

# ***IRIS*** ***International Railway*** ***Industry Standard***

*Rev. 02.1 Change summary*  
*English*



# COLOR LEGEND

## of the changes

BLACK color = IRIS Rev02

BLUE color = Corrigendum 1:2010

RED color = Corrigendum 2:2012

CYAN color = Advisories 4, 5, 6, 7, 8, 9, 10

GREEN light color = TFI + IMC modifications

### Note:

The reference for the IRIS documentation is the Revision 02.1.  
This document is only to inform about the origin  
of the changes. It is available only in English.

*IRIS*  
*International Railway*  
*Industry Standard*

***Rev. 02.1 Change summary***

# IRIS Certification Process

## 2 Requirements for certification bodies

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- ▶ The certification body shall be globally accredited in accordance with ISO/IEC 17021 at least three years prior to submit an application for an IRIS approval.

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## 3 Requirements for auditors

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Detailed requirements for auditors are specified in the framework agreement.

All IRIS scopes of certification needed for an IRIS certification or surveillance or re-certification audit shall be covered by the audit team respectively.

During readiness review or re-audit, it is accepted that all scope(s) may not be covered and therefore it is the certification body responsibility to identify the auditor(s) who shall execute the readiness review or re-audit. They shall be the lead auditor or an auditor from the original audit team. In any case, the lead auditor remains responsible for the audit.

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An observer status can be temporarily assigned when auditors lose their approval.

An auditor shall not undertake more than five annual IRIS audits for the same client. For multi-Site organizations, the five annual IRIS audits time starts from the last audited location.

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## 4 Certification Process

The certification Process shall be in accordance with ISO/IEC 17021.

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### 4.1 Preparation and request for IRIS certification

To start the IRIS certification process and be suitable to achieve an independent IRIS Certificate, an Organization shall:

- a) be a legal entity or belong to a corporation, and
- b) have an autonomous Business Management System, and
- c) have at least one IRIS activity: design or manufacturing or maintenance (see Chapter 3, 1.2 Application), and

- d) be eligible for one of the IRIS scopes of certification (see Annex 1), and
- e) being located in a single site.

The public area of the IRIS Portal supports clients in finding appropriate information (e.g. guidelines) to prepare or to request for IRIS certification.

The client can purchase IRIS booklets in different languages directly from the IRIS Portal.

The booklet is available in electronic version.

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### 4.2 Evaluation Process

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The handling and monitoring of corrective or improvement actions are described in chapter 2: IRIS Assessment Guideline.

If a client fails an audit due to not meeting a Knock-Out requirement, the audit can be continued, if wished by the auditee, until its scheduled end, but to become IRIS certified, the certification Process shall begin again starting with a new request and followed by a full evaluation Process.

The client is asked to evaluate each auditor separately after the audit is conducted.

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#### 4.2.1 Readiness review

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The Readiness review shall be:

- ▶ performed on Site before the certification audit and (or) in case of change of certification body,
- ▶ performed maximum ninety (90) calendar days before starting the audit and
- ▶ repeated if failed.

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#### 4.2.2 Certification audit

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If a client fails the audit, it shall be repeated within a period of 90 days (re-audit or closure of corrective actions by document review only).

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#### 4.2.3 Surveillance audit

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The date of the first successful surveillance audit shall not be more than 12 months from the last day of the certification audit.

The date of the second successful surveillance audit shall not be more than 24 months from the last day of the certification audit.

Surveillance audits should be planned 90 days before the anniversary of the last day of the certification audit to avoid the risk for the company of being suspended due to potential CARs.

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#### 4.2.4 Recertification audit

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The date of the successful recertification audit shall not be more than 36 months from the last day of the certification audit.

