Welcome to your training in the International Railway Industry Standard…

…we will be focusing on the IRIS requirements beyond ISO 9001

So, before starting please refresh your knowledge of our basic management systems standard ISO 9001.

…and be ready with your copy of the International Railway Industry Standard (please refer to the pre-purchase introduction or our leaflet 173 for details on how to purchased IRIS).
Let us start by studying the:

- Purpose of IRIS
- The preliminary requirements of IRIS
- …and some IRIS terminology
You already know and understand how process-based management systems work

You already know and understand the requirements of ISO 9001 for process-based quality management systems

You need to understand the terms as used by IRIS

You need to understand the additional requirements specified in clauses 0 to 4 of IRIS for process-based business management systems

You need to know what is required in terms of additional processes, controls and documents

Your learning objectives probably include one or more of the following:

You need to understand the terms in the context of the International Railway Industry Standard (IRIS)

You need to understand the additional requirements specified in clauses 0 to 4 of IRIS for process-based business management systems

You need to know what is required in terms of additional processes, controls and documents for conformity to IRIS requirements

As you study the requirements from IRIS please make notes on the following aspects of your management system: new processes, new controls and new documents.

Please note that new controls become part of existing processes. New processes become part of an existing system. By the way, a process is work that converts inputs into outputs and controls are requirements or criteria for a task or decision within a process.
The purposes of the International Railway Industry Standard are many.

• It is a global standard for the rail industry that is based on ISO 9001
• It expects to result in cost reduction (better value)
• It expects to result in effective business processes (that is they fulfill their objectives)
• It expects to result in efficient business processes (that is they deliver more with fewer inputs)
• ...IRIS applies regardless of role in supply chain
• ...IRIS will eliminate multiple audits

• The standard includes the IRIS certification rules including up to 12 applicable knock-out questions (failing a knock-out question would stop an auditor’s recommendation for certification – see Annex 4)
• Applicable knock-out IRIS requirements are a prerequisite for IRIS certification
• These critical requirements are identified throughout this course with a red stop sign
• Chapter 2 of IRIS specifies the scoring threshold for certification

...IRIS is published by European Railway Industries (UNIFE)
The preliminary requirements of IRIS lay out rules for interpreting the standard:

- Where IRIS specifies use of a process it shall be documented and controlled by key performance indicators (see 4.1c)
- All processes are to be integrated into the organization’s business management system (in line with our eLearning for developing and documenting a management system)
- The system must result in conformity with Euro Norm (EN) 50126 (for hardware reliability) and EN 50128 and 50129 (for communications and signaling software reliability) remain the primary standards if they contradict IRIS requirements – Please download the handout for more information on the three EuroNorm standards
- The terms, definitions and abbreviations from Annex 5 and Annex 7 apply throughout the IRIS standard
- For Reliability, Availability, Maintainability and Safety (RAMS) refer to IRIS requirements specified in clause 7.11

IRIS includes guidelines and these are to be interpreted as follows:

- “Should” is not mandatory but organization may consider it necessary to take its management system to the next level of maturity or performance
- IRIS recommends the business management system also conforms with ISO 14001 and BS OHSAS 18001 for environmental management and health and safety management
IRIS uses terms with specific meanings as described here:

“Abnormal Work” is out of scope work or parts required to attain acceptance (probably subject to a contract change)
“Consignment Stock” describes replacement parts as listed, stored and maintained
“Critical Product” has the potential to introduce risks that threaten health, safety or business performance
“Criticality” is a rating of how much risk is attached to the failure of a Critical Product
“Component” is a sub-device above the integration level of the smallest exchangeable unit of a system
### Engineering Change
- Implementation of new or revised standards, product designs, processes, procedures, suppliers that have the potential to impact health, safety or business performance

### First Article Inspection (FAI)
- Verification (or validation of one-off items/software) and documentation of an item representing the first production run of new or upgraded product

### Key Performance Indicator (KPI)
- Indicator to measure the performance of a process

### Multidisciplinary approach
- All needed specialists for a project working as one team
### Rail Terms and Definitions (see Annex 5) 3/3

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outsourcing</td>
<td>Temporary delegation of product realization processes</td>
</tr>
<tr>
<td>Project</td>
<td>Temporary endeavor to create a unique product/outcome</td>
</tr>
<tr>
<td>Quality deficiency costs</td>
<td>All costs that result from product not being produced right the first time</td>
</tr>
<tr>
<td>Tender</td>
<td>Formal proposal to buy for specified product requirements to be fulfilled at a quoted price (not in Annex 5)</td>
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Other more familiar terms are defined in Annex 5 and ISO 9000

**Outsourcing** is a temporary delegation of a product realization process or processes

**Project** is a temporary endeavor to create a unique product or outcome

**Quality deficiency costs** means all costs that result from product not being produced right the first time

...other more familiar terms are defined in Annex 5 and ISO 9000

**Tender** is a formal proposal to buy for specified product requirements to be fulfilled at a quoted price (not in Annex 5)
4.1 General Requirements

- Requires a business management system
- Requires any outsourcing of processes 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
- Requires a product life cycle cost management process
- Requires a project cost management process
- Requires a key performance indicator for certain processes

- IRIS requires a business management system (to fulfill requirements beyond a traditional quality management system)
- IRIS requires any outsourcing of processes or products to be governed by a documented transfer (of responsibility) procedure including the following controls:
  - Feasibility study
  - Risk analysis
  - Planning
  - Communication to customer
  - First article inspections
- IRIS requires the management system to include a product life cycle cost management process
- IRIS requires the management system to include a project cost management process
- …and please note that IRIS requires key performance indicators for certain processes (see 4.1c and Annex 3)
IRIS specifies more documentation in the business management system:

- Including any documents imposed by regulators
- Document the processes specified by IRIS (per 4.2.1c)
- Include the safety policy statement
- Include the safety objectives
- Personnel access to and awareness of relevant procedures
- Access to business management system documents to:
  - Customers
  - Regulators
- Show the relationship between the documented procedures and the IRIS in the Quality Manual (see 4.2.2)
- Extend scope to all sites involved with projects (see 4.4)
- See ANNEX 1 for scopes of IRIS certification
In controlling documents, IRIS additionally requires the organization to:

• Show effective management and control of all documents pertaining to its products
• Name personnel who authorize and review system and product related documents (and are competent)
• Review the impact of requirements specified in external documents on the supply of product
• Provide traceability to customer requirements throughout the supply chain for:
  • Design
  • Manufacturing
  • Field support
• Identify, describe and communicate customer interfaces and communication channels
• Record by date/serial number to signify when each change is implemented
IRIS requires updating of the procedure for controlling records so it includes the following additional controls:

• Approve the results recorded before their official release
• Make records available for review by, or release to:
  • Customers
  • Regulators
  ...per legal requirements
IRIS requires the organization’s business management system to manage knowledge (KM) as follows:

• Document best practices and continually update to improve processes and products, such as:
  • Design standards and design rules
  • Lessons learned after projects
  • Methods
  • Manufacturing engineering standards
  • Process and product nonconformities
  • Feedback from the field
  • Failure analysis
• Should define and implement a process to identify, obtain, protect, use and evaluate information, knowledge and technology

…these are examples of knowledge to be managed by the system

…KM should define and implement a process to identify, obtain, protect, use and evaluate information, knowledge and technology (remember that should is an optional requirement to achieve a higher maturity level or the performance to be expected from a mature management system—see 0 Introduction)
### 4.4 Management of Multi-site Projects

- Extend the documented business management system to include other sites involved in projects, to cover:
  - Each site’s scope of responsibility (see 4.2.2a)
  - Internal operational interfaces and responsibilities (see 4.2.1c)
  - Customer-related interfaces and responsibilities (see 7.1)
  - Processes, procedures, documents and records applicable to each site (see 7.1)
  - Plan to fulfill customer requirements (see 7.1)
  - Assurance of conformity to the IRIS (5.4.2 and 8.2.2)

- Assess the efficiency of cross-site processes and improve as necessary (KPIs may be set and used for this)

- Also refer to clause 7.7 and consider the fact systems are extended via the:
  - System planning process (per 5.4.2) if a large project or
  - Quality planning process (per 7.1) for smaller projects

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For multi-site projects extend the documented business management system to include other sites involved in projects, to cover:

- Each site’s scope of responsibility (see 4.2.2a)
- Internal operational interfaces and responsibilities (procedures - 4.2.1c)
- Customer-related interfaces and responsibilities (7.1)
- Processes, procedures, documents and records applicable to each site (7.1)
- Plan to fulfill customer requirements (7.1)
- Assurance of conformity to the IRIS (5.4.2 and then 8.2.2)

- Assess the efficiency of cross-site processes and improve as necessary (please note that many processes are “cross-site” by their nature and key performance indicators may be set and used to assess the efficiency of these processes)

- …also refer to clause 7.7 (Project Management) and consider the fact that management systems are extended by way of their system planning processes (per clause 5.4.2 for larger projects) and the quality planning processes (per clause 7.1 for smaller projects)
We have two pages summarizing the changes from sections 0 to 4 inclusive, before the quiz:

- **IRIS** requires effective and efficient *business* management systems (comprising many more processes than is customary in quality management systems) you may be interested in our eLearning course for developing such a process-based management system
- Govern outsourcing with a documented transfer procedure to examine and control feasibility, risk, planning, customer communications and first article inspections (KO)
- Include documented safety policy and safety objectives
- Show the relationship between the documented procedures and the IRIS in the Quality Manual
- Name those who authorize and review documents
- Ensure traceability of customer requirements throughout the supply chain
- Identify, describe and communicate customer interfaces and communication channels
- Record implementation of changes by date/serial number
- Approve results recorded before official release

<table>
<thead>
<tr>
<th>Summary of IRIS Sections 0 to 4</th>
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IRIS.003-15

We have two pages summarizing the changes from sections 0 to 4 inclusive, before the quiz:

- **IRIS** requires effective and efficient *business* management systems (comprising many more processes than is customary in quality management systems) you may be interested in our eLearning course for developing such a process-based management system
- Govern outsourcing with a documented transfer procedure to examine and control feasibility, risk, planning, customer communications and first article inspections (this is a knock-out requirement)
- Include documented safety policy and safety objectives
- Show the relationship between the documented procedures and the IRIS in the Business System Manual
- Name those who authorize and review documents
- Ensure traceability of customer requirements throughout the supply chain
- Identify, describe and communicate customer interfaces and communication channels
- Record implementation of changes by date/serial number
- Review and approve the results recorded before they are released officially
Here is the second summary page to recap before the quiz on these initial sections:

Document for knowledge management and continually update to improve processes and products

Extend the documented business management system to 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 for each site
- Plan to fulfill customer requirements
- Assurance of conformity to the IRIS

Assess the efficiency of cross-site processes and improve as necessary (KPIs may be set and used for this)
Let us now continue by studying the additional requirements for:

Management Responsibility

…and Resource Management
Learning Objectives – sections 5 to 6

• You already know and understand the requirements of clauses 5 and 6 of ISO 9001 for process-based quality management systems

• You need to understand the additional requirements specified in clauses 5 to 6 of IRIS for process-based business management systems

• You need to know what is required in terms of additional processes, controls and documents so please continue to make a note of them

• Your learning objectives probably include one or both of the following:

  • You need to understand the additional requirements specified in clauses 5 and 6 of IRIS for process-based business management systems

  • You need to know what is required in terms of additional processes, controls and documents for conformity to IRIS requirements

• As you study the requirements from IRIS please make notes on the following aspects of your management system: new processes, new controls and new documents.

• Please note that new controls become part of existing processes. New processes become part of an existing system. By the way, a process is work that converts inputs into outputs and controls are requirements or criteria for a task or decision within a process.
IRIS specifies an additional policy requirement under customer focus perhaps to further emphasize the change from quality to business management system:

• Ensure the documented policy (business management systems include the organization’s quality policy)…

  … reflects the organization’s willingness to satisfy customer needs (see 5.2)

• Remember, needs are undefined requirements and…

  … successful companies anticipate customer requirements by focusing on customer needs so design can translate customer needs into product requirements

• Ensure the quality policy extends top management’s commitment to customer satisfaction throughout the life of each project – from Note to Proceed to end of warranty or final customer approval (see 5.2)

  … to the end of the warranty or to final customer approval (see 5.2)
As you would expect with a business management system, IRIS requires Business Planning.

