

English

Addendum, 19th June 2008

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

**IRIS**   
Certification

**UNIFE** 



# IRIS Addendum

as per 19th June 2008 to the  
IRIS booklet, revision 01, November 2007

The aim of this addendum is to inform you about:

- o the extension of IRIS to maintenance activities,
- o improvements / clarifications in the IRIS booklet, revision 01, November 2007.

This addendum is provided in each IRIS booklet sold from June, 23rd 2008 or can be accessed via the IRIS Portal (<http://www.iris-rail.org/>).

Modifications are marked ***bold italic***.

## CHAPTER 1: IRIS CERTIFICATION PROCESS

### 4.4

#### **Award of certificates; page 15**

An ISO certificate is awarded independently of the IRIS certificate according the ISO 9001 rules and can be awarded even if the conditions for awarding of an IRIS certificate are not fulfilled.

***After certification of all sites of a multi-site corporation, the IRIS Management Centre can issue a letter of compliance on request.***

The IRIS portal contains an on-line database that provides all important and necessary information about

the audit results.

***Railway companies can register as member in the IRIS portal by paying a fee.***

On level 1 of the database only non-detailed data on passed audit and certification are available to all members, ...

### 5

#### **Withdrawal of IRIS certificates; page 17**

Withdrawal of IRIS certificate does not necessarily affect other certificates such as ISO 9001.

***Finally, the IRIS Management Centre will inform the initiator of the complaint about the results after maximum 10 days of resolution.***

***The above described process is applicable to justified customer claims concerning the business management system; Not concerning non-conforming products.***

***Claims regarding non-conforming products shall be initially discussed with the partner concerned.***

## CHAPTER 3: IRIS REQUIREMENTS

### 1.1

#### General; page 28

This standard, in conjunction with ISO 9001:2000, defines the business management system requirements for the design and development, **manufacturing, maintenance** and when **applicable**, installation, customer service of rolling stock and signalling-related products.

### 1.2

#### Application; page 28

All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product, provided that they have activities in design **and / or manufacturing and / or maintenance (fleet maintenance, refurbishment and component overhaul / repairs)**.

### 4.2.3

#### Control of documents; page 30

***The organization shall demonstrate effective management and control of all documents pertinent to the products it supplies. Names of personnel who authorize and carry out reviews of the necessary documentation shall be identified.***

***Effective systems shall be in place to review impact of external documentation on product supply e.g TSI's, Notified National Technical Rules (NNTR's), ISO, EN etc.***

The organization shall have a process to ensure...

### 4.2.4

#### Control of records; page 30

Records shall be available for review **by / release to**

customers and regulatory authorities in accordance with contract or regulatory requirements.

### 6.2.2.3

#### Training; page 35

The organization shall establish and maintain documented procedures for identifying and planning training needs in order to achieve the necessary competence of personnel performing activities affecting product quality and safety at all levels of the organization, **consistent with the local regulatory requirements, e.g in the UK the Office of Rail Regulation (ORR) Railway safety publication 1, "Developing and Maintaining Staff Competence"**.

Output of...

Personnel performing specific assigned tasks (e.g. special processes, **engineering change activities**) shall be **competent and** qualified, as required, with particular attention to the satisfaction of customer, **local and regulatory** requirements.

A system shall be in place to maintain and upgrade the qualifications of such personnel.

### 7.2.2.

#### Review of requirements related to the product; page 37

Multidisciplinary approach (including suppliers when appropriate) shall be used. Project management and design / development **shall** be appropriately represented in all requirements reviews.

The organization shall **have a process to** ensure that requirements identified are:

- a) individually compliant (e.g. clause by clause),
- b) negotiated and updated with impact on the offer identified,
- c) evaluated and taken into account,

- d) properly transferred, understood, acknowledged and committed to by everybody involved, and
- e) complete, clear, precise, unequivocal, verifiable, testable, maintainable and feasible.

***This process shall also control contract variation including liaison with customers.***

NOTE 1 The requirements ...

### **7.3.2. Design and development inputs; page 39**

This new technology / new **product** shall apply the design and development requirements described in this clause.

***The organization shall demonstrate appropriate awareness of the criticality of the product and the function and risks of a product within the system / vehicle of which it forms a part.***

RAMS / LCC shall be considered as design inputs.

### **7.4.1 Purchasing process; page 41**

The organization shall:

- a) maintain a register of approved suppliers which includes the scope of their approval,
- b) ensure where required that both the organization and all suppliers use customer approved special processes,
- c) ensure that the function having responsibility for approving supplier quality systems has the authority to reject the use of sources, and
- d) assess and manage the risks for supply of critical products throughout the supply chain.***

The organization ...

