

1 General Requirements

The regulations set forth herein apply in addition to the General Terms and Conditions of Certification TÜV Rheinland (China) Ltd.

The regulations herein apply for any railway industry related corporation (Client) intending to obtain and maintain certification of a management system according to ISO/TS 22163 based on the requirements for certification defined by UNIFE (in the following called “IRIS Certification”).

2 Evaluation Process

2.1 Certification Audit

2.1.1 Information Required for the audit planning

The client agrees to provide the following data (documents with detailed information) shall be provided by the organization to the lead auditor, latest sixty (60) calendar days in advance of the audit:

- Stakeholder analysis,
- Customer perception data,
- Turtle diagrams for mandatory processes for performance evaluation;
- List of organization’s processes and interactions.

Sixty (60) calendar days before to the audit, the client will sign and upload to the IRIS Portal a confirmation statement as proof of submission of the documental package to the lead auditor. This confirmation statement will confirm the list of documents submitted to the lead auditor and the date of submission. This step is compulsory for Silver or Gold levels.

If the client does not provide the above information at least 60 days before the audit, the client agrees to add at least 0.5 days to the originally planned number of audit days on site. Only the basic quality performance level (Bronze) can be achieved. In general, this case is for exceptional situations and cannot be repeated every year.

2.1.2 Readiness review

The first step in the process of IRIS certification is a “Readiness Review”, which is designed to assess the client’s level of organizational conformance to the prerequisites of the IRIS certification process.

The review must be undertaken as follows:

- Performed on site before a certification audit and in the case of a change in certification body;
- Performed not more than 60 calendar days before starting the audit;
- Repeated if it fails; and It should be:
- Performed on site before a recertification audit and in the case of a change in auditor team.

In addition to a review of the client's business management manual, quality policy and organizational charts, the following prerequisites shall be reviewed to ascertain the client's readiness for the audit:

- Cross-reference check against the mandatory procedures/processes/KPIs' of IRIS certification process;
- Detailed pre-assessment of the requirements linked to knock-out questions;
- Evaluation of the client's location and site-specific conditions (e.g. remote locations);
- Verification of the agreed scope of IRIS certification and the allocation of resources to the audit, with agreement reached with the client on all such details; and
- Audit planning.

The client's data will be downloaded from the IRIS Portal prior to the readiness review and the audit tool will be used to report the results.

2.1.3 Certification audit

The next step after a positive Readiness Review is a certification audit. If certification is successful, an IRIS Certificate valid for 3 years will be issued.

Once certified, the client will be required to undergo surveillance audits on an annual basis. Before the expiry of its IRIS Certificate, the client will be recertified through a recertification audit, which constitutes a renewal of the IRIS Certificate. A supplementary IRIS Certificate will be issued.

If an audit fails, it must be repeated within 3 months (re-audit). Corrective actions resulting from the audit must be closed at this time.

2.1.4 Time requirements for stage 2 the audit must not exceed 60 days.

Prior to the certification audit, a minimum of six months' worth of data and other records must be made available for related IRIS certification activities within the scope of certification.

If TÜV Rheinland is unable to verify the implementation of actions to prevent or correct non-conformities within 90 days of the last day of stage 2 of the audit, the audit will be deemed to have failed, and an entire new certification process will begin.

2.2 Surveillance Audits

The last day of stage 2 of a site audit is the reference date (“due date”) for the entire 3-year audit cycle. A positive certification decision is required not later than this date for all successive audits, including renewal audits.

3 Multi-Site Audits – Remote Functions and Site Extensions

The IRIS Certification process follows exclusively a single-site certification approach, therefore a multi-site certification approach, as referred by other certification process e.g. ISO 9001, does not apply for the IRIS Certification. However, remote functions and site extensions for supporting activities may be involved in IRIS certification.

3.1 Remote Functions and Site Extensions

3.1.1 Remote functions

Remote functions are supporting functions in remote locations (e.g. design, sales, logistics and purchasing operations and warehouses). Remote functions must be audited, but cannot seek their own IRIS certification. If a remote function supports more than one site, it must be visited along with the first audited site. Remote functions shall be audited at the time of the certification or recertification audit and at least once more during the life of the certificate.