• Establish the Business Plan (with reviews at least annually) covering the organization’s scope of rail industry activities including:
  • The organization’s mission and vision
  • The organization’s business objectives (see 5.4.1)
  • The organization’s plan to reduce risks (see 5.4.2)
  • The organization’s market strategy
  • The organization’s product strategy including obsolescence (see 7.12)
  • Impact of changes in technology and legal requirements
  • Plans for developing new products/processes (see 5.4.2)
  • Make or buy strategy
  • Company capacity (now and future)
• Support the fulfillment of the Business Plan with a process for predicting, monitoring and controlling costs (see 7.7.4)

...and the organization is to support the fulfillment of its Business Plan with its process for predicting, monitoring and controlling or managing costs (see 7.7.4)
5.4.1 Quality Objectives

With the documented quality objectives include:

• Business objectives deployed to the processes (via the KPIs) or to the functions and levels
• Plan for regular reviews at each level from system/organization to project/department/process and down to each individual (see 6.2.2.4)
• Conduct the reviews per the plan (audit is not to be used as the review tool so the reviews can be audited)
• Address customer expectations in the objectives
• Include dates for achievement of objectives
• Should define and deploy a planning process to address external trends and the needs of interested parties

With the documented quality objectives IRIS requires the following:

• Business objectives deployed to the processes (via KPIs) or to functions and levels…
• Plan for regular reviews at each level from system/organization to project/department/process and down to each individual (see 6.2.2.4)
• Conduct the reviews per the plan (audit is not to be used as the review tool so the reviews can be audited)
• Address customer expectations in the objectives
• Include dates for achievement of objectives
• ...and should define and deploy a planning process to address external trends and the needs of interested parties
Here we see IRIS requirements to strengthen the assignment of authorities and responsibilities:

- Identify customer interfaces and communication channels (see 7.2.3)
- Describe roles and responsibilities for all processes that:
  - Effect customer satisfaction
  - Are validated (see 7.5.2)
  - Effect reliability, availability, maintainability or safety
- Ensure employees know they are responsible for raising issues/deviations to manager for action (see 8.2.3 & 5.5.3)
- Define who “owns” each process
- Define authority and responsibility of process owners
- Please note that the procedures can define the roles, authorities (can do) and responsibilities (must do)
Here we see additional IRIS requirements for the Management Representative and the Customer Relationship Management (these authorities and responsibilities could be assigned to the same person)...

Provide him or her the organizational freedom to:
• Resolve matters pertaining to quality
• Stop work if critical requirements are not met

Customer Relationship Management (5.5.4):
Appoint a member of management and define responsibilities and authorities that include:
• Ensuring process needed to satisfy customers and their requirements are in-place and maintained
• Reporting to top management on the performance of these processes and any need for improvement
• Ensuring training for and awareness of customer satisfaction

**COULD BE THE SAME PERSON**
IRIS specifies communication processes as follows:

- Policies (quality, safety etc, per 5.3d)
- Mission and Vision (see 5.3.1)
- Organizational performance
- Customer related issues (see 7.2.3)
- Issues/deviations (see 5.5.1)
IRIS specifies additional requirements for the management review process:

**General:**
- Review the system at least every 12 months
- Review the processes and projects before reviewing the system (so Top Management can see how well their system supports its processes and projects)

**Additional Review Input:**
- Key issues from previous project and process reviews
- Results of field-failure analyses including impact on quality, safety or the environment
- KPI outcomes
- Customer on-time delivery performance
- Customer reported nonconformity

**Additional Review Output:**
- Any improvement plans for: integration of business processes, KPI fulfillment and customer satisfaction
- Other suggested outputs include: performance of the organization and the State of the System report (describing what the system does well and where it will be improved)
IRIS specifies use of a documented procedure for managing resources:

• Plan the provision of resources including their:
  • Identification (as in determination)
  • Provision
  • Monitoring

• Use documented procedure for providing resources to fulfill current order book and considering the mid-term and long-term order forecasts:
  • Personnel (abilities/skills/knowledge)
  • Equipment/Facilities
  • Purchased materials and components
  • Outsourced materials and components
### 6.2 Human resources

#### 6.2.1 General
- Should define, use, measure and review HR processes including appraisals to help identify training needs

#### 6.2.2f Competence training and awareness
- Ensure personnel are aware of how their work contributes to the achievement of safety objectives

#### 6.2.2.1 Product Design Skills
- Identify the applicable design tools and techniques
- Ensure designers are skilled in the tools and techniques
- Provide competent designers (also required by ISO 9001)

#### 6.2.2.2 Employee Motivation and Empowerment
- Create and maintain a work environment to promote innovation (see 6.4) and enable employees to motivate themselves to achieve objectives and to continually improve (see 6.2.2d and 8.5.1)

IRIS specifies many additional requirements for the management of human resources:

6.2.1 General

*Should* define, use, measure and review HR processes including appraisals to help identify training needs

Quality Management Systems usually include both recruiting and training processes to provide competent people

6.2.2f Competence training and awareness

Ensure personnel are aware of how their work contributes to the achievement of safety objectives

6.2.2.1 Product Design Skills

Identify the applicable design tools and techniques

Ensure designers are skilled in the tools and techniques

Provide competent designers (this is not additional)

6.2.2.2 Employee Motivation and Empowerment

Create and maintain a work environment to promote innovation (see 6.4) and enable employees to motivate themselves to achieve objectives and to continually improve (see 6.2.2d and 8.5.1)
IRIS requires use and improvement of a documented procedure for quality and safety training:

- Identify learning needs for competence
- Include engineering changes and local regulatory requirements
- Plan training to fulfill learning needs
- Deploy organizational knowledge (see 4.3)
- Fulfill process and customer requirements
- Identify quality and safety critical activities
- Maintain records of those able to complete critical activities
- Maintain and upgrade qualifications of such personnel
- Explain the consequences of nonconformity on the customer
- Train temporary workers and induct new employees

**6.2.2.4 Regularly appraise performance against:**
- Individual/team objectives linked to business objectives
IRIS specifies additional requirements of the organization’s infrastructure and work environment:

**Infrastructure includes:**
- Use of planned and predictive maintenance
- Packaging and preservation of tooling and equipment
- Availability of replacement parts for key equipment
- Objectives and continual improvement of maintenance

Define and use processes to ensure work environment complies with legal requirements

Minimize potential risks to health and safety of employees (see 7.3.2 and 7.5.1)

Maintain premises in a state of order, cleanliness and repair consistent with needs of product and production processes

**Work environment:**
- Define and use processes to ensure work environment complies with legal requirements
- Minimize potential risks to health and safety of employees (see 7.3.2 and 7.5.1)
- Maintain premises in a state of order, cleanliness and repair consistent with needs of product and production processes (the discipline of 5S delivers this)
IRIS specifies requirements for a contingency plan or plans to reduce the effects of:

- Utility interruptions,
- Supply chain disruptions
- Labor shortages
- Key equipment failures
- Field returns
- Any loss of leadership (succession planning)
Here is a summary to recap before the quiz on sections 5 and 6:

• The BMS must anticipate customer requirements so design translates customer needs into product requirements
• Review Business Plan (at least annually) and fulfill the plan with the BMS via its objectives, KPIs and processes
• Conduct planned reviews at every level from company, its processes and projects to each individual
• Objectives include customer expectations and the dates for their achievement
• Name the customer relationship manager and include all processes in the BMS that effect customers
• Validate processes that effect reliability, availability, maintainability or safety
• Ensure employees know they are responsible for raising issues/deviations to manager for action
• Define who “owns” each process and the authority and responsibility of process owners
Let us now continue by studying the additional requirements for:

Realizing and delivering the product
Learning Objectives – section 7

• You already know and understand the requirements of clause 7 of ISO 9001 for process-based quality management systems

• You need to understand the additional requirements specified in clause 7 of IRIS for process-based business management systems

• You need to know what is required in terms of additional processes, controls and documents so please continue to make a note of them

• Your learning objectives probably include one or both of the following:

  • You need to understand the additional requirements specified in clause 7 of IRIS for process-based business management systems

  • You need to know what is required in terms of additional processes, controls and documents for conformity to IRIS requirements

• As you study the requirements from IRIS please make notes on the following aspects of your management system: new processes, new controls and new documents.

• Please note that new controls become part of existing processes. New processes become part of an existing system. By the way, a process is work that converts inputs into outputs and controls are requirements or criteria for a task or decision within a process.
IRIS suggests more planning to for timely production and satisfying customers:

• *Should* define, use and manage processes such as those related to product realization and customer satisfaction
IRIS requires determination of the internal costs related to each requirement including:

- Costs from suppliers
- Costs of operating (based on experience)
- Also consider disposal costs (if in scope)

This can facilitate risk management, value engineering and cost management.
IRIS suggests use of a change process including a Change Control Board (we also recommend this)

IRIS requires:
- Review by the disciplines involved in realization including project managers (and suppliers as appropriate)
- Measure the performance of the product requirements review process by the application of a KPI
- Apply the review process to all stages before commitment to meet requirements: commitment to bid, submission of bids/proposals, forming contracts to supply, after sales services, accepting any changes to requirements
- Issue reports to senior management for preventive action:
  - Progress (planned v. actual)
  - Completion date
  - Contingencies and mitigation plans
  - Risk management progress and issues
  - Follow up of open issue list

Reports issued to senior management in time for preventive (proactive) action:
- Progress (planned v. actual)
- Completion date
- Contingencies and mitigation plans
- Risk management progress and issues
- Follow-up of open issue list
IRIS requires use a process to ensure identified requirements are:

- Deployed from statutes and regulations (also see 8.2.1)
- Complete, clear and precise
- Unequivocal, verifiable and testable
- Maintainable and feasible
- Individually shown to comply (legal) or conform (non-legal)
- Negotiated/updated with impact on offer identified
- Evaluated and accounted for (including contract variations)
- Effectively liaised with customers and transferred so they are understood, acknowledged and committed to (by every party involved)
- Manage and mitigate deficiencies identified in the reviews
- Identify and communicate the risks (including customer)
- Monitor and mitigate identified risks

...and identified risks are monitored and mitigated
IRIS specifies additional requirements for communicating customer’s requirements to certain suppliers:

- Use effective arrangements for communicating all information related to the delivery of the customer’s contractual requirements down the value (supply) chain

IRIS suggests use of a process for internal and external communications:

- Organization *should* define and implement communications process (internal and external), perhaps as follows:
  - Identify interested parties
  - Define supply chain
  - Identify topics
  - Define authorities and responsibilities
  - Define how new information is considered
  - Define how significant information changes the management system’s policy, objectives and processes

Note how the IRIS requirements are less prescriptive than the suggestions…
IRIS repeats the requirements from clause 7.2.2 (pre-tender) for the review of the tender itself:

- Multidisciplinary team (and appropriate suppliers) uses a process to develop and address customer and regulatory requirements for the products and processes so:
  - Each requirement complies or conforms
  - Are negotiated/updated with impact on offer identified
  - Risks are identified, controlled and validated
  - Opportunities are identified, controlled and validated
  - Feasibility of specifications is confirmed and recorded
  - Responsibilities are effectively transferred (understood, acknowledged and committed to by every party involved)
  - Identify, control and validate risks/opportunities
  - Establish the budget
  - Approve the offer

- Feasibility of specifications is confirmed and recorded
- Responsibilities are effectively transferred (that means understood, acknowledged and committed to by every party involved)
- Identify, control and validate risks and/or opportunities
- Establish the budget
- Approve the offer

- …also the organization measures the performance of its Tender Management using a Key Performance Indicator
IRIS requires use of a documented procedure for designing and developing the product and any equipment used to manufacture the product, this procedures includes the following controls:

- Measure performance of design process by use of a KPI
- Apply relevant EN standards as design input
- Focus on prevention of nonconformity in design, manufacture, installation, use, maintenance and recycling of the products
- Include documentation and training for the safe use and maintenance of the product
- For IRIS scope 19 (signaling) the principles applied in developing high integrity systems shall conform to applicable EN standards or agreed equivalent
- Software design shall conform to EN 50128 or agreed equivalent

**STOP**
### 7.3.1 Design and Development Planning

| Determine sequence of tasks, mandatory steps, significant stages and configuration control |
| According to complexity of design use the following approach: |
| 1. Structure the design effort into significant elements (including verifications at each level of detail (see 7.3.5)) |
| 2. For each element, determine tasks & necessary resources |
| 3. Identify the person responsible for each task |
| 4. Determine the design content, input data, constraints and performance conditions for the product (additional?) |

**According to complexity of design use the following planning approach:**

1. **Structure the design effort into significant elements (including verifications at each level of detail (see 7.3.5))**
2. **For each element, determine tasks & necessary resources**
3. **Identify the person responsible for each task**
4. **Determine the design content, input data, constraints and performance conditions for the product (additional?)**

**Apply design for the environment, design for maintainability and design for safety as applicable and per the applicable requirements of EN 50126, 50128 and 50129**

**Should define and implement a collaboration process and measure its efficiency**

---

In keeping with its Project Management requirement (see clause 7.7), IRIS requires the design plan to determine:

- The sequence of tasks, mandatory steps, significant stages and configuration control

**According to complexity of design use the following planning approach:**

1. **Structure the design effort into significant elements (including verifications at each level of detail (see 7.3.5))**
2. **For each element, determine tasks & necessary resources**
3. **Identify the person responsible for each task**
4. **Determine the design content, input data, constraints and performance conditions for the product (additional?)**

**Apply design for the environment, design for maintainability and design for safety as applicable and per the applicable requirements of EN 50126, 50128 and 50129**