### **7.4.2 Purchasing information; page 42**

In addition to the ISO 9001:2000 requirements purchasing information shall include

- d) the name or other identification, and applicable issues of specifications, drawings, process requirements (including special ones), inspection instructions, ***appropriate details from the organization's quality plan*** and other relevant technical data,
- e) requirements for design,...

### **7.5.1 Control of production and service provision; page 43**

In addition to the ISO 9001:2000 requirements, controlled conditions shall include for all shifts:

- g) accountability for all products during manufacturing (e.g., parts quantities, split orders, nonconforming product),
- h) evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized.

***The organization shall demonstrate appropriate awareness of the criticality of the product and ensure it has appropriate production control procedures to implement risk mitigation.***

### **7.7.7 Communication management; page 47**

The organization shall ensure that the project team determines and communicates needs of the stakeholders (e.g. communication plan).

This information, including performance information, ***product specific requirements, defect reporting and railway industry risks***, shall be made available to project stakeholders in a timely manner.

NOTE 1 This is in addition....

**7.7.9**  
**Change management; page 48**

The organization shall have a process to control and react to changes that impact product realization.

***For maintenance activities, the organization shall have a procedure to control and react to changes that impact product realization including the definition of which Engineering Changes need to be referred back to the Customer for authorisation in line with local and customer requirements. The organization shall have a process to control deferred and abnormal work.***

The effects of any change, including those changes caused by any supplier, shall be assessed and verified. Validation and approval activities shall be defined, to ensure compliance with customer requirements before implementation.

***Where the organization does not undertake design and development activities in the relevant scope it shall have controls in place which prevent engineering changes from being implemented without prior authorization from all appropriate stakeholders.***

For proprietary designs, impact on form, fit and ...

**8.2.1**  
**Customer satisfaction; page 50**

***In addition to the ISO 9001:2000 requirements, the organization shall monitor external incident reports associated with their products and have a process in place to manage the information and take action where necessary.***

**8.2.4**  
**Monitoring and measurement of product; page 50**

***The Organization shall be able to demonstrate that the product complies with customer requirements.***

Measurement requirements for product ...

### ANNEX 3

#### Processes/activities to be documented in procedures

Procedure	Clause	Processes/activities to be documented in procedures
15	7.7.9	<i>Change management</i>

### ANNEX 4

#### Processes required by IRIS

Process	Clause	Processes required by IRIS
20	7.2.2	<i>Review of requirements related to the product</i>
21	8.2.1	<i>Customer satisfaction</i>

### ANNEX 6

#### Terms and definitions for the railway industry

Term	Definition
<i>Abnormal work</i>	<i>Abnormal work with respect to maintenance of rolling stock, is work or supply of parts which is not included within the scope of work and could not have been reasonably anticipated by the supplier, but is required to be completed in order to attain acceptance.</i>
<i>Critical Product</i>	<i>Product which has been identified as having the potential to introduce risks that can directly or indirectly threaten health and safety and/or a business performance.</i>
<i>Criticality</i>	<i>The rating of how much risk is attached to the failure of a Critical Product.</i>
<i>Engineering Change</i>	<i>Implementation of new or revised standards, processes and procedures, suppliers and supply arrangements, or new or revised designs, that have the potential to impact on health and safety or the customer's business performance.</i>
First Article Inspection	Inspection, verification, and documentation of a representative item from the first serial production run of a new part <b>or major upgrade to an existing part</b> .  If the product is a one-off or a software, FAI is meant as validation.
Field support activities	Includes: commissioning and warranty, servicing, customer training, spare parts supply, maintenance, overhauling, etc.  Activities of the organization in support of the introduction of the products into operations, including the support for their reliable performance <b>including feedback of field experience</b> , during the warranty period and thereafter through product maintenance.

Term	Definition
Manufacturing process / Production process	Manufacturing: Activities to realize products <b>including overhaul and repair</b> . Part of an organization's value chain. Production: Activities to plan, design, buy, realize and deliver products, all parts of the organization's value chain.
Safety	<b>For signalling</b> , the term safety in this railway standard is to be understood in the spirit of the Safety Integrity Level according to EN 50129:2003.

**IRIS QUESTIONNAIRE**

**The mandatory/valid IRIS questionnaire is programmed in the IRIS Audit-Tool, to be used during the certification process.**