

# Risk Mitigation in Business



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A method of reducing risk in business has been the implementation of management system standards – one such uncompromising standard is IRIS – ‘The International Railway Industry Standard’.

Railway siding at Wight

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In recent years ISO 9001 has lost its popularity as a standard confirming the quality of a company's management system, but has become a 'commodity' or a 'badge' to be had. Certainly reports by the ISO organization go some way to support this view. According to the 2014 ISO survey 'the quali-

ty management standard ISO 9001:2008 continues to experience a lull, claiming a mere 1 % share of the market compared to 2 % and 3 % in the previous two years'. Growth has plateaued and in countries with a longer-established tradition of certification many of the largest companies are already certified.



In the meantime, the high risk industry sectors such as rail, aerospace, automotive, energy and food sectors require stringent process requirements from both quality and safety perspectives to enable them to meet the justifiably high level of stakeholder's expectations. One such standard, IRIS, is setting the stringent process requirements that the railway industry expects companies to meet. This standard was developed by four major global players in the rail industry Alstom Transport, AnsaldoBreda, Siemens Transportation Systems and Bombardier Transportation, which is now owned and managed by the UNIFE Group (The Association of the European Rail Industry). The IRIS

standard is based on ISO 9001 structure adding railway specific requirements to the business management system, e.g. Project Management, Design, Life Cycle costs etc. Its aim is to develop and implement a global system for the evaluation of companies supplying to the railway industry with uniform: language, assessment guidelines and mutual acceptance of audits, which create a high level of transparency throughout the supply chain.

### Risk Mitigation through IRIS certification

IRIS differs from ISO 9001 as it is a system that both defines the requirements in content, procedures and evaluation of audits as well as a requirement profile for the certification bodies and auditors. The requirements for certification bodies and auditors are regulated by a single body – UNIFE. All certification bodies are required to have an accreditation in accordance with ISO/IEC 17021:2006 and an IRIS approval. Only IRIS approved auditors (who have participated in the IRIS training, passed a written and oral examination) can audit against the standard. The auditors can only audit against their competence in a certain product category. Finally, auditors who comply with these requirements can only work for one IRIS approved certification body which certainly is not the case with ISO auditors. This greater level of regulation by a single global body ensures consistency of compliance with the IRIS standard to a greater degree than is currently experienced with the ISO 9001 system.

IRIS is a global standard for the rail industry that is based on ISO 9001 requiring cost reductions hence better value to the users, effective business processes, so meeting objectives, efficient business, meaning delivering more with fewer inputs and it applies to all suppliers regardless of role in supply chain. Most readers have heard positive claims about numerous standards, but IRIS has actually but mechanisms in place through specific requirements to achieve such aims.

Further many of these could be translated and used in other industry sectors for the more beneficial implementation or improvement of the newly revised ISO 9001:2015. To understand these mechanisms it should be noted that the certification rules differ from the ISO. The IRIS certification ru-

4.1	General Requirements – require any outsourcing of process or products to be governed by a documented transfer procedure including the following controls: Feasibility study, Risk analysis, Planning, Communication to customer, First article inspections.
7.3	Design and Development – for IRIS scope 19 (Signalling) the principles applied in developing high integrity systems shall conform to applicable EN standards or agreed equivalent.
7.3.2	Design and Development Inputs – application of design input controls to the adoption of any new technology or development of new products.
7.3.6	Design and Development Validation – ensure the design and development process: validates designs for all identified operational conditions.
7.3.8	Design Approval – apply special safety controls to signalling equipment as specified in EN standards.
7.5.2	Validation of Production Processes – manage 'special processes' per organisation's documented procedure and any contractual requirements.
7.7	Project Management – describe KPI, roles and responsibilities
7.7	Project Management – 7.7.5 Quality management – associate each project deliverables with its processes.
7.9	First article inspection (FAI) – use documented procedures to specify FAI, verification and record keeping requirements.
7.10	Commissioning/Customer service – organise suppliers and demonstrate adequate customer support during commissioning until product validation is complete and accepted by the customer.
7.13	Change Management
8.3	8.3.1 Control of Nonconforming processes

Table 1 : IRIS 'knock out' areas

les include up to 12 applicable 'knock-out' questions (failing a knock-out question would stop an auditor's recommendation for certification – major nonconformity for those of used to 'ISO speak') which are prerequisite for IRIS certification. These are clearly documented in IRIS so there are not to be any interpretation of the requirements. These 'knock out' areas are listed in Table 1.



Launch of Pendolina in Wrocław

The preliminary IRIS requirements state the rules for interpreting the standard which include the principle that where the use of a process is specified it shall be documented and controlled by key performance indicators (see 4.1c), all processes must be integrated into the organization's business management system, the system must result in conformity with Euro Norm (EN) 50126 (for hardware reliability) and EN 50128 and 50129 (for communications and signalling software reliability), and that there must be a documented procedure for RAMS (Reliability, Availability, Maintainability and Safety) and LCC (Life Cycle Costing). Additionally IRIS recommends that the business management system also conforms with environmental and health and safety management according to ISO 14001 and BS OHSAS 18001. For multi-site projects IRIS requires that the documented business management system include other sites involved in projects to cover: each site's scope of responsibility, internal operational interfaces and responsibilities, customer-related interfaces and responsibilities, processes, procedures, documents and records ap-

plicable to each site, and assess the efficiency of cross-site processes and improve as necessary.

