Rules for the certification of Quality Management System

according to IRIS standard

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Technical regulations

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CHAPTER 1
GENERAL

1.1

In the present Rules are defined the further procedures, and not substitutive, applied by RINA for the certification of Quality Management Systems according to IRIS (International Railway Industry Standard) standard, respect to what defined in

Rules for the certification of the Management System.

1.2

RINA issues the IRIS certificate according to the requirements of the UNI CEI EN ISO/IEC 17021: 2006 standard to Organizations whose Quality Management System has been recognised as fully conforming to the IRIS standard (International railways Industry Standard) issued and managed by the Railway Organization UNIFE.

1.3

Moreover what described in the General Rules for the Certification of Management Systems, the aim of the Certification has to be agreed between the client and RINA according to Annex 1 of the standard IRIS. The Organization accepts the following condition:

- In case of termination before the Evaluation Process has been carried out and the IRIS Certificate has been issued, the Client is not entitled to claim the IRIS Certificate.
- The Client agrees that the IRIS Certification terminates and cannot be used for any purposes if any Surveillance Audit is missed or failed.
- The Certification Body is obliged and irrevocably authorized by the Client 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 the IRIS Management Centre and will provide for restricted access rights.
- IRIS Group is irrevocably authorized to make Non-Detailed Data on passed audits available via the Database in accordance with its access rights.
- The Client itself decides to whom (e.g. customers) the Detailed Data (i.e. results of passed or failed audits) may be made available via the Database by the IRIS Management Centre providing the access rights.
- The Client accepts to pay the Audit fee to the Certification Body.
- The Client agrees to evaluate the Certification Body and its Auditors. The Client shall login to the Portal and use the proper function to issue an evaluation for each auditor who was part of the audit team.
- The Client agrees the language to be used during the audit and the language of the audit report.

- The Client accepts delegates of the IRIS Management Centre supervising witnessing audits performed by the Certification Body in order to verify that the activity performed by RINA are compliant to the standard.
- The Client is perfectly aware that 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 System remain vested in UNIFE, and that no provisions of the agreement between the Certification Body and the Client shall give rise or shall be deemed to give rise to an assignment, transfer or licensing of the intellectual property rights of UNIFE.
- The Client 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 members of its group to use only the original IRIS Standard and Software and to refrain from using any document or copies of software which might infringe the intellectual property rights of UNIFE.

CHAPTER 2
REFERENCE STANDARD / CERTIFICATION REQUIREMENTS

2.1

Organisations, wishing to obtain RINA certification of their Quality Management System according to the IRIS standard, must first and henceforth satisfy the requirements of IRIS standard and those indicated in the following paragraphs of this Chapter, plus possible further requirements defined by UNIFE.

Moreover what described at point 2.1 in General Rules for the Certification of Quality Management Systems, during its accreditation activities, RINA must abide by certain reference documents issued by UNIFE. These documents can be obtained from RINA or directly from UNIFE (consulting their Internet sites, for example).

The issue of the Certificate according to the IRIS standard is based on the fulfillment of the following criteria:

- All the requirements associated to the applicable KO questions are met, and
- All IRIS corrective action requests are closed, and as a consequence
- The threshold of the global score is met.

CHAPTER 3
INITIAL CERTIFICATION

3.1

The evaluation process is based on a scoring methodology (see IRIS standard - Chapter 2: IRIS Assessment Guide Lines), on the standard (see IRIS standard - Chapter 3: IRIS Requirements) and on the evaluation scheme (IRIS questionnaire in the Audit Tool).

Moreover what described at point 3.3 of General Rules for the Certification of Quality Management Systems, the stage 1 (Readness Review) audit shall be performed
to review the client's status and understanding regarding requirements of the standard, in particular with respect to the KO questions, the processes and the procedures defined In the IRIS standard;

In substitution to what described at point 3.5 and 3.6 in General Rules for the Certification of Management Systems, at the end of stage 2 a signed copy of the final report, including the possible non conformities and/or the extract of the Action Plans. The contents of the final report are confirmed by RINA through a written communication. If no written communication is sent by RINA, the report is considered confirmed after 3 working days starting from the issuing to the company.

After analyzing the reasons for any non-conformities indicated in the Stage 2 report, the Organisation must, within one week, inform RINA, sending the excel file extracted from the IRIS Tool adequately compiled, of its proposals for handling the non-conformities, as well as the corrective action required and the dates envisaged for its implementation.
In the event of non-conformities, a Corrective action Request (CAR) is generated and recorded in a Preliminary Report, using the Audit Tool, which records the effective score achieved.
Any corrective action requested must be closed within 90 calendar days from the end of the on site visit and according to the requirements defined in the standard IRIS, Chapter 2, §6.

