DESCRIPTION OF THE IRIS CERTIFICATION® REV.04 PROCEDURE

Complete revision-no change of marking

CONTENT

If you should require any further information then please do not hesitate to contact us. We will be please to help you.

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The certification procedure for the management system based on the IRIS Certification® Rev.04 scheme (based on and IRIS Certification® Performance Assessment:2023 and ISO 22163:2023).
Only companies, which described in the IRIS Certification® Performance Assessment, Applicability section can take part in the certification procedure.
Special Rules issued by IMC/UNIFE in case of special circumstances will be applicable in addition to this certification procedure, e.g. transition phase.
The current editions and amendments to the IRIS standards always apply in addition to this Service Description; including the Advisories and Interpretation of UNIFE / IMC, see also www.iris-rail.org.

1. CERTIFICATION PROCEDURE

1.1. Audit and Audit Cycle

The IRIS Certification® process is based on ISO/IEC 17021. Multisite or group certification approach is not possible for IRIS Certification®.
The audit and certificate cycle are on a three (3) year basis.
The relationship between audit and certificate cycle is;

IRIS Certification® Cycle 1	Time frame
Readiness Review and Data Review	Max 60 days before certification audit
Certification audit	
CARs Closure for Certification audit	Max 90 days after the last date of the audit
Data Review and Surveillance audits	-150 to -30 days before the reference date
CARs Closure for Surveillance audits	Before reference date

IRIS Certification® Cycle 2	Time frame
Data Review and Recertification and Surveillance audits	-150 to -30 days before the reference date
CARs Closure for Recertification and Surveillance audits	Before reference date

The last day of the Certification audit is called a Reference Date.

1.2. Audit Preparation

Before the start of the certification procedure, the following activities have to be carried out by the company in the IRIS WEB Portal (www.iris-rail.org): entry of the relevant company master data (e.g.: Headcount, business categories, certification activities, supporting functions, project management type), identification of TÜV NORD as responsible IRIS certification body.
Company master data shall be confirmed by the organization in the IRIS portal latest ninety (90) days in advance of the audit.

At the latest when the next audit is planned, these data have to be updated in the IRIS WEB portal by the company in so far as necessary. Any necessary changes must be communicated to TÜV NORD in good time within the framework of the audit planning.
The scope of the certification shall be agreed between the client and the certification body in accordance with IRIS Certification® Performance Assessment; Business category, Certification activities and Product scope(s), Simplified IRIS certification applicability.
TÜV NORD Questionnaire will be sent to organizations to ask company master data before offer submission and each audit.
Before an IRIS Audit can be started, a certification contract must be concluded with TÜV NORD.
The auditors are selected from the auditor pool of TÜV NORD. When selecting the auditors, it must be ensured that the audit team covers the related IRIS scopes.
The minimum time needed for the certification, surveillance and re-audits, preparation and reporting times can be found in IRIS Certification® Performance Assessment, Clause 5.2. When translator shall be needed, the audit time shall be increased by %20 for those areas, where the translator used. Remote auditing time shall be added as described in the Performance Assessment, if applicable.
Following detailed information shall be uploaded to the IRIS portal by the organization latest sixty (60) days in advance of the audit (certification, surveillance, re-certification) for Data Review:

- 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

Minimum 6 month data for certification audits and minimum 3 month data for transfer audits/changes impacting Rail Quality Management System (RQMS) is required.
The timeframe for the data to be considered, shall include and focus on the period since the last audit conducted for surveillance audits.
5 key processes are;

- Project management (ISO 22163 clause 8.1.3),
- Requirements for product and services (ISO 22163 clause 8.2),
- Control of externally provided processes, products and services (ISO 22163 clause 8.4),
- Design and development of product and services (ISO 22163 clause 8.3),
- Production and service provision (ISO 22163 clause 8.5)

In the case the organization does not upload the required documentation sixty (60) calendar days in advance to the IRIS portal, 0,5 audit days shall be used for the data review on-site.
Before application for certification the company should carry out self-assessment according to ISO 22163 requirements to evaluate their business management system. Using of IRIS audit web tool is recommended.
The organization shall provide internet connection to the audit team during the onsite audit if requested.

