IRIS Assessment Sheet Rev. 02

Assessment sheet version 2.4

No.:	Defined:	Qualified:	Optimized:	Processes	Procedures	KPIs	Records	Finding/Evidences
4	Quality management system							
4.1	General requirements							
4.1-1	The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard. The organization shall a) determine the Processes needed for the quality management system and their application throughout the organization (see 1.2), b) determine the sequence and interaction of these Processes, c) determine criteria and methods needed to ensure that both the operation and control of these Processes are effective. These Processes shall be managed by the organization in accordance with the requirements of this International Standard.	Plus: Regular review of Processes and its performance. Actions are taken as necessary. Processes are clearly structured and visualized (1).	Plus: There is evidence that the effectiveness of operation and control of the Processes is continually improved.					xxx

4.1-2	The organization shall d) ensure the availability of resources and information necessary to support the operation and monitoring of these Processes. These Processes shall be managed by the organization in accordance with the requirements of this International Standard.	Plus: Regular review of resources and information. Actions are taken as necessary.	Plus: Efficiency of actions is evident (regularly checked during management review).					
4.1-3	The organization shall e) monitor, measure where applicable, and analyse these Processes, and f) implement actions necessary to achieve planned results and continual improvement of these Processes (1). These Processes shall be managed by the organization in accordance with the requirements of this International Standard.	Plus: Systematic root cause analysis supported by adequate methodologies / tools (2). Counter and/or improvement actions are implemented and regularly tracked (3).	Plus: There is evidence that the effectiveness of the management system is continually being improved (4).					
4.1-4	Where an organization chooses to outsource any Process that affects Product conformity to requirements, the organization shall ensure control over such Processes. The type and extent of control to be applied to these outsourced Processes shall be defined within the quality management system.							

4.1-5 KO	In the case of a Transfer of Processes or parts thereof, that affects Product conformity to requirements within the execution of a contract, a documented Procedure including feasibility study, risk analysis, planning, communication to customer and First Article Inspection to the appropriate level shall exist.				X			
4.2	Documentation requirements							
4.2.1	General							
4.2.1-1	The quality management system documentation shall include a) documented statements of a quality policy and quality objectives, b) a quality manual, c) documented procedures and records required by this International Standard, and d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its Processes.	Plus: The hierarchy and application of documentation such as manuals, handbooks, directives, Procedures, guidelines, instructions, plans, reports etc., including templates are defined.	Plus: Efficiency of the business management system documentation is being continually improved.					
4.2.1-2	The qualitymanagement system documentation shall include: e) documented statements of a technical Safety policy and Safety objectives.							
4.2.1-3	The quality management system documentation shall include: f) Management system requirements imposed by the applicable regulatory authorities.							

4.2.1-4	The organization shall ensure that personnel have access to business management system documentation and are aware of relevant documents.	Plus: Training on relevant Processes and Procedures.	Plus: Efficiency of the communication is being continually improved . Training includes evidence that participants understood its content (1).					
4.2.1-5	Customer and (or) regulatory authorities' representatives shall have access to the business management system documentation.							
4.2.2	Quality manual							
4.2.2-1	The organization shall establish and maintain a quality manual that includes a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2), b) the documented Procedures established for the quality management system, or reference to them, and c) a description of the interaction between the Processes of the quality management system.	Plus: Every revision of an IRIS standard triggers an analysis of the impact on quality management system.	Plus: When referencing to the documented Procedures, the relationship between the requirements of this document and the documented Procedures should be clearly shown (1). Every revision of a document of the business management system is reviewed against the applicable IRIS standard.					
4.2.3	Control of documents							

4.2.3-1	Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4. A documented Procedure shall be established to define the controls needed a) to approve documents for adequacy prior to issue, b) to review and update as necessary and re-approve documents, c) to ensure that changes and the current revision status of documents are identified, d) to ensure that relevant versions of applicable documents are available at points of use, e) to ensure that documents remain legible and readily identifiable, f) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.				X		X	
4.2.3-2	The organization shall demonstrate effective management and control of all documents pertinent to the Products it supplies.							

4.2.3-3	Names of personnel, who authorize and carry out reviews of the necessary documentation, shall be identified.	Plus: Authorized signatories are identified, as well as evidence of appropriate signatories (1).	Plus: Control of documents is supported by an adequate electronic document control system, where authorities are assigned to the workflow release and release status is traceable.					
4.2.3-4	Effective systems shall be in place to review impact of documents of external origin.							
4.2.3-5	The organization shall have a Process to ensure the traceability of customer documents throughout the entire Supply Chain, e.g. specifications, requirements.			X				
4.2.4	Control of records							
4.2.4-1	Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled. The organization shall establish a documented Procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of Records. Records shall remain legible, readily identifiable and retrievable. The documented Procedure shall also include approval of recorded results before official release.	Plus: There is evidence that the retention periods comply to operational, legal, fiscal, contractual and historical requirements. Archiving media, including electronic tools are defined. Methodology for destruction of outdated or duplicate Records is defined.	Plus: Regular review and continual improvement of the Records management Process. An electronic records management solution is implemented.		X			

