided to the Organisation. This date coincides with the Validity Date (the end date of the certification audit).

Every surveillance audit following initial certification must be performed within and not later than the Validity Date.

6.4 RECERTIFICATION AUDIT

6.4.1

The recertification audit is performed at the Organisation's site(s) in order to confirm the continual conformity and effectiveness of the entire management system, as well as the continual applicability of the certification scope. It mainly consists of an on-site audit that is usually performed with the same criteria of the certification audit.

The recertification audit must be performed within and not later than the Validity Date.

CHAPTER 7
MANAGEMENT OF CERTIFICATES OF CONFORMITY

7.1

The certificate of conformity issued by RINA, which is the owner of the same, is valid for three years starting from the end date of the certification audit, or the closing date of the CARs, if any.

In case of multi-site Organisations, RINA will issue an ISO/TS 22163:2017 certificate for each site.

CHAPTER 9
PECULIARITIES CONCERNING MULTISITE ORGANISATIONS

Contrary to Chapter 9 of the General Rules for the Certification of Management Systems, the multi-site certification approach as set out in clause 3.3 of ISO/IEC Guide 62:1996 does not apply to IRIS certification process.

CHAPTER 10
TRANSFER OF ACCREDITED CERTIFICATES

10.1

In addition to the requirements of the corresponding paragraph 10.1, an Organisation which, in the last 3 years, has already transferred its certificate cannot request RINA for any certificate transfer.

Contrary to the provisions of the General Rules for the Certification of Management Systems, the transfer of ISO/TS 22163:2017 certificates can be accomplished only following a recertification audit.

CHAPTER 11
SUSPENSION, REINSTATEMENT AND WITHDRAWAL OF CERTIFICATION

11.1

The validity of the certificate of conformity can be suspended in accordance with the provisions of the "GENERAL CONTRACT CONDITIONS FOR THE CERTIFICATION OF SYSTEMS, PRODUCTS AND PERSONNEL" and in the following specific cases:

- if the Organisation refuses to allow the surveillance or recertification audits to be performed as scheduled;
- if any non-conformities are found in the Quality Management System which have not been corrected within the time limits established by RINA and in any case not later than 90 days from the date of the audit;
- if the Organisation does not observe the deadlines established for the communication of corrective actions, following non-conformities/observations indicated on the audit report;
- if the Organisation has made important internal changes to its Site(s), moves to another site or sites without informing RINA of such changes;
- if the Organisation has made important changes to its Quality Management System that have not been accepted by RINA;

- if the Organisation structure has undergone important changes that have not been reported to RINA;
- if the Organisation refuses or hinders the participation by any observers of an Accreditation Body to the audits;
- in the presence of an evidence showing that the Quality Management System does not comply with the laws and regulations in force applicable to the activities and/or site(s);
- if the Organisation receives a notice of claims from building Customers not suitably managed;
- in case of late payments;
- in the presence of any justified and serious claims received by RINA.

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