The IRIS system certification process (provided the mandatory areas are passed) requires the audit results to be scored based on a questionnaire with 253 questions of which 111 questions relate to ISO requirements and 142 questions are relative to IRIS requirements. The scoring system allows the company and other interested parties to see the maturity of the system and the year on year improvements.

### Review of IRIS risk mitigating requirements

'Knock out' areas have been defined and agreed by the rail industry as the greatest areas of risk which are not acceptable and must therefore be mitigated. The first is outsourcing of process or pro-



Welder at work



Train at Kings Cross Station, London, United Kingdom

ducts – IRIS requires their management, but specifies how this should be done (see Table 1). Design and development inputs clause dictates the validation of new designs before they are introduced to customer as a 'knock out', but also suggest that consideration should be given to Reliability, Availability, Maintainability and Safety (R.A.M.S.) and Life Cycle Costing (LCC) as input requirements to design as well as determining the criticality and risks of the product

and function within the finished product or vehicle. By the inclusion of such elements at the design stage the Organization can have an impact on cost reductions and effective business processes as was discussed earlier.

A particularly beneficial area is introducing a project management requirement which not only refers to the design stage, but specifies extensive additional requirements for the project system within the organization's corpora-

te system which include the development and use of project management system or plan or a new product development process; a description of key performance indicators, roles and responsibilities; the integration of relevant functions into one multidisciplinary team and the inclusion of functions as necessary to address all applicable areas as Integration Management, Scope Management, Time Management, Cost Management, Quality Management, ➔

- Human Resources Management, Communication Management, Risk and Opportunity Management and Change Management.

The description of the IRIS requirements only touched the 'tip of the iceberg' as the standard contains a large number of railway specific issues which need to be addressed in the same comprehensive manner as the management issues described here. IRIS has addressed risk with respect to quality, safety and reliability from product design to disposal mitigating it through the requirements set in the standard itself through the requirements for the certification bodies and auditors. Although the ISO organisation believes that with the publication of the new ISO 9001:2015 version the trend in its popularity will change, for risk mitigation in business organisations would be well advised to study and use the more specific requirements in IRIS as a reference point for the implementation of for ISO 9001:2015. ■



The Railway past



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since 2009)

The implementation of an IRIS-certified management system has enhanced the overall professionalism in dealing with long-term project business and has brought it to the level that is increasingly expected by the process and automation sector. Developed and manufactured according to company processes compliant with the tough IRIS requirements, Alstom Konstal products meet the highest quality standards and customers who use these products benefit from reliability, availability and easy maintenance. The IRIS standard require-

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ments for lifecycle costs for product development, operation and maintenance have ensured that these are calculated in collaboration with customers, ensuring a high degree of cost transparency across the entire product lifetime. The optimum operational reliability and system availability are guaranteed through comprehensive support, starting in the development phase through production and servicing right up to obsolescence management. Working with AFNOR has enabled Alstom Konstal to unify the requirements through the use of the same team of auditors across all plants in the group Alstom, including units that are both our suppliers and customers.

#### Summary

Risk Mitigation in Business is described by the implementation of an uncompromising stringent standard as adopted by the railway sector – IRIS 'The International Railway Industry Standard'. The article reviews some of the key risk clauses of this standard and the differences in the certification process approach which mitigate risks in business. This includes a discussion relating to the influence of just a single global accreditation body for IRIS and the benefits from a stringent approach to requirements. The article also proposes the adoption of IRIS as a reference document by business during the implementation of the new revision of the ISO 9001:2015 which is sadly lacking specific requirements relating to risk mitigation. Finally a short case is presented of the benefits of IRIS certification by one of the IRIS's founders ALSTOM.

#### Ograniczanie ryzyka w biznesie

Ograniczanie ryzyka w biznesie jest opisane poprzez wdrożenie bezkompromisowej rygorystycznej normy przyjętej przez sektor kolejowy – IRIS (International Railway Industry Standard). Artykuł przedstawia niektóre kluczowe rozdziały tej normy dotyczące ryzyka oraz różnice w podejściu procesu certyfikacji, które zmniejszają ryzyko w biznesie, a także wpływ globalnego organu akredytacyjnego dotyczącego IRIS oraz korzyści z rygorystycznego podejścia do wymagań. W artykule zaproponowano także przyjęcie IRIS-u jako dokumentu odniesienia przez biznes w trakcie wdrażania nowej rewizji ISO 9001:2015, w którym niestety brakuje szczegółowych wymagań dotyczących ograniczenia ryzyka. Na końcu artykułu został przedstawiony krótki opis korzyści z certyfikacji według normy IRIS przez jednego z założycieli IRIS – Alstom.

# Jak kontrolować ryzyko w kontekście niepewności?

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