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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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# Description of the Certification Procedure MS - IRIS Certification® rev.03



## 1 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® Conformity Assessment:2020).It is consist 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® Conformity Assessment, Appendix 1, can take part in the certification procedure. These are companies from the entire supply chain for products related to,

- Rolling-stock,
- Signaling 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).

The IRIS Certification® scopes of certification are aligned with the standard EN 15380-2.

Remote functions and site extensions are included in the audit, but cannot achieve an independent IRIS certification.

## 2 CERTIFICATION PROCEDURE

### 2.1 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 given at clause 12.

### 2.2 AUDIT PREPERATION

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](http://www.iris-rail.org)): entry of the relevant company data, identification of TÜV NORD CERT GmbH as responsible IRIS certification body.

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.

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The scope of the certification shall be agreed between the client and the certification body in accordance with IRIS Certification® Conformity Assessment, 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 NORD branch offices abroad, both the audit time and the names of the auditors planned for the intended audit date must be laid before the certification body for review and release with the Audit Team Effort Approval (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, preparation and reporting times can be found in IRIS Certification® Conformity Assessment, 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 rounded 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:

- Stake holder analysis (see IRIS Certification® Conformity Assessment, Appendix 4, A1)  
The stakeholder analysis is a structured approach for the organization to understand the needs and expectations of interested parties and define (if/as required) relevant actions (see ISO/TS 22163 clause 4.2).
- Customer perception data (see IRIS Certification® Conformity Assessment, Appendix 4, A2 and A5)
  - list of the organization's main/relevant customers including their feedback,
  - for achieving the Gold level: the direct feedback from customers,
  - customer complaint status,
  - warranty claim statistics,
  - management review report,
  - KPI's with link to internal/external process customer (including product and service quality and delivery performance). If applicable, KPI for safety related aspects. For each KPI the definition and the values for the audited period shall be provided.

The timeframe for the data to be considered, shall include and focus on the period since the last audit conducted

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- turtle diagrams for mandatory processes for performance evaluation (see IRIS Certification® Conformity Assessment, see Appendix 5),
  - Project management (ISO/TS 22163 clause 8.1.3),
  - Requirements for product and services (ISO/TS 22163 clause 8.2),
  - Control of externally provided processes, products and services (ISO/TS 22163 clause 8.4),
  - Design and development of product and services (ISO/TS 22163 clause 8.3),
  - Production and service provision (ISO/TS 22163 clause 8.5)
  - 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.

Before application for certification the company should carry out self-assessment according to ISO/TS 22163 requirements to evaluate their business management system. Using of IRIS audit tool is recommended.

## 2.3 PRE AUDIT

As an option, a pre-audit according to ISO/TS 22163 can be carried out. 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.

## 2.4 READINESS REVIEW

Prior to start onsite readiness review, the documentation in the clause 1.2-Audit Preparation, 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 IRIS Certification® Conformity Assessment , clause 5.4.

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## 2.5 CERTIFICATION AUDIT

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.

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

- all mandatory Knock-Out requirements,
- all 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® Conformity Assessment, appendix 4),
- process performance through process performance evaluation (see IRIS Certification® Conformity Assessment, 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), IAR's (improvements) and potential level of the certification. 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. 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 Conformity Assessment, clause 5.5

## 2.6 ISSUE 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 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](http://www.iris-rail.org).

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## 3 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 surveillance 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).

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.

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

- all mandatory Knock-Out requirements,
- customer perception (see IRIS Certification® Conformity Assessment appendix 4),
- all mandatory processes for performance evaluation (see IRIS Certification® Conformity Assessment appendix 6),
- all processes, where a corrective action request was raised in the previous audit

For further details, please see IRIS Certification® Conformity Assessment , clause 5.6.

## 4 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.

For further details, please see IRIS Certification® Conformity Assessment , clause 5.7.

## 5 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 body. Changes can happen with an impact on its business management system;

- change of location (manufacturing, design, maintenance)
- additional IRIS scope of certification
- change of main owner

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.

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For further details, please see IRIS Certification® Conformity Assessment, clause 6.2.

## 6 TRANSFER OF CERTIFICATE 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 three( 3) months data shall be available. There shall be minimum three (3) 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® Conformity Assessment , clause 6.1.

## 7 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® Conformity Assessment, clause 8, figure 1.

## 8 CERTIFICATION OF COMPANIES WITH SEVERAL LOCATIONS

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

For further details, please see IRIS Certification® Conformity Assessment, clause 4.1.

## 9 MANAGEMENT OF NONCONFORMITIES 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.



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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® Conformity Assessment , clause 13
- Non-conformity management, please see IRIS Certification® Conformity Assessment, clause 14

## 10 QUALITY PERFROMANCE 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

Bronze Level - (Basic Level)	Silver Level- (transparency on performance )	Gold Level- (clear evidence of optimized customer perception performance)
achieved by reaching the <b>threshold</b> of enablers in a <b>successfully passed audit</b>	<b>enabler evaluation</b> (assessment sheet based on ISO/TS 22163 requirements): seventy percent <b>(70%)</b> of the maximum score	<b>enabler evaluation</b> (assessment sheet based on ISO/TS 22163 requirements): eighty percent <b>(80%)</b> of the maximum score,
---	<b>customer perception:</b> seventy five percent <b>(75%)</b> of the maximum score,	<b>customer perception:</b> eighty five percent <b>(85%)</b> of the maximum score plus
---	<b>process performance through performance evaluation:</b> eighty percent <b>(80%)</b> of the maximum score.	<b>process performance through performance evaluation:</b> ninety percent <b>(90%)</b> of the maximum score.
---	it is <b>mandatory that the documents and data</b> for the preparation of the audit are <b>available for the lead auditor sixty (60) calendar days in advance</b>	it is <b>mandatory that the documents and data</b> for the preparation of the audit are <b>available for the lead auditor sixty (60) calendar days in advance</b>
<b>issued after a confirmation</b> by the certification body that the documental veto check (see 3.3) was performed successfully. The IMC may perform a spot check	<b>issued after a confirmation</b> by the certification body that the documental veto check was performed successfully and after a successful check of the related documentation by the IMC	<b>issued after a confirmation</b> by the certification body that the documental veto check was performed successfully and after a <b>successful check of the related documents by the IMC</b> . The decision shall be confirmed by a <b>committee appointed by the IRQB</b> and the respective criteria defined and communicated at the implementation.

For further details, please see IRIS Certification® Conformity Assessment, clause 13.



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## 11 ADDITIONAL REQUIREMENTS OF UNIFE, IMC

The client automatically accepts the following UNIFE / IMC (IRIS Management Center) 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 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.

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## 12 OTHER

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](http://www.iris-rail.org).

Relationship between audit and certificate cycle:

**IRIS Certification® Milestones and Certificate Validity (Issuance and maintenance of IRIS Certification® Certificate)**