3.1.2 Design functions in remote locations

When a design and development function is in a remote location, it shall be part of each surveillance audit. Such a function is considered remote only when the client has no autonomous business management system.

3.1.3 Changes to organization

In the case of changes to the organization’s scope, activities and/or location after a certification audit, all remote functions impacted by the changes shall be audited prior to the next surveillance audit.

3.1.4 Remote functions supporting several sites

If a remote function supports more than one site, it shall appear on each certificate.

3.1.5 Site extensions

Site extensions shall be audited during each audit but cannot be awarded their own IRIS Certificates. A site extension is defined as such if it meets the following conditions:

- It involves a manufacturing or maintenance activity belonging to the connected certified site;
- It is included within the scope of certification of the connected certified site;
- It performs exclusively manufacturing or maintenance processes; and
- It is included in the audit plans (at least plans for certification and recertification audits) for the connected certified site.
- The site is not autonomous regarding objectives and processes definition (quality processes and objectives are defined by the certified organization,
- The percentage of people working for manufacturing/maintenance activities (reporting to manufacturing/maintenance certified organization) is higher than 75% of the total number of employees of the site extension.

4 Transfer Audits

4.1 Definition of Transfer Audit

A transfer audit takes place when a client holding an IRIS Certificate decides to move from its existing certification body to TÜV Rheinland. A transfer audit is possible only if no such audit has taken place in the last 3 years.

4.2 Transfer audit process

A transfer audit can be performed during any type of audit, such as a surveillance audit or recertification audit. A Readiness Review is mandatory, and a minimum of 3 months' worth of data and other documentary information must have been retained and made available. The minimum number of days required for a transfer audit is equivalent to that for a recertification audit.

4.3 Activities Required Prior to a Transfer Audit

- The existing IRIS Certificate must be valid;
- The client must request a change of certification body through the IRIS Portal;
- After the request has been approved by the IRIS Management Centre, TÜV Rheinland will be able to see the client data in the IRIS Portal and access the last audit documentation;
- TÜV Rheinland will perform a review of all the documentation at the start of the transfer; and

- TÜV Rheinland must ensure that none of the audit team members have previously audited the client.

5 Audit after changes impacting the management system

The client could evolve during an audit cycle, with an impact on its business management system:

- Change of location (manufacturing, design, maintenance),
- Additional IRIS Certification scope of certification,
- Change of main ownership.

To assess the impact of the changes on the business management system, a template has to be filled in by the client and evaluated by the lead auditor, sixty (60) calendar days prior to the audit.

In these three (3) cases, a readiness review is mandatory and a minimum of three (3) months data and retained documented information shall be available for the related IRIS activities within the scope of certification before this audit can be performed.

The client shall provide the following information to certification body in a template.

- Geographical constraints,
- Transfer of manpower, machines, techniques, processes, etc.,
- Any further needed information to ensure a proper audit execution.

In case the total amount of the points assessed in the template is ten (10) or more points, the minimum number of audit days for this type of audit shall be equivalent to a recertification audit.

6 Withdrawal of IRIS Certificate

6.1 Process of Withdrawal of IRIS Certificate

The process of withdrawing an IRIS Certificate can start with any of the following actions:

- The certified organization issues a complaint to the IRIS Management Centre or to the current certification body;
- The certified organization does not accept the result of a maturity review by the certification body; and
- The certified organization requests that the IRIS Management Centre or TÜV Rheinland cancel a certificate or reduce its scope.

6.2 Withdrawal Process

The IRIS Management Centre will analyze any such requests and complaints and forward its conclusions to TÜV Rheinland, with two possible outcomes:

- If the complaint is not justified, TÜV Rheinland will confirm the validity of the IRIS Certificate; or
- If the complaint is justified, TÜV Rheinland will request corrective actions on behalf of the client.

6.3 Review of Corrective Actions

If an assessment of the corrective actions undertaken by the client reveals satisfactory improvement, TÜV Rheinland will confirm the validity of the IRIS Certificate and update the audit results if necessary.

However, an unsatisfactory result (a lower score, but still above the threshold) may result in the client's being downgraded.