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### 4.3 Remote functions and site extensions

#### 4.3.1 Remote functions

**4.3.2****Site extensions**

A site extension is defined as such if:

1. it cannot achieve an independent IRIS Certificate and
2. it has a manufacturing or maintenance activity belonging to the connected certified site and
3. it is included in the same scope of certification of the connected certified site and
4. it is performing exclusively manufacturing or maintenance processes and
5. it is included in the audit plans (at least at the certification and recertification audit) of the evaluation process of the connected certified site.

If the site extension has maintenance activity only, the visit can be excluded if:

- ▶ all the evidences and information are available in the in the Site during the audit,
- ▶ the size of the site extension allows it and
- ▶ the responsible people of the site extension participate in the audit face to face or via an agreed communication pathway.

The certificate shall include all site extensions.

**4.4****Award of certificates**

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The IRIS certificate shall bear the IRIS logo.

The IRIS certificate has a validity of maximum 3 years, starting when all the criteria are met (see chapter 2, clause 8) and ending 36 months after the last day of the certification audit, on the precondition that all subsequent surveillance audits during this time are successful in meeting the requirements.

In case of successful re-certification audit, the validity of the certificate will be extended for 3 more years starting the day after the expiration of the previous one, on the precondition that all subsequent surveillance audits during this time are successful in meeting the requirements.

In case of a certificate transfer between certification bodies:

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**5****Withdrawal of IRIS certificates**

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Complaints regarding non-conforming Products shall be discussed with the partner concerned.

In addition, an IRIS complaints management procedure is available on the IRIS Portal.

# IRIS Assessment Guideline

### 3

#### Audit results

##### 3.1

#### Audit report

The IRIS Audit-Tool shall be used for audit documentation. Each audit shall be recorded in an audit report. Remote function and site extension results shall be compiled in each report of the Sites they support.

Audit reports shall be compiled in the respective language agreed with the client (local language and (or) English).

Form and structure of the audit reports are given by the IRIS Audit-Tool. The report shall include or refer to the following:

- ▶ all audit result summaries required by the Audit-tool (in both English and the agreed audit language is mandatory),

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The audit report shall be approved by the lead auditor.

In addition, a documental veto check shall be performed by the certification body.

Audit reports shall be archived within the Record management system of the certification body.

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The audited client should receive a signed paper copy and he may access the electronic report on the IRIS Portal.

##### 3.2

#### Documental veto check

In order to ensure a complete and compliant documentation available in the IRIS Portal database and therefore provide the rail stakeholders the clearest assessment results, the certification body shall perform a documental veto check review.

Once the audit is completed, with all activities described in the audit plan carried out, and the audit report has been finalized, the Lead Auditor shall send to the certification body representative the following documents and information, as a minimum:

- a) The audit file (file saved with the Audit-tool),
- b) The audit report (PDF report exported from the Audit-tool),
- c) The list of CARs/IARs (Excel file exported from the Audit-tool),
- d) Comments on the CARs and IARs and information about their follow-up [may be part of point c)],
- e) Confirmation of the information provided to the certification body used in the preparation phase.

The target of the documental veto check is to verify the completeness and accuracy of the data:

- ▶ **Completeness:** English summaries, collected evidences, justification for N/A questions, closure of the Audit-tool audit report, company's proposals for CARs, product categories, fulfillment of the applicable requirements of chap. 1 & 2 of the IRIS booklet.
- ▶ **Accuracy:** raised CARs and IARs, quality of the findings and evidences, scope of activities.

It is the certification body's duty to request complementary actions if the documentation is not complete as expected.

The documental veto check shall be done by a "documental veto checker", employed and nominated by the certification body and not being part of the audit team responsible for the audit.

The "documental veto checker" shall understand the applicable standard and certification requirements, and shall have demonstrated competence to evaluate the audit processes and related recommendations of the audit team.

The aim of the documental veto check is not to validate the key figures needed to perform the audit (eg.: employees, mendsays,...), which shall be ensured in a preventive way.

#### 4 Scoring methodology

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- ▶ closed questions (answer is "YES" or "NO") without progressive maturity levels.