1.3. Pre audit

As an option, a pre-audit can be carried out prior to the Readiness Review. The auditor of the pre-audit is not allowed to participate in the readiness review, the certification audit and the first and second surveillance audit. Only one pre-audit is allowed. Pre-audit is not a part of the certification process.

1.4. Readiness Review

The readiness review (if applicable) shall be performed on site or remotely and together with Data Review.

Within the framework of the readiness review, it is considered if the company fulfils the basic prerequisites for an IRIS certification. The readiness review

- must be carried out before the certification audit, and also if the certification body is changed
- must be carried out maximum 60 calendar days before the start of the certification audit
- must be repeated if it was not successful
- should be carried out before the recertification audit and in case of the audit team change
- Shall be conducted at audits after changes impacting the RQMS

The Lead Auditor is responsible for coordination of the activities during readiness review and for any coordination between the participating auditors.

The results of the readiness review are documented with the IRIS tool and are reported back into the IRIS database. Following a positive readiness review, the Audit Plan for the next audit is created and agreed with the client.

For further details, see IRIS Certification® Performance Assessment, Clause 6.4.

1.5. Certification Audit

The first audit is called as Certification audit. The last day of the certification audit is called as Reference Date which will be taken as for next audits plannings. During the on site audit, the auditors verify and evaluate the effectiveness of the management system that has been implemented. The basis for this is always the current edition of the IRIS standard including the supplementary documents such as advisories, amendments, additions etc.

The task of the auditors is to examine the level of fulfilment of the individual requirements and of the entire management system. This is carried out by interviewing the employees, viewing other relevant documents, records, orders, projects and guidelines, and also by visiting relevant areas of the company.

Minimum six (6) months data and records shall be available for the related IRIS activities of the certification scope prior to the certification audit.

In the final meeting, the lead auditor presents the results of the audit, including the Audit findings, Corrective Action Requests (CARs) if any, Potential Improvement Action Requests (IARs),

(Preliminary) enabler score, Customer perception result, Performance evaluation results, Strengths and areas for improvement, Potential Quality Performance Level (QPL) .

Employees who have a management function in the company and whose areas were involved in the audit should attend this meeting.

The audit result, including the required documents, must be reported to the IRIS portal within 30 days after the audit or closure of the CAR's. In the case of certification audits, the entire IRIS questionnaire must be assessed.

The IRIS Audit Web-Tool shall be used for the documentation of the audit. If the company fails the audit, re-audit or documents review shall be completed within ninety (90) calendar days. The last day of the certification audit is recorded in the audit portal as Audit Reference Date for all further audits.

For further details, please see IRIS Certification® Performance Assessment , clause 6.5

1.6. Award of Certificate

The certification decision (e.g. granted or not granted) is communicated by the lead auditor during the closing meeting as result of the performed audit.

The certificate can only be issued if the audit was concluded with a positive result within the set deadlines, and if the requirements for issue of the certificate were fulfilled.

After a documental veto check, all required documentation shall be uploaded to the IRIS portal and IMC issues the certificate in the audit portal.

The certificates which contains the IRIS Certification business category, the certification activities, and the product scope(s) are valid for 3 years.
Only certificates carrying the IRIS Certification® logo issued by IRIS Certification approved certification bodies are recognized by IRIS stakeholders. The validity of the IRIS Certification® certificate can be found exclusively at www.iris-rail.org.

2. SURVEILLANCE AUDIT

Surveillance audits onsite must be performed once per year within the period of validity of the certificate. The IRIS audits must be concluded (closed) at the latest 11 or 23 months after successful first certification. The last day of the certification audit is always the reference date for the following years. The allowed time frame for the surveillance audits are -150 to -30 days before the reference date.
If the above deadlines are not fulfilled, the IRIS certificate is removed from the WEB portal (cancelled).
The data review results prior to the audit shall be used to selection of the processes to be audited, at least weak areas. Within two (2) surveillance audit all processes shall be audited at least once.

3. RECERTIFICATION AUDIT

The IRIS recertification audit must be concluded (closed) at the latest 36 months after the successful first IRIS certification. For recertification audits, the minimum scope is the same as the scope of the first certification audit.

4. RE AUDIT

Re-audit shall be conducted on site in the case of CARs score “insufficient”.
If the CARs score is “Poor” the lead auditor may decide to conduct re-audit or other methods to review corrective actions effectiveness.

