IRIS
Certification

IRIS
International Railway Industry Standard
A Quality Standard for the Railway industry

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Giuseppe Greco
UNIFE

IRIS
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What is IRIS ?

IRIS - International Railway Industry Standard

- IRIS stands for **International Railway Industry Standard.**

- IRIS aims at developing and implementing a **common global system** for the evaluation of Business Management Systems **specific to the railway industry,** including:

  - One internationally recognized standard based on the key principles of ISO 9001 and specific to the railway industry;

  - One harmonized evaluation process to be performed by approved certification bodies;

  - A web-based IRIS Portal (common database) and Audit-Tool (software).

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- Operators have complained about the quality of some Rolling Stock and requested to improve the quality of the Supply Chain.

- Railway equipment manufacturers have complained about the number of different requirements and audits from Rolling Stock Manufacturers and requested rationalization.

IRIS is an answer to these requests

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- The goal of IRIS is to improve the quality of the railway industry supply chain.
- The systems aims at a global recognition and acceptance of audit results, the avoidance of multiple auditing and therefore increased cost efficiency.
- Audit records and audit results will be collected and stored in a central database.
- IRIS will enable high quality in audits.

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- The development of the standard is **transparent** and involve all market participants via UNIFE.

- The standard is owned and managed by UNIFE **(ensure independency)**.

- Audit results are traced **confidentially** and published only with allowance of the Audit Client. Rules for protection of data privacy will be followed.

- Approval of certification bodies is **fair and transparent**.

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- Improved product quality & supply chain efficiency.

- Reduction of effort and cost.

- More accurate and reliable Information about suppliers to the railway industry.

- Fair evaluation by independent certification bodies.

**It's a win - win situation
for all those concerned**

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- Is based on the ISO 9001 Structure.

- IRIS adds a layer, which contains railway specific requirements for the Business Management System, e.g.
  - ◆ Project Management,
  - ◆ Design, etc…

- IRIS contains:
  - ◆ Mandatory requirements with «Shall» wording.
  - ◆ Optional requirements with «Should» wording.

- Some requirements are "KnockOut" criteria.

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0. Foreword

1. Scope

2. Normative Reference

3. Terms and Definitions

4. Quality Management System
   4.1 General Requirements
   4.2 Documentation Requirements
   4.3 Knowledge management
   4.4 Management of multi sites projects

5. Management Responsibility
   5.1 Management commitment
   5.2 Customer focus
   5.3 Quality Policy
   5.4 Planning
   5.5 Responsibility, authority & communication

6. Resource Management
   6.1 Provision of resources
   6.2 Human resources
   6.3 Infrastructure
   6.4 Work Environment

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The Standard (3/3)

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7. Product Realization
- 7.1 Planning
- 7.2 Customer related process
- 7.3 Tender Management
- 7.4 Project Management
- 7.5 Design & development
- 7.6 Configuration Management
- 7.7 Purchasing
- 7.8 Production & Service provision
- 7.9 Commissioning / Customer service
- 7.10 RAMS / LCC
- 7.11 Control of monitoring & measuring devices

8. Measurement, analysis and improvement
- 8.1 General
- 8.2 Monitoring and measurement
- 8.3 Control of nonconforming products
- 8.4 Control of nonconforming processes
- 8.5 Analysis of data
- 8.6 Improvement

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Evaluation methodology

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- Audit results are scored, its not a fail/pass system

- Questionnaire has 253 questions :
  - 111 questions relative to ISO Requirements
  - 142 questions relative to IRIS Requirements

- 10 K.O. questions, not scored, fulfilment mandatory

- 32 Closed questions
  - ◆ Yes/No question

- 211 Open questions
  - ◆ scored using maturity levels

- Threshold
  - ◆ Section score $\geq$ 50% of maximum possible score
  - ◆ Global score $\geq$ 50% of maximum possible score

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1. additional railway specific requirements, e.g. such as

- Knowledge management
- Management of multi sites projects
- Requirements management
- Competences, awareness and training
- Infrastructure management
- Tender management
- Integration management
- Scope management
- Time management
- Cost management

- Communication management
- Risk and opportunity management
- Change management
- First article inspection
- Configuration management
- Outsourcing (Make or Buy)
- Supply chain management
- Commissioning / Customer service
- RAMS / LCC
- Control of nonconforming processes
- ....