**IRIS also suggests the organization should define and implement a collaboration process and measure its efficiency**
**7.3.2 Design and Development Inputs**

<table>
<thead>
<tr>
<th>Design and development process must include:</th>
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<tbody>
<tr>
<td>• Consideration of reliability, availability, maintainability and safety (RAMS) as input requirements to design of the product and manufacturing equipment</td>
</tr>
<tr>
<td>• Consideration of life cycle costing (LCC) as input requirements to design</td>
</tr>
<tr>
<td>• Determine and be aware of criticality of product and function/risks of product within finished product/vehicle</td>
</tr>
<tr>
<td>• Application of design input controls to the adoption of any new technology or development of new products</td>
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<tr>
<td>• Integrate maintainability of signaling equipment as part of the design (see 7.5.1.5)</td>
</tr>
<tr>
<td>• Validation of new designs before they are introduced to customer projects (repeat of 7.3.6)</td>
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</tbody>
</table>

IRIS specifies essential design inputs for the rail industry:

• **Consider Reliability, Availability, Maintainability and Safety (R.A.M.S.)** as input requirements to design of the product and manufacturing equipment

• **Consider life cycle costing (LCC) as input requirements to design**

• **Determine and be aware of criticality of product and the function and risks of product within the finished product or vehicle**

• **Apply design input controls to the adoption of any new technology or in the development of new products** (this is a knock-out requirement)

• **Integrate maintainability of signaling equipment as part of the design** (see 7.5.1.5)

• **Validate new designs before they are introduced to customer projects** (repeat of 7.3.6) - (this is a knock-out requirement)
IRIS specifies verifiable product design output for input to the design of production processes:

- Specifications and Drawings (acceptance criteria)
- Information on materials (MSDS etc)
- Flowchart/layout of production process
- Control Plan (see 7.1c)
- Work Instructions (see 7.5.1b and 7.5.2c)
- Process acceptance criteria (see Specs and WIs)
- Product acceptance criteria (see Specs and Drawings)
- Data for quality, measurements, reliability and maintainability (of manufacturing equipment)
- Results of error-prevention (FMEA)
- Results of error-proofing (in production design)
- Methods of rapid detection and feedback of nonconformity during production (or before for input assemblies/materials)
Under IRIS, design reviews must also ensure the design and development process:

• Specifies the design phases and the measurements to be applied and reported to management reviews of design progress (really this is a design planning 7.3.1 requirement)
• Specifies who is involved in each design review with consideration for manufacturability, costs, RAMS, serviceability etc…
• Requires reviews (and verifications – see 7.3.5) of each level of design detail
• Requires results of design reviews to be input to phase review
• Defines points at which design phases are reviewed and authorized to proceed to the next phase
### 7.3.6 Design and Development Validation

Ensure the design and development process:

- Validates designs for all identified operational conditions (freeze, thaw, bake and shake etc...)
- Adopts validation methods specified by EN standards
- Requires documented procedure for validation testing:
  - Test objectives and conditions (for reproducibility)
  - Configuration of product/prototypes for testing
  - Method of testing and recording of results
  - Test per the test plan and procedures
  - Fulfill the specified testing criteria

Design validation makes sure the design works in the actual conditions of use, therefore IRIS specifies additional requirements:

- Validate designs for all identified operational conditions (freeze, thaw, bake and shake etc...)
- Adopt validation methods specified by EN standards (both of these are knock-out requirements)
- Require use of a documented procedure for validation testing:
  - Test objectives and conditions (for reproducibility)
  - Configuration of product/prototypes for testing
  - Method of testing and recording of results
  - Test per the test plan and procedures
  - Fulfill the specified testing criteria
IRIS specifies an additional requirement and makes one suggestion for controlling design changes:

• Control design and development changes using a process:
  • Including changes from deferred and abnormal work
  • Should define and implement a design and development change process

7.3.8 Design Approval:
• Apply special safety controls to signaling equipment as specified in EN standards

...also IRIS specifies an additional design control in 7.3.8 Design Approval: to apply special safety controls to signaling equipment as specified in EN standards (a knock-out requirement)
IRIS requires the organization to use a documented procedure to control its purchasing including:

• Suppliers use of 3rd party certified ISO 9001 systems, unless otherwise specified by customer
• A register of approved suppliers and for what goods and services (incl. verification) they are approved to supply
• Identify, assess and manage risks of supply of critical items
• Use of customer approved suppliers of special (7.5.2) processes
• Approval authority must also have authority to stop use of an approved supplier
• Rank suppliers according to periodic reviews of supplier performance and adjust purchasing controls accordingly
• Require recovery actions of suppliers not meeting requirements
• Ensure conformity of all goods & services received including those designated or supplied by customer (see 7.5.4)
  
  Specify performance targets and use KPIs (see 8.4d)

…and specify and use key performance indicators for purchasing
IRIS specifies additional requirements for the purchasing process to include negotiation before accepting supplier’s offer with due consideration for:

- Level of conformity with specifications
- Total cost including cost of doing business with the supply and the life-cycle costs
- Previous performance in terms of quality/cost/timeliness

Ensure Purchase Orders/Subcontracts include:

- Identity & issue of documents that specify requirements
- Appropriate details from the organization’s quality plan
- Spec to verify conformity of goods/services (also FAI)
- Nonconformity notification and dispositioning rules
- Rights of access to records by customer and regulators
- Flow-down customer requirements to supplier/sub-suppliers
- Commissioning, warranty and spare parts requirements

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- Total cost including cost of doing business with the supply and the life-cycle costs
- Previous performance in terms of quality/cost/timeliness

- IRIS specifies the content of purchase orders and subcontracts:
  - Identity and issue (revision) of documents that specify requirements
  - Appropriate details from the organization’s quality plan
  - Spec to verify conformity of goods and services (also First Article Inspection)
  - Rules for notification and dispositioning of nonconforming goods and services
  - Rights of access to records by customer and regulators
  - Flow-down customer requirements to the supplier and their sub-suppliers
  - Requirements for commissioning, warranty and spare parts
IRIS specifies additional requirements for verifying incoming products:

- Ensure purchasing procedure specifies verification according to organization’s delegation of verification responsibilities (see 7.4.1 scope and selection criteria):
  - Obtain evidence of purchased product’s conformity
  - Review required documentation for acceptable evidence of conformity (products and raw materials)
  - Organization to conduct receipt inspection (extent is determined by completeness of above verifications)
  - Ensure Product Documentation is delivered (see 7.5.5)
- Do not use product until it is known to conform unless released under customer waiver
- Should define and implement verification process (recommend selection of suppliers based on their competence to verify their own systems, processes, products) IRIS suggests “checklists and templates” for pre-shipment verifications
IRIS adds a new section with requirements for supply chain management to:

- Support ordering with information covering the entire supply chain
- Provide customer access to production information at key stages in the order-driven process
- Regularly communicate forecasts to suppliers so they manage their capacity
- Identify shortages in time to recover delivery schedule
- Ensure suppliers schedule deliveries to fulfill purchasing requirements

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<th>7.4.4 Supply Chain Management</th>
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- Identify shortages in time to recover the delivery schedule
- …and ensure suppliers schedule their deliveries to fulfill purchasing requirements
IRIS specifies additional production requirements:

- Verify conformity of production to the design outputs (see 7.3.3 acceptance criteria)
- Maintain the controlled conditions for all shifts
- Account for all product during manufacturing, including:
  - Parts
  - Quantities (to avoid sale to gray market)
  - Split Orders
  - Nonconforming Product (to avoid sale to gray market)
- Maintain evidence that all operations (manufacturing and inspection) have been authorized and completed as planned
- Include process to control deferred (delayed) work and Abnormal Work (see definition)
- Demonstrate due awareness of product criticality and mitigate risks for critical products
- Minimize potential health and safety risks for employees (also see 6.4)
IRIS adds a new subsection of production scheduling to:

- Support scheduling process with production information at key stages in the process
- Identify bottlenecks in production and take action to improve the process
- Use customer forecasts and orders to plan production
- Schedule production and testing (short/mid/long-term) to fulfill customer requirements
- Measure capacity and adjust resources as necessary with due regard for urgent orders and supply problems

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- Schedule production and testing (short/mid/long-term) to fulfill customer requirements
- …and measure capacity and adjust resources as necessary with due regard for urgent orders and supply problems
Here we see IRIS re-stating requirements from 8.2.3 and 8.2.4 regarding conformity of production and product to:

- Drawings
- Part Lists
- Flowcharted Procedures
- Inspection Procedures and Specifications
- Work Orders, Travelers, Routers or Process Cards
- Manufacturing Plans
- List of Tools
- List of numerical control machine programs and specific instructions for their use
Changes to production processes are to be controlled per a process that:

- Identifies persons authorized to approve changes (see 5.5.1)
- Documents changes to production processes, equipment, tools and programs (whether internal or contractual)
- Obtains acceptance of changes from customer (per contract) and from regulator (per regulation) (see 7.2.1)
- Reviews results of change to confirm achievement of desired effect without adverse affects to product conformity (see 8.2.3)
- ...and maintains the record (date/serial number) of each change implemented in production (see 7.13)
IRIS requires design and control of manufacturing equipment and tooling:

- Apply design and development to the manufacturing equipment, fixtures, jigs and tools
- Use a documented procedure for providing conforming manufacturing equipment and tools (see First Article Inspection clause 7.9)
- Periodically check to ensure equipment and tooling is stored per specified requirements

7.5.1.4 Control of Equipment and Tools
IRIS makes the management of special processes a knock-out question:

- Manage “special processes” per organization’s documented procedure(s) and any contractual requirements
- Ensure personnel performing special processes are identified, trained/competent and authorized
- Validate process before approval for production per the documented procedure(s)
- Change and revalidate special processes per the documented procedure(s)

A special process is where conformity of the resulting product cannot be readily or economically verified
IRIS suggests measures for preserving product that remain a requirement in ISO 9001:

• Organization *should* provide for the following in accordance with the product specifications and applicable regulations:
  • Cleaning
  • Special handling for sensitive products (example, ESD)
  • Marking and Labeling
  • Shelf-life control and stock rotation (example, FIFO)
  • Special handling for hazardous materials
  • Protect product documentation (also see 7.4.3) against loss and deterioration

*Please note version 01 of IRIS specified this as a requirement and we recommend it continues to be treated as such to conform to ISO 9001*
IRIS specifies additional more prescriptive requirements for the control of measuring devices:

- List all devices that determine product quality, including employee and customer-owned devices; using the following headings:
  - Equipment Type
  - Unique Identification
  - Location
  - Frequency of verification and verification method
  - Acceptance Criteria (including due dates)
  - Reference to the calibration methods
- Recall devices for calibration per defined process
- Ensure ambient conditions are suitable for calibration, inspection and testing (see 6.4)
IRIS specifies extensive additional requirements for the project system within the organization’s corporate system:

• Develop and use a project management system or plan (see 7.1) or new product development process:
  • Describe KPI, roles and responsibilities (see 5.5.1)
  • Integrate relevant functions (see list below) into one multidisciplinary team
  • Address all applicable areas (see list below):
    7.7.1 Integration Management
    7.7.2 Scope Management
    7.7.3 Time Management
    7.7.4 Cost Management
    7.7.5 Quality Management
    7.7.6 Human Resources Management
    7.7.7 Communication Management
    7.7.8 Risk and Opportunity Management
    7.7.9 Change Management

• …we shall now study each of these brief requirements
### 7.7 Project Management 2/6

<table>
<thead>
<tr>
<th>7.7.1 Integration Management:</th>
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<tbody>
<tr>
<td>• Ensure the product realization process integrates the work of the entire project team and establishes the rules by which the team operates throughout the project life cycle including change control</td>
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<tr>
<th>7.7.2 Scope Management:</th>
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<td>• Identify the entire scope of work, subdivide into work packages, control and verify the work to assure consistency and scope change control</td>
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<tr>
<th>7.7.3 Time Management:</th>
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<tr>
<td>• Identify the following to ensure timely completion:</td>
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<tr>
<td>• Deliverables and associated tasks</td>
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<td>• Interdependencies of tasks (including suppliers’)</td>
<td></td>
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<tr>
<td>• Sequence of tasks, resources, durations and milestones</td>
<td></td>
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<tr>
<td>• Critical path (chain of task durations = time to complete project)</td>
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...continued on the next slide
7.7.3 Time Management (continued):
• Regularly review and record progress against milestones
• Take counter-measures to avoid impact of any delay on customers (see 8.2.3)
• Obtain customer authorization before changing the schedule
• Manage long-lead items including those from suppliers

7.7.4 Cost Management:
• Use a KPI and cost management process to:
  • Plan all project related costs during the whole project life cycle
  • Track the cost progress of each work package
  • Estimate and report the cost of completion
• Identify cost savings to pay for any cost over-runs

...this suggests use of Microsoft Project or similar project management software

...and identify cost savings to pay for any cost over-runs
Project Quality Management to manage project deliverables is a knock-out clause:

7.7.5 Quality Management:
• Associate each project deliverable with its process
• Establish Key Performance Indicators
• Include identification, clarification, fulfillment and control
• Include design and process validation
• Include on-time delivery
• Manage suppliers within the Project
• Include customer approvals and handovers
• Review and record project progress at regular intervals throughout the life of the project
• Review project phases and authorize progress to next phase
• Apply appropriate resources and tasks to overdue issues
7.7.6 Human Resources Management (see 6.2):
- Identify and assign project roles
- Document roles and responsibilities
- Identify reporting relationships
- Acquire and assign appropriate human resources
- Develop competencies to enhance project performance

7.7.7 Communication Management (see 5.5.3):
- Determine the needs of the project’s stakeholders
- Communicate these needs to the project team
- Plan the communications from project team to fulfill needs including product specific requirements, defect reporting and rail industry risks
- Share project information per the plan (without undue delay)

7.7.6 Human Resources Management (see 6.2):
- Identify and assign the project roles
- Document the roles and responsibilities
- Identify the reporting relationships
- Acquire and assign appropriate human resources
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7.7.7 Communication Management (see 5.5.3):
- Determine the needs of the project’s stakeholders
- Communicate these needs to the project team
- Plan the communications from project team to fulfill needs
- Include the product specific requirements, defect reporting and rail industry risks
- ...and share project information per the plan (without undue delay)
The final IRIS project management requirement is for managing risks and opportunities:

**7.7.8 Risk and Opportunity Management:**

- Identify the risks and opportunities
- Analyze and assess the risks and opportunities (quantitatively or objectively and qualitatively or subjectively)
- Consider use of SWOT, FMEA and other techniques
- Decide on the risk response (avoid, transfer, mitigate or accept)
- Earn the benefits of opportunities (plan>do>check>act)
- Document and communicate to stakeholders (see 7.7.7)
- Demonstrate awareness of criticality, risks and risk mitigation
- Review and update risk assessment during the project
- Apply the lessons learned throughout the organization

...for further information on risk (and opportunity) management consult ISO 31000
IRIS specifies additional requirements for configuration management:

- Use a documented procedure to manage configuration appropriate to each product on the critical products list
- List critical products and their components (including software) starting with safety critical items
- Obtain customer approval of the list
- Maintain traceability of all items on the list during (design), production, (installation) and operations
- Use the change management process (see 7.7.9) when managing configuration
- Manage configuration to include replacement products and spare parts for the agreed life cycle (even when obsolescent – see 7.12)
IRIS specifies *knock-out* requirements for first article inspection:

- Use a KPI and process to plan, initiate and conduct FAI (recommend this be part of the documented procedure)
- Use a documented procedure to specify FAI, verification and record keeping requirements
- Verify the production process to ensure process conformity
- Then inspect a representative item from the first serial production run of a new part
- Also apply to one-off items and software
- Re-inspect following any subsequent change that invalidates the previous FAI result
- Apply the FAI process to suppliers (specify in subcontract or purchase order see 7.4.2)
IRIS specifies *knock-out* requirements for Commissioning and Customer Service:

• Organize suppliers (see 7.4.2) and demonstrate adequate customer support during commissioning until product validation is complete and accepted by the customer

• Where commissioning is a specified requirement ensure processes provide for:
  • After-sales support per agreed requirements
  • Manage maintenance per clause 7
  • Action on problems identified after delivery
  • Technical documentation updates (see 4.2.3)
  • Approval before use of any repair schemes (repair is a design change – see 7.3.7)
  • Management of Consignment Stock (see 7.5.5)
IRIS specifies requirements for assuring reliability, availability, maintainability and safety (shortened to RAMS) of the product (rail equipment):

- Standardize routines to maintain conformity of software to EN 50126, EN 50128 or EN 50129
- Use a documented RAMS procedure to calculate and document, collect and analyze data and take improvement actions
- Use a documented procedure to manage LCC requirements
- Collect data from operations during and after the warranty period
- Analyze LCC data and use information to continually improve the products, processes and the business management system
When it comes to the management of obsolescence and change IRIS specifies the following:

7.12 Obsolescence Management:
• Establish a process to ensure the availability of qualified spare parts (same configuration) for the defined and agreed life cycle.

7.13 Change Management is a knock out requirement:
• Use a documented procedure to execute, control and react to changes that impact product realization.
• Determine which changes need to be referred to customer per contract/project requirements.
• Assess and verify impact of any change.
• Validate and approve changes per contract/project requirements.
• Stop implementation of external changes without prior authorization from applicable stakeholders.
• Enable customer review of any change to form, fit, function, performance or durability of product per proprietary designs.

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7.12 Obsolescence Management:
• Establish a process to ensure the availability of qualified spare parts for the defined and agreed life cycle.

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• Determine which changes need to be referred to customer per contract/project requirements.
• Assess and verify impact of any change.
• Validate and approve changes per contract/project requirements.
• Stop implementation of external changes without prior authorization from applicable stakeholders.
• ...and enable customer review of any change to form, fit, function, performance or durability of product per proprietary designs.
As you can see you will need a cross-functional team to develop your BMS especially if your QMS is written around ISO 9001 instead of the way your company designs and delivers quality to satisfy its customers. Your BMS development team will need expertise in the following processes:

- Managing tenders (remember that tenders are proposals and quotes before they become contracts)
- Life cycle costing (of the product)
- Approving product designs
- Managing obsolescence (of products and spare parts)
- Managing supply chains
- Controlling changes
- Scheduling production
- Managing configurations (of products and spare parts)
- Production documentation
- Inspecting product (FAI)
- Changing production processes
- Commissioning
- Equipping and tooling
- Assuring RAMS

...and assuring Reliability, Availability, Maintainability and Safety
Beyond ISO 9001, the BMS must include controls for the following aspects of the project management process:

<table>
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<tr>
<th>Managing projects:</th>
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<tr>
<td>- Integration</td>
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<tr>
<td>- Assuring quality control</td>
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<tr>
<td>- Risk and opportunity</td>
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</table>

*These aspects of project management are often fulfilled as an integral part of the entire product realization process.*

Here is the second and final part of a summary to recap before the quiz on section 7, as you can see it requires the full engagement of project managers in the development of the BMS to specify the project management process including the following aspects:

- Integration (of the disciplines as one multifunctional project team)
- Assuring quality control
- Scope
- Human resources
- Timeliness
- Communications
- Assuring cost control
- Risk and opportunity

*...these aspects of project management are often achieved as an integral part of the entire product realization process when the project team uses and improves its well-designed process-based management system (aka BMS)*
Let us now continue by studying the additional requirements for:

• Measurement, analysis and improvement
• The additional documented procedures
• …and key performance indicators
Learning Objectives – section 8

• You already know and understand the requirements of clause 8 of ISO 9001 for process-based quality management systems

• You need to understand the additional requirements specified in clause 8 of IRIS for process-based business management systems

• You need to know what is required in terms of additional processes, controls and documents so please continue to make a note of them

• Your learning objectives probably include one or both of the following:
  • You need to understand the additional requirements specified in clause 8 of IRIS for process-based business management systems
  • You need to know what is required in terms of additional processes, controls and documents for conformity to IRIS requirements

• As you study the requirements from IRIS please make notes on the following aspects of your management system: new processes, new controls and new documents.