Non applicable questions (enter 'N/A') and questions related to excluded clauses, are not scored. For these a relevant justification shall be documented.

Some clauses cannot be excluded (e.g. chapter 3; clause 7.13) and some questions cannot be put as 'N/A'. The Audit-Tool takes question 7.10-3 and K.O. questions identified as per Annex 4 automatically into account.

Individual questions are scored in points.

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#### 6 Management of Corrective Action Requests

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In the case of "poor" fulfilment of requirements, the Lead Auditor may decide about the necessity of a re-audit or other appropriate methods to review the effectiveness of the corrective actions.

If an auditor re-opens a CAR which was closed during the previous audit (certification or surveillance), the need of a re-audit becomes mandatory to verify the effectiveness of the new corrective action.

Once all Corrective Action Requests are closed, the scores shall be adjusted accordingly and the final result shall be documented in a final audit report.

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# IRIS Requirements

## 0

### Introduction

IRIS requirements consist of:

- ▶ ISO 9001:2008 requirements: Grey text refers to ISO 9001:2008 requirements, which are fully applicable.
- ▶ Rail sector specific requirements.

## 1

### Scope

#### 1.1

##### General

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This standard defines business management system requirements to be applied throughout the whole Supply Chain of rolling stock-related and signalling-related Products.

#### 1.2

##### Application

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Where exclusions are made, claims of conformity to this standard are not acceptable unless these exclusions are limited to the following requirements: 7.3, 7.5, 7.9, 7.11.

All requirements of this standard are generic ...

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## 2

### Normative reference

...

ISO 9004, Managing for the sustained success of an organization – A quality management approach IEC 62278 (EN 50126)  
IEC 62279 (EN 50128)  
IEC 62425 (EN 50129)  
IRIS advisories and IRIS corrigenda issued after the publication of this standard.

In case of a conflict between the IRIS booklet and the referenced standard please use the referenced standard as valid.

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## 5

### Management responsibility

#### 5.5.3

##### Internal communication

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The organization should also define and implement a Process for external communication (see 7.2.3).

**6  
Resource management**

**6.3  
Infrastructure**

...

The organization should periodically review the infrastructure and related processes with the future in mind.

***NOTE 1** Predictive Maintenance methods may also be applied to equipment and tools (see clause 7.5.1.4).*

**6.4  
Work environment**

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***NOTE 1** Other factors might be cleanliness and protection from electrostatic discharge.*

The organization should define and implement Processes to ensure that the work environment complies with all applicable statutory or regulatory requirements.

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**7  
Product realization**

**7.2.3  
Customer communication**

...

***NOTE 2** Proactive communications on specific supplier management within a Project may be established.*

The organization should also define and implement a Process for external communication (see 5.5.3).

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**7.3.2  
Design and development inputs**

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***NOTE 1** In particular, customers are expected to collect all the information needed and demanded by the organization in order to enable the organization to have complete and reliable design inputs.*

**7.3.4  
Design and development review**

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***NOTE 3** Design and development reviews are conducted on each level of detail (e.g. architecture design, modular design).*

...

**7.3.5  
Design and development verification**

...

***NOTE 1** Design and development verification are conducted on each level of detail (e.g. architecture design, modular design).*

**7.4.1  
Purchasing Process**

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The organization shall ensure that a Process for purchasing of Products is in place.

The performance of this Process shall be measured by a KPI (see annex 3).

The organization should define and implement a Process to select, evaluate, re-evaluate and rank suppliers.

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**7.5.1.4****Control of equipment and tools**

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**NOTE 1** *The validation of the manufacturing equipment is part of the First Article Inspection (FAI) (clause 7.9).*

**7.6****Control of monitoring and measuring equipment**

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The organization shall maintain a register of this monitoring and measuring equipment and define the Process employed for its calibration or verification, or both, including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

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**7.8****Configuration management**

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c) maintain traceability during Production and operations.