In particular, corrective actions requested due to "insufficient" fulfillment of requirements must be re-audited by 90 calendar days at sites, while , in case of "poor" fulfillment of requirements the Lead Auditor may decide about the necessity of a re-audit or other appropriate methods to review the effectiveness of corrective actions.

Once all CAR's are closed the global score has to be adjusted accordingly and the final results shall be documented in a final audit report. The IRIS certificate will show only the global score after the corrective action is closed.

After the above 90 days period has elapsed with no positive outcome of the assessment, RINA reserves the right to definitively close the certification file and charge the time spent and expenses incurred up to that moment. In such a case, if the Organisation wishes to proceed with RINA certification, it must submit a new application and repeat the certification procedure.

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

4.1

Moreover what described at point 4.5 in General Rules for the Certification of Quality Management Systems Certification, the maintenance audits are divided into two types:

- surveillance audits, generally performed at least once a year.
  Sample checks of the Quality Management System are made according to the IRIS standard as indicated in point 3.7 of the General Rules for the certification of the management System.
- recertification audit (see chapter 1, § 4.2.4).

The Quality Management System according to the IRIS standard must be totally reviewed every three years.

4.2

Moreover what indicated at point 4.4 in the general Rules for the Certification of management System, the following aspects will be considered during the surveillance audits:

- all the mandatory "Knock-Out" (KO) requirements
- the ISO 9001:200 requirements as defined by RINA for the surveillance audit
- all specific areas, where RINA identified non-compliance or improvements in the previous audit, if they were not part of a re-audit
- specific areas, at the request of the client in order to improve a score.

4.3

Moreover what described at point 4.5 in General Rules for the Certification of Quality Management Systems, the first surveillance audit must be performed at intervals of not more than 12 months and the date within which the audits must be performed is indicated on the three yearly audit plans in the Organisation's possession.

The second surveillance audit must be performed at intervals of not more than 24 months from the date of the certification audit.

If extra audit (quarterlies or biyearlies) are planned, the validity of the certificate is confirmed if the results of the mentioned audits are positive.

CHAPTER 5
MANAGEMENT OF CERTIFICATES OF CONFORMITY

In substitution to what described at point 6.2 in General Rules for the Certification of Quality Management Systems, the IRIS certificate of conformity issued by RINA is valid for three years starting from the last date of the first certification audit.

The ISO 9001 certificate can be issued independently by the IRIS Certificate, according to the ISO 9001 norm and relative applicable RINA Rules, even if the specific IRIS requirements are not completely fulfilled.
In case of multi-site organizations, RINA shall issue an IRIS certificate for each site.

After certification of all sites of a multi-site corporation, the IRIS Management Centre can issue a letter of compliance on the corporation's request (as indicated in IRIS standard Chapter 1, §4.4.).

CHAPTER 6
SPECIAL PROCEDURES FOR MULTI-SITE ORGANISATIONS

Different from what described at Chapter 8 in General Rules for the Certification of Quality Management Systems, a multi-site approach as referenced in clause 3.3 of ISO/IEC Guide 62:1996 does not apply for IRIS certification process.

CHAPTER 7
TRANSFER OF ACCREDITED CERTIFICATES

If an Organisation with a valid certificate issued by another body which is accredited by UNIFE and registered in the list of the recognized Certification Body, presents a certification application, moreover to what described at point 9.1 in General Rules for the Certification of Quality Management Systems, RINA proceeds as follows:

before the second surveillance audit: RINA shall issue a new certificate keeping the same validity date, after having performed a readness review and the next scheduled surveillance audit. Upon agreement with the customer, a new audit cycle can also start without reduction of audit time;

after the second surveillance audit: RINA shall perform a readness review and a certification audit without reduction of audit time (see Annex 2 of the standard).

CHAPTER 8
SUSPENSION, REINSTATEMENT AND WITHDRAWAL OF CERTIFICATION

Moreover to what described at point 10.3 in General Rules for the Certification of Quality Management Systems Revocation of the certificate of conformity may be decided as indicated in "GENERAL CONTRACT CONDITIONS GOVERNING SYSTEM, PRODUCT AND STAFF CERTIFICATION" and in the following specific cases:

- claims to the IRIS Management Centre, which are considered justified after the analysis of the IRIS Management Centre and RINA. If claims are justified, RINA shall raise corrective actions and be closely in contact with the IRIS Management Centre during the follow up assessment. If the assessment of the corrective action is positive, the Certificate is confirm, otherwise RINA will withdrawal the IRIS Certificate and update audit results in the IRIS and RINA Portal. (as defined in IRIS standard , Chapter 1, §5). The withdrawal of IRIS Certificate does not necessary affect other certificates such as ISO 9001.

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