• Please note that new controls become part of existing processes. New processes become part of an existing system. By the way, a process is work that converts inputs into outputs and controls are requirements or criteria for a task or decision within a process.
IRIS requires use of a process for measurement, analysis and improvement...

When it comes to assuring customer satisfaction, IRIS require use of a key performance indicator and process for obtaining and evaluating customer satisfaction data that leads to action to remove the root causes of potential dissatisfaction (with preventive action – see clause 8.5.3) and actual dissatisfaction (with corrective action – see clause 8.5.2)

Clearly internal auditors must be competent in implementing the recommendations of ISO 19011 and understanding the requirements of this International Rail Industry Standard

All shifts are to be audited and audit criteria include external requirements such as the contract and the applicable EN standards
IRIS requires key performance indicators from the measurement and monitoring of the processes governed by the business management system.

When it comes to inspection and testing the product, IRIS requires evidence that products conform to customer requirements and that the following be documented for the acceptance of goods and services (these requirements repeat what ISO 9001 specifies in the clauses shown in parentheses):

- Provide criteria for acceptance or rejection (see 7.3.3)
- Specify where in the production sequence to verify (see 7.1c)
- Record the measurement results (see 4.2.4)
- Specify the equipment and usage of equipment (see 7.1b)
- Show the test results data as specified (see 8.2.4)
- ...and show the test results for validated processes (see 7.5.2)
IRIS requires the documented procedure for controlling nonconforming product to be extended to include any failure of project deliverables to fulfill requirements (including the time and cost requirements)

With a knock-out requirement IRIS says nonconforming processes are to be controlled as follows:

- Correct nonconforming processes (per clause 8.2.3) but also record the process variation
- Evaluate whether the process variation has caused nonconforming product
- If so, control nonconforming product per clause 8.3

IRIS specifies additional requirements for obtaining customer concessions
- Obtain a customer concession or deviation permit whenever product or process deviates from approved requirements (and indicate status in shipping documents) – record costs
- Record the expiration date or quantity limit and revert to original or superseding specifications thereafter
- Apply these rules to suppliers before involving customer

…and organization is to apply these rules to its suppliers before involving its customer
IRIS requires organization to use a key performance indicator and process for collecting and analyzing data to result in information to make fact-based decisions…

…these data are to include data from external incidents regarding the products in service and product safety
IRIS recommends use of processes to manage:

• Continual improvement (based on preventive action and corrective action)
• Taking action to prevent nonconformity (preventive action), and
• Stopping recurrence of nonconformity (corrective action)

• …both preventive and corrective action should include multidisciplinary reviews and assessments…
Here is the first part of a summary to recap before the quiz on section 8:

Use a process for measurement, analysis and improvement

Use a monitoring process for obtaining and evaluating customer satisfaction data

Remove root causes of potential/actual dissatisfaction

Use auditors competent in ISO 19011 and IRIS

Audit all shifts and verify conformity to IRIS and other external requirements (example, EN standards)

Apply KPIs to measure and monitor processes

Show how the product conforms to customer requirements

Document the criteria for acceptance of goods and services, how and when these criteria are determined and recorded

Control as nonconforming product any failure of project deliverables to fulfill requirements (including time/cost)
Here is the final part of a summary to recap before the quiz on section 8:

- Correct nonconforming processes and record the process variation and evaluate whether process variation has caused nonconforming product.
- Obtain a customer waiver whenever product or process deviates from approved requirements (and indicate status in shipping documents) – record the costs of nonconformity.
- Record the expiration date or quantity limit and revert to original or superseding specifications thereafter.
- Apply these rules to suppliers before involving customer.
- Use a process for collecting and analyzing data and include data from external incidents re products and product safety.
- Should define the preventive action and corrective action processes with multidisciplinary reviews and assessment.
Here we see that in addition to the six documented procedures specified by ISO 9001, IRIS specifies ten other processes that are to be governed by documented procedures:

- Transferring and outsourcing contract activities
- Providing Resources (staff, equipment, tooling and facilities)
- Training - people with the required attributes so they are competent
- Validating design and development of the product (testing prototypes)
- Approving designs of control commands and signaling
- Purchasing (from supplier selection to receipt of conforming goods and services)
- Maintaining equipment and tools (for production)
- Inspecting first production run articles (First Article Inspections)
- Assuring and improving product Reliability, Availability, Maintainability and Safety
- ...and Controlling Changes
- ...please remember that more documented procedures are normally required by the organization
Here we see that in addition to the records required to depend specified by ISO 9001, IRIS specifies ten other processes that are to be governed by documented procedures:

• Transferring and outsourcing contract activities
• Providing Resources (staff, equipment, tooling and facilities)
• Training - people with the required attributes so they are competent
• Validating design and development of the product (testing prototypes)
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• Purchasing (from supplier selection to receipt of conforming goods and services)
• Maintaining equipment and tools (for production)
• Inspecting first production run articles (First Article Inspections)
• Assuring and improving product Reliability, Availability, Maintainability and Safety
• …and Controlling Changes
• …please remember that more documented procedures are normally required by the organization
Review of Learning Objectives

- You understand the terms as used by IRIS
- You understand the additional requirements specified by IRIS for process-based business management systems that already meet the requirements of ISO 9001
- You know what is required in terms of additional processes, controls and documents

Please re-study the requirements from IRIS here and from the standard itself and note the new processes, new controls and new documents as necessary to develop your business management system.

- You understand the terms in the context of the International Railway Industry Standard (IRIS)
- You understand the additional requirements specified by IRIS for process-based business management systems
- You know what is required in terms of additional processes, controls and documents for conformity to IRIS requirements

Please re-study the requirements from IRIS here and from the standard itself.

...and note the new processes, new controls and new documents required to develop your business management system.