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2a. Assessment methodology

		7.4	Project management		
Knock-Out & process			Does the organization implement a project management (PM) or new product development process addressing the applicable areas of PM, describing roles and responsibilities, integrating the whole functions of the organisation in a multidisciplinary team? De **K.O. QUESTION**		The organization has defined criteria for project / non-projects business including appropriate procedures. New product development has to be run as project. Projects have defined roles and responsibilities for the actors; integrating the whole functions

- 13 procedures to be documented (ISO 9001: 6)
- 19 processes required (ISO 9001: 3)

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2b. Maturity levels & scoring

Clause	Question	POOR (1 point)	DEFINED (2 points)	QUALIFIED (3 points)	OPTIMIZED (4 points)
7.3	**Tender management**				
	How are risks related to the product reviewed? Does the organization has a multidisciplinary approach prior to commitment to start the quotation process? **OPEN QUESTION**	- Process defined and implemented. - multi-disciplinary approach, prior to the submission of the quotation and records maintained	Plus: - formal review and defined process available - risks are continuously monitored, updated	Plus: The effectiveness of the risk assessment was analysed on a regular basis	Plus: Continuous improvement of the risk assessment process including tools
	As a minimum, are project / product requirements identified, controlled and validated? **CLOSED QUESTION**		Identification of requirements as before formal validation process- formal approval process		

∑ of points / max points ≥ Threshold (~ 50 %)

3. Corrective or improvement actions

Concluding the answers of each individual requirement (question) there might be corrective or improvement actions required. Therefore the following scheme shall be applied:

Compliance	Level	Points	Actions requested	
			open question	**closed question**
Compliant	*optimized*	4	no specific action expected	
	qualified	3	**improvement action** might be expected	
	defined	2	**improvement action requested**; to be closed within 12 months	no specific action expected
Non Compliant	*poor*	1	**corrective action requested**; to be closed within 90 days	
	insufficient	0	**corrective action requested**; to be re-audited within 90 days	**corrective action requested**; to be re-audited within 90 days

4. Compensative and rewarding approach

Once certified, the client has to undertake so-called surveillance audits on a regular basis, however <u>a minimum of once per year</u>.

Following compensative and rewarding approach will apply for audited organizations with a global score of $\geq 75\%$:

- **IRIS requirements main clauses scoring individually $\geq 80\%$**
  - **- will not be audited during surveillance audits**
  - **- will be dealt with only during the re-certification process (after 3 years)**
- **IRIS requirements main clauses scoring individually between 75% and 80%**
  - **- will be partially audited with the purpose to improve the related processes and achieve 80% scoring.**

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5. Requirements to auditors (experiences/examination)

- **Auditors shall comply with ISO 19011**

- **Auditing Experience:**
  Auditors shall have participated in at least 4 certification audits or for a minimum of 20 audit days covering all the requirements of ISO 9001 within the last 4 years.

- **Work Experience:**
  After the implementation phase, new IRIS auditors shall have a minimum of 3 years railway industry experience in the last 10 years.

- **Railway Certification:**
  Auditors shall have passed the IRIS training and examination.

- **Communications skills**
  Basic English & local language.

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6. Certification Body may only carry out audits in the areas of the particular railway equipment in which its Auditors are approved.