For software development and software Production a configuration management for applied tools should be available.

**NOTE 1** *Guidance on configuration management is given in ISO 10007.*

**NOTE 2** *In cases where a change impacts a Product which is subject to configuration management, the principles described in clause 7.13 apply.*

**7.10****Commissioning / Customer Service**

For customer service and commissioning (when commissioning is a contractual requirement) a Process shall be in place.

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The organization shall demonstrate that adequate customer support is provided:

- ▶ during commissioning,
- ▶ until Product validation is complete,
- ▶ during warranty,
- ▶ until final customer acceptance.

...

**8****Measurement, analysis and improvement****8.2.3****Monitoring and measurement of Process**

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Mandatory KPI's shall be established and recommended KPI's should be established as listed in annex 3 to measure and monitor Processes.

**8.4****Analysis of data**

...

- e) external incident reports associated with the organization's Products and
- f) Product Safety.

The organization should ensure that a Process for the analysis of data is in place (see clause 8.2.2) and the performance of this Process should be measured by a KPI (see annex 3).

### ANNEX 1 IRIS scopes of certification

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No	Description - 1st level	No	Description - 2nd level
18	Rolling Stock	18.1	Light Rail Vehicles
		18.2	Regional and Commuter Trains
		18.3	Metros
		18.4	Coaches and Passenger Cars
		18.5	High Speed Trains
		18.6	Locomotives
		18.7	Freight Wagons
		18.8	Transportation Systems

Table 2: IRIS scopes of certification

### ANNEX 2 IRIS auditor time chart

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- ▶ auditor time only for IRIS reporting. In the case of combined certification schemes (e.g. ISO 9001) additional auditor time for reporting shall be considered.

For the required auditor days assessed as a minimum, the table on the following page shall be applied.

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#### Auditor time definition

The auditor time chart is stated in terms of auditor days spent to perform an audit.

An auditor day is typically a full normal working day of 8 hours. The number of auditor day calculated shall not be reduced by programming longer hours per work day (only exception allowed may be night-shifts).

The auditor time includes the time spent by an auditor or audit team in planning (including off-site document review, if appropriate), executing the audit (readiness review, interfacing with the organization, personnel,

records, documentation and processes), and report writing.

The auditor time shall be divided into:

- ▶ audit time on-site, and
- ▶ audit time NOT on-site.

In addition to the activities included in the definition of the auditor time, there are additional tasks to be performed by the certification body personnel in order to complete the IRIS certification process, such as appointing the Lead Auditor, defining the objectives, determining the feasibility and closing of CARs or IARs or both.

The table on the next page summarizes the activities typically in force during an IRIS certification process, and clarifies how those activities shall be considered with respect to the auditor time.

The sum of the auditor coordinating time (4.6) and the preparing of audit conclusions time (4.8) shall not be more than 15% of the audit plan time on-site.

The sum of the opening meeting time (4.3) and the closing meeting time (4.9) shall not exceed 2 hours of the audit plan time on-site.