5. CHANGES TO IRIS CERTIFICATES

Any changes within the framework of the surveillance or recertification audit must be communicated in advance and agreed with the certification body. Changes can happen with an impact on its RQMS;

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

In this case, a readiness review is mandatory and a minimum of three (3) months data and retain documented information shall be available for the related IRIS activities within the scope of certification, before such audit can be performed.
The form “Appendix 6- Changes Impacting The Management System” shall be downloaded from the IRIS portal, filled and sent to the lead auditor sixty (60) days before the audit. The audit duration can be decided according to assessment result of the given information.
For further details, please see IRIS Certification® Performance Assessment, clause 6.9.

6. CERTIFICATION OF COMPANIES WITH MULTIPLE LOCATIONS (MULTI-SITE)

Group or matrix certification is not possible for IRIS Certification®, each production location can only be certified individually.

Supporting functions can be included to the certification process and certificate as

- Remote Function: Together with the site or alone
- Site Extension: Together with the site
- Guiding function: Together with the site or alone

For further details, please see IRIS Certification® Performance Assessment, clause 4.6.

7. MANAGEMENT OF NON-CONFORMITIES AND IMPROVEMENTS

In the case of nonconformities (CAR), an action plan has to be submitted to the lead auditor in a sufficient time according to the audit reference date. The audit must be concluded (closed) and reported in the IRIS WEB portal by the certification company within 90 days from the last audit date but before the audit reference date.

If an individual question is assessed with “0 points”, an additional re-audit has to be performed in order to check the corrective actions.
By identification of a nonconformity on an applicable K.O. item during an on-site audit, it is deemed to be a major nonconformity and a re-audit is mandatory.
In case of improvement actions (IAR), it is recommended to request the close-out of an improvement action by the next audit, but there may also be acceptable reasons to increase this period.

For further detail of

- Scoring methodology, please see IRIS Certification® Performance Assessment , clause 12
- Non-conformity management, please see IRIS Certification® Performance Assessment, clause 13

8. QUALITY PERFORMANCE LEVEL

IRIS Certification® has three (3) pillars (enabler evaluation, customer perception and performance evaluation). According to assessment of these pillars the organization achieves following quality performance levels;

- Top performance-Gold
- Transparent-Silver
- Capable-Bronz
- IRIS Certified- No QPL
- Simplified-No QPL

For further details, please see IRIS Certification® Performance Assessment, clause 14.2.

9. COMPLAINT PROCESS

Railway sector customer complaints to IRIS certified companies can start via;

- Customer complaint to IMC,
- Customer complaint to the current certification body.

First analysis of customer complaint is done by IMC and informs TÜV NORD CB Representative about the conclusion. The complaint can be evaluated for the justification by document review or onsite. Corrective actions shall be requested if the complaint is justified.

The impact on the IRIS certification according to the evaluation result can be;

- Continuing of certificate and QPL
- Continuing of certificate but downgrading of QPL
- Withdrawal of certificate

For further details, please see IRIS Certification® Performance Assessment, clause 15.2. and IRIS Complaint Management Procedure in IRIS web portal download area.

10. ADDITIONAL REQUIREMENTS OF UNIFE AND IMC

The client automatically accepts the following UNIFE / IMC requirements when an order is placed for IRIS certification.

The certification body must be approved by UNIFE to conduct IRIS audits and certifications and such approval lapses in the event this Agreement terminates. In case of termination before the IRIS certification 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 IMC, independent of the result of the audit; the data will be stored in the database, will be administered by the IMC and will provide for restricted access rights.
- IMC 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 IMC providing the access rights.
- The client agrees to evaluate the certification body and its IRIS auditors. The client shall login to the portal and use the proper function to issue an evaluation for each IRIS 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 IMC witnessing audits performed by the certification body on prior written reasonable notice to the certification body.
- The client is perfectly aware that any proprietary and/or confidential information, know how or other intellectual property of UNIFE/IMC, 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 documents and software and to refrain from using any document or copies of software which might infringe the intellectual property rights of UNIFE
- The client acknowledges and accepts that UNIFE and its representatives and employees cannot be held liability for any direct or indirect damages suffered by the Client relation to the IRIS certificate or the System. This limitation of liability shall only to apply to the 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.