6.4 Unsatisfactory Improvements

If assessment reveals that the corrective actions undertaken by the client have failed to ensure compliance with the standard, TÜV Rheinland will withdraw the IRIS Certificate and update the client's information in the IRIS Portal accordingly.

Withdrawal of an IRIS Certificate does not automatically change the validity of other certificates, such as ISO 9001.

7 Additional Conditions

7.1 Extraordinary termination

TÜV Rheinland has been appointed by UNIFE to conduct IRIS audits and issue IRIS Certificates. The right to issue such certificates requires a valid agreement on IRIS certification between TÜV Rheinland and the client. If the client contract is terminated before the IRIS certification process has been completed and the IRIS Certificate issued, the client will not be entitled to claim the IRIS Certificate.

7.2 Failure to Meet Surveillance or Recertification Audit Requirements

The client shall agree that IRIS certification will terminate immediately if deadlines for a Surveillance or Recertification Audit are missed or the audit is failed, whereupon the IRIS Certificate can no longer be used.

7.3 Use of Audit Data by IRIS Management Centre

TÜV Rheinland is obliged and irrevocably authorized by the client to transmit the request for IRIS certification, IRIS certification information and any related data to the IRIS Management Centre, irrespective of the results of an audit. Such data will be stored in the database and administered by the IRIS Management Centre. The right to grant access to, adjust, remove and/or public data stored in the database is granted irrevocably to the IRIS Management Centre.

The client acknowledges that TÜV Rheinland cannot be held responsible for the publication, maintenance or deletion of the data stored by the IRIS Management Centre after such data has been transferred to its database.

7.4 Publication of Detailed or Non-detailed Data in IRIS Management Center

According to the rules governed by the IRIS Management Center, the Client decides to whom (e.g. customers) 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. Client 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.

7.5 Obligation to Evaluate Auditors

The client agrees to evaluate the auditors that have conducted the IRIS certification and related follow-up audits. For this purpose, the client shall access the respective portal and enter the required information for each auditor that has participated in the process.

7.6 Audit language

The client agrees the language used during audit and the language in audit report.

7.7 Obligation to Accept Witnesses to Audits

The client herewith acknowledges its obligation to accept delegates of the IRIS Management Centre wishing to supervise and/or witness audits performed by TÜV Rheinland, and to grant these delegates access to its sites, including remote locations and site extensions.

The selection of sites at which to conduct such supervisory activities is made by the IRIS Management Centre. The dates of such supervisory activities must be communicated to the organization 7 calendar days prior to the start of the witnessed audit.

7.8 Intellectual Property of UNIFE

The client is aware that:

- Any proprietary 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;
- All intellectual property rights to the system shall remain vested in UNIFE; and
- No provisions of the agreement between TÜV Rheinland (China) Ltd and its affiliates/branch offices and the client shall give rise or be deemed to give rise to the reassignment, transfer or licensing of the intellectual property rights of UNIFE

7.9 Commitment to Use Original Software

The client undertakes to use and to require its employees, directors, agents and other representatives, as well as its shareholders and other companies in or members of its group, to use only the original software; none of these entities should use either documents or copies of software that might infringe the intellectual property rights of UNIFE.

The client should remain aware that as a user of IRIS copyright material, it must respect and observe IRIS copyright rules. Furthermore, the client should support every other relevant user in complying with these copyright rules.

7.10 Compensation

The client understand that if client or one of its employees, directors, agents, or other representatives, or one of its shareholders or another company or member of its group infringe the intellectual property rights of UNIFE, which results in UNIFE's and/or TUV Rheinland's reputation damage or financial losses, TUV Rheinland is entitled to claim from the client, a compensation that equals to UNIFE's and/or TUV Rheinland's financial losses.

7.11 Exclusion of Liability

The client acknowledges and accepts that TÜV Rheinland (China) and its affiliates, branch offices, representatives and employees cannot be held liable for any direct or indirect losses or damages suffered by the client in relation to the IRIS Certificate or the IRIS certification system. This exclusion of liability shall not apply in cases where an exclusion of liability is prohibited by mandatory applicable law.