Description of the Certification Procedure
MS - IRIS Certification™ Rev.03

Certification

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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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MS - IRIS Certification™ Rev.03

Certification

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MS - IRIS Certification™ Rev.03

0. SCOPE

The certification procedure for the management system based on the **IRIS Certification™ Rev.03 scheme** (based on ISO/TS 22163:2017 and IRIS Certification™ Rules: 2017).

It is consists of the following phases:

- Audit preparation
- Readiness Review
- Certification audit
- Issue of certificate
- Surveillance / Recertification audit.

Only companies, which fall under the scope as described in the IRIS Certification™ Rules, Appendix 1, can take part in the certification procedure. These are companies from the entire supply chain for products related to,

- Rolling-stock,
- Signalling and
- infrastructure (industrial elements, e.g. as per TSI)

with the activities of

- production and/or
- development and/or
- Maintenance (fleet Maintenance, refurbishment and Component overhaul and (or) repairs).

Remote functions and so-called “site extensions” are included in the audit, but cannot achieve an independent IRIS certification.

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 is on a three (3) year basis.

The relationship between audit and certificate cycle is as below.

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 data, identification of TÜV NORD CERT GmbH as responsible IRIS certification body.

It is recommended to complete full IRIS internal audit using the turtle method and management review before application.

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 CERT GmbH 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™ Rules, appendix 1.

Before an IRIS Audit can be started, a certification contract must be concluded with TÜV NORD CERT GmbH.

The TNCERT head of the certification body appoints the corresponding auditor.

The auditors are selected from the auditor pool of TÜV NORD CERT corresponding to the data stored in SAP (TNCERT auditor administration). When selecting the auditors, it must be ensured that the audit team covers the related IRIS scopes.

In the case of international clients who are supported by the TÜV branch offices abroad, both the audit time and the names of the auditors planned-in for the intended audit date must be laid before the certification body for review and release with the ATEA (ATEA workflow in SAP) at least 90 days before the audit. The released ATEA is archived together with the audit documentation as evidence.

The minimum time needed for the certification, surveillance and re-audits, preperation and reporting times can be found in IRIS Certification™ Rules Clause 4.2.

Official IRIS Certification™ audit days calculator for the determination of audit days shall be used.

Audit time for each audit team member shall be minimum 0.5 days.

The calculated audit days shall be rounde up to the higher half day.

When translator shall be needed, the audit time shall be increased by %20 for those areas, where the translator used.

Following detailed information shall be provided by the client to the lead auditor, latest sixty (60) days in advance of the audit:

- customer perception (stakeholder analysis, key customers, related KPIs),
- customer feedbacks,
- customer complaint status and warranty claim statistics since the previous audit,
- turtle diagram for mandatory processes for performance evaluation,
- definition KPIs with link to internal/external process customer,
- KPIs values for the audited period,
- list of organization processes and interactions

In the case the organization does not send the required documentation sixty (60) calendar days in advance to the lead auditor, 0,5 audit days shall be used for the data review on-site.

1.3 Pre Audit

As an option, a pre-audit according to IRIS Certification™ rules can be carried out.

The auditor of the preliminary 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

Prior to start onsite readiness review, the documentation listed in IRIS Certification™ rules, clause 9.1, is to be received from the organization or a mandatory data review to be performed.

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 on site 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 on site before the recertification audit and in case of the audit team change

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 Stage 2 Audit is created and agreed with the client.

For further details, please see IRIS Certification™ rules, clause 5.4.

1.5 Certification Audit

During the audit 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.

The scope of the certification audit shall include the assessment of all:

- mandatory Knock-Out requirements,
- mandatory processes and KPIs,
- the applicable ISO/TS 22163 requirements,
- enablers through the assessment sheet based on ISO/TS 22163 requirements,
- customer perception (see IRIS Certification™ rules appendix 4),
- process performance through process performance evaluation (see IRIS Certification™ rules appendix 6),

In the final meeting on site, the lead auditor presents the results of the audit, including an analysis of the strengths, weaknesses, opportunities and risks (SWOT analysis) and a presentation of possible

CARs (nonconformities) and IAR's (improvements). 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 14 days. In the case of certification audits, the entire IRIS questionnaire must be assessed.

