1 General Requirements

The regulations set forth herein apply in addition to the General Terms and Conditions of Certification defined by TÜV Rheinland companies in different countries.

The regulations herein apply for organization (hereinafter referred to as the client) intending to obtain and maintain management system certification performed by TÜV Rheinland ((hereinafter referred to as the certification body) according to IRIS 04 requirements defined by UNIFE.

Below are concepts and requirements defined in IRIS 04 certification and other requirements required by UNIFE.

2 Evaluation Process

2.1 Pre-Audit

The certification body can perform on request of a client a pre-audit prior to the Readiness Review. A pre-audit is an assessment but it is not part of the IRIS Certification® process.

The audit team involved in the pre-audit is not allowed to participate in the readiness review, the certification audit and the first and second surveillance audit. Furthermore, only one pre-audit is allowed.

2.2 Certification Audit

2.2.1 Information Required for the audit planning

The client agrees to upload the following data (documents with detailed information) into IRIS Portal diary, latest sixty (60) calendar days in advance of the audit:

- Management review report,
- List of organization's processes and interactions,
- Customer complaint status,
- Warranty claims statistics,
- Mandatory PIs including their definition and the values for the audited period,
- Turtle diagrams or comparable for the max. five (5) key processes,
- Process PIs including their definition and the values for the audited period for the max. five (5) key processes,
- Evaluation eligibility for simplified approach if marked in the organization master data,
- For achieving the gold level: the direct feedback from customers.

If the client does not provide the above information at least 60 days before the audit, the client won't be awarded quality performance certificate by UNIFE.

2.2.2 Readiness review

The readiness review (if applicable) shall be performed together with the data review, remotely or on site but not earlier than sixty (60) days before the start of the audit.

The readiness review aims to assess the organization's level of conformity to the IRIS Certification prerequisites.

The readiness review shall be repeated, if failed.

The readiness review should be performed before the recertification audit and in case of change of auditor team within the same certification body.

The following data shall be reviewed to ascertain the organization's readiness for the audit:

- Quality policy,
- Organization charts,
- Business category (-ies),
- Certification activity (-ies),
- A cross reference check against the IRIS Certification mandatory processes/PIs,
- Customer perception performance,
- A detailed pre-assessment on the requirements linked to KO items,
- An evaluation of the organization's location and site-specific conditions (e.g. supporting functions)
- A verification of the agreed product scope(s) of certification,
- The resource allocation for the audit and the agreement with the organization on all details,
- The audit planning.

The KO items in IRIS Certification are the core requirements to be fulfilled by an organization in the railway sector and their positive assessment is essential to pass the readiness review.

2.2.3 Certification audit

The client's first audit is a certification audit.

The certification audit shall be conducted on site. It aims to assess the implementation, including the effectiveness of the RQMS.

The last day of the certification audit is called reference date.

If an client fails the audit, a re-audit or closure of the CARs by document review only shall be performed within 90 days after the end of the audit.

After successfully passing the certification audit, an IRIS Certification certificate is issued by the certification body.

2.3 Surveillance audit

Once certified, the organization needs to request surveillance audits on an annual basis.

Surveillance audits shall be planned and performed thirty (30) days and up-to one hundred and fifty (150) calendar days before the anniversary of the reference date to avoid the risk of the organization losing the IRIS Certification certificate, due to potential CARs.

The selection of the processes to be audited during the surveillance audit shall be based on the analysis of the data sent prior to the audit (at least weak areas, complaints, issues found in the data package, etc.).

During surveillance audit, the audit report of the previous assessment is updated with the respective scores.

The reassessment will result in a new audit report.

Ass scores which were not re-assessed remain unchanged.

The certification body shall confirm the certification based on evidence that the organization continues to fulfil the ISO 22163 requirements.

2.4 Recertification Audit

Before the expiry of the IRIS Certification certificate, the organization needs to be recertified (recertification audit), which consists in a reassessment of all requirements. Recertification audits shall be planned and performed thirty (30) days and up-to one hundred and fifty calendar days before the anniversary of the reference date to avoid the risk of the organization losing the IRIS Certification certificate, due to potential CARs.

It aims to confirm the continued fulfilment of the ISO 22163 requirements of the RQMS.