First level

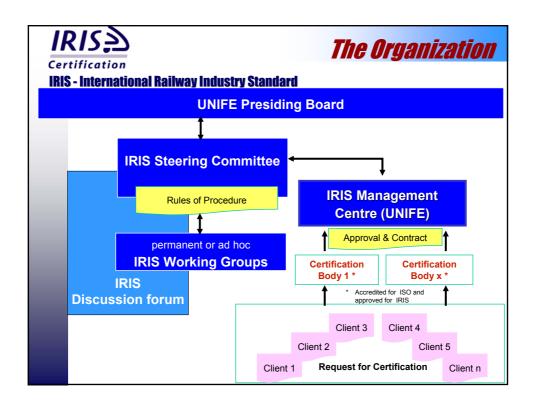|	
1 Car body	10 Passenger Information Systems
2 Car body fittings	11 Communication systems
3 Guidance (Bogies and running gear)	12 Cabling and Cabinets
4 Power System	13 Door System
5 Propulsion	14 HVAC
6 Auxiliary systems	15 Tilt System
7 Braking System	16 Lighting
8 Interiors	17 Coupler
9 On board vehicle control	

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7. Availability / maintenance of information

◆ <u>IRIS web portal</u> http://www.iris-rail.org/

provides valuable information about, e.g.:

 ◆ IRIS approved Certification Bodies
 ◆ IRIS Certificates (list of companies, scope and validity)
 ◆ Auditor performance (access restricted to CBs)
 ◆ Audit results (reports, scores, corrective action plans, incl. status; access restricted)
 ◆ supports sales/distribution of IRIS booklet and data transfer via XLM data export interface

◆ <u>IRIS audit tool</u>

 ◆ contains the IRIS questionnaire and supports audit execution and reporting
 ◆ Automatically transfers audit results into the web portal

IRIS Certification — The Organization

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UNIFE Presiding Board

IRIS Steering Committee

Rules of Procedure

IRIS Management Centre (UNIFE)

Approval & Contract

permanent or ad hoc
IRIS Working Groups

IRIS Discussion forum

Certification Body 1 *

Certification Body x *

* Accredited for ISO and approved for IRIS

Client 1   Client 2   Client 3   Client 4   Client 5   Client n

Request for Certification

IRIS Certification — IRIS Steering Committee Members

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BOMBARDIER

Faiveley TRANSPORT

SIEMENS

HARTING People | Power | Partnership

KNORR-BREMSE

UNIFE

ANSALDOBREDA Finmeccanica Group

ALSTOM

Sécheron

VOITH
Engineered reliability.

- Development and implementation of the IRIS System, including
  - International standard
  - Evaluation process with an audit and scoring methodology
  - Global database
- Admittance and removal of members
- Cooperation with other organization/associations
- Approval of certification bodies
- Setting up Working Groups
- Setting up and monitoring the IRIS Management Centre

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- Implementing and promoting of IRIS System
- Setting up, administrate and maintaining
  - IRIS website
  - IRIS database
  - IRIS audit software
- Contracting and monitoring certification bodies
- Organizing of IRIS information sessions and seminars
- Managing the day-to-day operation and activities:
  - Administrates the standard and training material
  - Administrates the IRIS database

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Certification Bodies

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- ■ ISO 9001 accreditation and IRIS approval
  consent to framework agreement:
  - 1. At least 25 certificates specific to the railway industry
  - 2. Global presence
  - 3. Capability and experience in the railway industry
  - 4. Availability of experienced auditors

- ■ Mutual recognition of IRIS certificates between approved certification bodies
  (to enable issuing of corporate certificates for multi-site organizations)

- ■ Acceptance of « witness audits »

- ■ Execution of IRIS in-house training/examination by certification bodies

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- One demanding International recognized Standard for the Railway Industry.

- Reduction of non conformity costs due to suppliers deficiencies

    => IRIS will support the manufacturers and the suppliers in improving their process quality continuously.

- Increase the number of approved suppliers

    => whilst stopping of audits performed by internal resources.

- Reduction of efforts in terms of time and expenses for approving suppliers

    => Thus enhance focus on supplier performance and on specific product requirements.

- Reduction of costs for maintaining the "approved supplier lists" in ERP systems.

    => They will become obsolete. In future, the data will be maintained on one common IRIS web database.

- Improvement of Quality of Equipments & Rolling Stock

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IRIS Management Centre

UNIFE
Avenue Louise, 221
1050 Bruxelles
Belgium

Michael Wix

Giuseppe Greco

Judit Sandor

Tel: +32 2 626 12 60
Fax: +32 2 626 12 61
Mail: iris@unife.org
Web: http://www.iris-rail.org/