The IRIS Audit-Tool shall be used for the documentation of the audit.

For further details, please see IRIS Certification™ rules, clause 5.5.

1.6 Issue of Certificate

The IRIS Certification™ Certificate is issued on the recommendation of the IRIS lead auditor and following positive assessment of the certification procedure by the specialist manager or appointed veto persons. The assessor or veto person may not have taken part in the auditing.

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.

The certificates are valid for 3 years.

Only certificates carrying the IRIS Certification™ logo issued by IRIS Certification™ approved certification bodies are recognised 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 12 or 24 months after successful first certification. The last day of the certification audit is always the reference date for the following years. It is recommended to start the follow-up audits approx. 90 days before this reference date, in order to ensure that there is sufficient time for implementation of any nonconformity management.

If the above deadlines are not fulfilled, the IRIS certificate is removed from the WEB portal (cancelled).

For surveillance audits, the minimum scope for the assessment is defined as followed:

- all mandatory Knock-Out requirements,
- customer perception incl. enabler evaluation (see IRIS Certification™ rules appendix 4),
- process performance evaluation for mandatory processes incl. enabler evaluation (see IRIS Certification™ rules appendix 6),
- project management with focus on interfaces checks, specially by corporations,
- Management review,
- Change management / Configuration management,
- ISO 9001 requirements as stipulated by the certification body for surveillance audits,
- all specific areas, where the certification body identified non-compliances in the previous audit, if they were not part of a re-audit,
- specific areas, where improvement activities have been agreed, and
- specific areas, at the request of the client in order to improve a score.

For further details, please see IRIS Certification™ rules , clause 5.6.

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.

Any changes which have an impact on the certification procedure can mean that it is necessary to carry out an additional Stage 1 audit. Such changes must therefore be clarified within the framework of audit preparation.
For further details, please see IRIS Certification™ rules , clause 5.7.

4. CHANGES TO EXISTING IRIS CERTIFICATES

Any changes within the framework of the surveillance or recertification audit must be communicated in advance and agreed with the certification company. Changes can happen with an impact on its business management system, e.g. change of location, IRIS scope of certification.

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 minimum number of audit days for this type of audit shall be equivalant to a re-certification audit

For further details, please see IRIS Certification™ rules, clause 6.2.

5. TRANSFER OF CERTIFICATION FROM OTHER CERTIFICATION BODIES

In case of takeover of IRIS certificates which were issued by another IRIS certification body, a readiness review shall be carried out. Transfer audit time is equal to recertification audit time. Minimum 3 months data shall be available. There shall be minimum three years between two transfer audits.

Following activities shall be done prior to transfer audit:

- the existing IRIS Certification™ certificate shall be valid,
- client shall request the change of certification body through the IRIS Certification™ portal,
- after the request is approved by the IMC, the certification body will be able to see the client data and access the last audit documentation,
- the new certification body shall perform a review of all the documentation to start the planning of the transfer audit,
- the new certification body shall ensure any audit team member has not previously audited the client.

For further details, please see IRIS Certification™ rules , clause 6.1.

6. WITHDRAWAL OF IRIS CERTIFICATES

The process of withdrawal of IRIS certificates can result from:

- A customer complaint
- Audit information
- A message from the company itself

Withdrawal of the IRIS certificate does not necessarily influence other certificates such as for example ISO 9001. The process must be applied if there are complaints regarding the management system, but not in the case of nonconforming products.

For further details, please see IRIS Certification™ rules, clause 8, figure 1.

7. CERTIFICATION OF COMPANIES WITH SEVERAL LOCATIONS

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

For further details, please see IRIS Certification™ rules, clause 4.1.

8. 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 details of

- Scoring methodology, please see IRIS CertificationTM rules , clause 12
- Non-conformity management, please see IRIS CertificationTM rules, clause 13

9. ADDITIONAL REQUIREMENTS, UNIFE/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 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 management centre 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 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 IRIS management centre 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/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

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.

10. OTHER

The current editions and amendments to the IRIS standards always apply in addition to this Description; including the Advisories and Interpretation of UNIFE / IMC, see also www.iris-rail.org.