The complete evaluation process starts again.

After successfully passing the recertification audit, a new IRIS Certification certificate is issued.

3.0 Transfer audits

A transfer audit takes place when an IRIS Certification certified organization decides to change its current IRIS Certification approved certification body.

A transfer audit can be performed during any type of audit (surveillance, recertification audits). Furthermore, there shall be a minimum of three (3) years between two (2) transfer audits.

The minimum number of audit days for a transfer audit shall be equivalent to a recertification audit plus a readiness review.

Activities prior to the transfer audit:

The existing IRIS Certification certificate shall be valid,

The organization shall request the change of certification body through the IRIS Portal,

After the request is approved by IMC, the new certification body can see the organization's data and access the last audit documentation,

The new certification body shall review all available documentation to start the planning of the transfer audit,

The new certification body shall ensure that no audit team member has audited the organization in the last two (2) years.

When the organization changes the IRIS Certification approved certification body, the reference date is kept, all other rules for the certification process and assessment method apply. After a successfully passed transfer audit, a new IRIS Certification certificate is issued for the remaining validity time, by the new certification body.

4.0 Audit after changes impacting the RQMS

An organization can evolve during an audit cycle, with an impact on its RQMS:

- Change of location (production, design, maintenance),
- Change certification activity,
- Change IRIS Certification product scope(s),
- Change of main ownership,
- Upgrading from simplified certification activity.

Note: change means adding or removing.

To assess the impact of the changes on the RQMS, the related template (available in the download area of the IRIS Portal) must be filled in by the organization and assessed by the lead auditor, sixty (60) calendar days prior to the audit.

The certification body shall ensure that following information is available:

- Geographical constraints,
- Transfer of workforce, 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, the minimum number of audit days for this type of audit shall be equivalent to a recertification audit.

After successfully passing the audit after changes impacting the management system, an updated IRIS Certification certificate is issued for the remaining validity time

5.0 Supporting – Remote Functions and Site Extensions and guiding functions

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 and guiding functions for supporting activities may be involved in IRIS certification.

5.1 Remote Functions and Site Extensions and Guiding function

The product scope of the certified site must always cover at least that one(s) of the supporting function(s). The detailed scopes are displayed for each supporting function on the second page of the certificate.
The definition of the supporting functions set-up is part of the organizations master data that shall be registered in the IRIS portal.

APPLICABILITY CRITERIA	Remote function	Site extension	Guiding function
Description	Remote functions are supporting functions on remote locations.	Production & maintenance activities performed in another location but connected with a certified site.	Group of processes that drive remotely several sites.
Impacted Processes	All processes except production.	Only production and/or maintenance process.	All processes except production.
Examples of impacted activities	Design, sales, logistics, purchasing, human resources, ...	Assembly lines, painting, warehouses, ...	Business lines, divisions, departments, projects organizations, ...
Certification	Possible, then for at least three certification activities: requirements management and two of the three others.	Not possible.	Possible, then for at least two certification activities: requirements management and one of the three others.
Site address	Physical address of remote location.	Physical address of site extension location.	Physical address of the related headquarters
General criteria	When the function has an autonomous RQMS, then it has to seek for its own certificate. When there is no autonomy, the connected site's RQMS shall cover the supporting processes. A dedicated audit plan is necessary in all cases.	The site extension does not have decision-making authority, autonomy, or independence. It always depends on the RQMS of the main production site. It is part of the audit plan of the connected site.	These functions are covered by a common RQMS. This specific set-up applies only when there are more than two locations and is fixed as follows: – is included in the audit landscape (global overview how the functions are connected and auditable), – is defined by the organization,
Audit frequency	Annual audit in line with the supported site.	Annual audit in line with the supported site.	Annual audit before the guided sites.
Audit specificities	On-site, remote or semi-remote audit is possible.	Only on-site audit is possible.	Semi-remote audit is recommended.

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 certification body, 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

certification body's reputation damage or financial losses, certification body is entitled to claim from the client, a compensation that equals to UNIFE´s and/or certification body'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.

7.12 provision of internet connection

IRIS certification use web-based audit tool, the client agrees to and shall provide an adequate internet connection to allow the audit team to conduct an efficient audit.