Activity	NOT PART OF AUDIT TIME	AUDIT TIME NOT ON-SITE	AUDIT TIME ON-SITE	Additional AUDIT TIME NOT ON-SITE	Additional AUDIT TIME ON-SITE
<b>1 - Initiating the audit</b>					
1.1 - Establishing initial or follow-up contacts with the auditee	X				
1.2 - Check of the IRIS Portal audit data	X				
1.3 - Determining the Feasibility of the audit	X				
1.4 - Selecting and appointing the audit team	X				
1.5 - Defining audit objectives, scope and criteria	X				
<b>2 - Conducting document review</b>					
2.1 - Reviewing relevant BMS documentation		X			
<b>3 - Preparing for the on-site activities (Readiness Review and audit)</b>					
3.1 - Preparing the audit plan		X			
3.2 - Assigning work to the audit team		X			
3.3 - Preparing work documents and electronic files (Audit-tool)		X			
<b>4 - Conducting on-site activities (Readiness Review and audit)</b>					
4.1 - Travelling time	X				
4.2 - Breaks (lunch, dinner, etc....)	X				
4.3 - Conducting opening meeting			X		
4.4 - Collecting and verifying information			X		
4.5 - Generating audit findings			X		
4.6 - Coordinating with other auditors			X		
4.7 - Daily communication to the Organization			X		
4.8 - Preparing audit conclusions			X		
4.9 - Conducting closing meeting			X		
<b>5 - Preparing and distributing the preliminary audit report and audit files</b>					
5.1 - Finalizing the preliminary audit report		X			
5.2 - Distributing the audit report and audit files		X			
<b>6 - Preparing for the follow-up of on-site activities (Closure of CARs/IARs or Re-Audit)</b>					
6.1 - Following-up documentally the closure of CARs/IARs				X	
6.2 - Following-up on site the closure of CARs (Re-Audit)					X
<b>7 - Preparing and distributing the final audit report and audit files</b>					
7.1 - Closing the final audit report		X			
7.2 - Performing documental Veto Check	X				
7.3 - Distributing the final audit report and audit files		X			

Table 4: Auditor time definition

### Reduction schemes

Reduction schemes can be applied for corporations only with 46 employees or more.

The cumulative reduction shall be limited to 50% maximum.

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### Upgrading from other standards (A)

Existing certification(s) (current status)			Conditions for upgrading to IRIS Rev. 02
ISO 9001	AS 9100 and (or) ISO/TS 16949	IRIS Rev. 00 or Rev. 01	Reduction from total IRIS auditor days for certification audit (see previous table)
X			Maximum 20%
	X		Maximum 30%
X	X		Maximum 30%
X		X	As a minimum the TOTAL IRIS auditor days for recertification audit
		X	As a minimum the TOTAL IRIS auditor days for recertification audit
	X	X	As a minimum the TOTAL IRIS auditor days for recertification audit
X	X	X	As a minimum the TOTAL IRIS auditor days for recertification audit

Table 5: Upgrading from other standards

### ANNEX 3

#### Activities to be managed by Procedures / Processes / KPI's / Records

Clauses	Activities	Mandatory <sup>1)</sup>					Recommended <sup>2)</sup>		
		K.O. questions	Procedure	Process	KPI	Records	Procedure	Process	KPI
6.2.2.3	Training		X			X			
6.4	Work environment						X		

Note: Item 6.3 has been deleted.

Table 8: Activities to be managed by Procedures / Processes / KPI's / Records

**ANNEX 4**  
**Knock-Out questions**

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<b>5</b>	Can be put as not applicable	<b>7.3.8</b>	<p><b>Design approval</b></p> <p>Does the organization provide a documented procedure defining the safety case and approval in line with IEC 62425 (EN 50129), in the case that IEC 62279 (EN 50128) in conjunction with a safety integrity level is required?</p>
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<b>10</b>	Always applicable	<b>7.10</b>	<p><b>Commissioning / customer service</b></p> <p>Does the organization provide a process for customer service and commissioning (when commissioning is a contractual requirement)?</p> <p>Is this process including:</p> <p>a) actions to be taken when problems are identified after delivery, including investigation, reporting activities and actions on service information?</p>
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**Table 9: Knock-Out questions**

**ANNEX 5**  
**Terms and definitions for the rail sector**

<b>Abnormal Work</b>	Abnormal <b>work is</b> work or supply of parts, which is not included within the scope of work and could not have been reasonably anticipated by the organization, but is required to be completed in order to attain acceptance.
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**Table 10: Terms and definitions for the rail sector**

A UNIFE initiative supported by

The rail industry



Pushing Performance



The rail operators



The rail associations



Verband Deutscher Verkehrsunternehmen



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