4.2.4-2	Records shall be available for review and (or) release by and (or) released to customers and regulatory authorities in accordance with contract or statutory and regulatory requirements.						X	
4.3	Knowledge management							

4.3-1	Best practices shall be identified, documented, implemented and regularly updated to improve the organization's Process efficiency and Product in quality, costs and delivery performance (1).	Plus: Best practices are communicated proactively within the organization. The organization should define and implement a Process to identify, obtain, protect, use and evaluate information, knowledge and technology. Knowledge capture is in place, for current Products and Processes. Protection for information and communication systems exist. Information, knowledge and technology are shared within the organization and periodic reviews take place. Critical technologies are controlled via patents and secondary sourcing where needed. There are mechanisms and forums for sharing information. A system for recognizing positive results from suggestions or lessons learned is in place. Learning is addressed in the strategy and policies.	Plus: Knowledge management is integrated in all relevant business Processes and linked to the efficiency of these Processes. Information, knowledge and technology are shared with partners and other interested parties. Knowledge obsolescence is considered. Learning is recognized as a key issue and networking, connectivity and interactivity is stimulated by top management to share knowledge. Management supports initiatives for learning, and leads by example. The organization's learning ability integrates personal competence and organizational competence. Learning is a foundation for the improvement and innovation processes. The culture of learning appreciates creativity, supports diversity, and the use of weaknesses as opportunities for improvement. There are external engagements for the purpose of learning.	X				
4.4	Management of multi-Site projects							

4.4-1	In cases where a Project involves multiple Sites, an appropriate business management system shall be documented (e.g. in a Project quality management plan) and implemented, and shall cover as a minimum: -work split and operational interfaces, including alignment of customer requirements, -authorities and responsibilities and communication channels (internal and with the customer) including feedback on the results for each Sites' scope of responsibility, -applicable Processes, Procedures, documents and Records on each Site, -assurance of IRIS compliance.	Plus: Efficiency of multi-Site Project activities should regularly be assessed to the appropriate level (1) and improved where necessary.	Plus: General indicator for efficiency of multi-Site Project activities are defined, measured and analyzed to allow continual improvement of multi-Site Project activities.					
5	Management responsibility							
5.1	Management commitment							
5.1-1	Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements, b) establishing the quality policy, c) ensuring that quality objectives are established, d) conducting management reviews, and e) ensuring the availability of resources.	Plus: Capacity analysis and objectives monitoring through the use of significant performance indicators.	Plus: Action plans to achieve the established objectives and to adjust resources are available.					

5.2	Customer focus							
5.2-1	Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1). Company policy shall reflect the organization's willingness to satisfy customer needs.	Plus: There is evidence (1) that customer satisfaction is permanently in focus.	Plus: Significant performance indicators allow the deployment of effective action plans aimed to enhance customer satisfaction.					
5.3	Quality policy							
5.3-1	Top management shall ensure that the quality policy a) is appropriate to the purpose of the organization, b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system, c) provides a framework for establishing and reviewing quality objectives, d) is communicated and understood within the organization, and e) is reviewed for continuing suitability.	Plus: The organization should define and implement a structured Process for strategy and policy formulation, which includes an analysis of the needs and expectations of customers along with an analysis of statutory and regulatory requirements.	Plus : Strategy, policies and objectives are formulated in a structured manner. Organization objectives are broken down with objectives allocated to involved parties/personnel (as far as their contribution to meeting the objectives are concerned). Continual improvement of Processes, based on objective measurement and appropriate action plans, is implemented.	X				
5.3.1	Business plan							

5.3.1-1	The organization shall establish and review at least annually a business plan for the scope of their rail sector activities, covering as a minimum the following topics: -company mission and vision, -plan to reduce identified risks, -market and Product strategy, including development plans of new Products and (or) Processes and phase out strategies, -impact of changes in technologies and in statutory and regulatory requirements, -make or buy strategy, -company capacity (current and future), and -business objectives.	Plus: This business plan should be effectively and appropriately communicated throughout the organization and supported by mid and long term action plans in accordance with the business plan vision.	Plus: Multi-year business plan. Involvement of stakeholders (1).					
5.3.1-2	A cost management Process shall be in place in order to manage the finances of the organization, including rules for accounting and controlling.	Plus: The organization should define and implement a Process for predicting, monitoring and controlling financial resources.	Plus: Financial resource risks are identified. Future financial needs are forecasted and planned.	X				
5.4	Planning							
5.4.1	Quality objectives							

5.4.1-1	Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.	Plus: Business objectives should be cascaded and broken down consistently in the organization and reviews should be organized on a regular basis at each level of the organization. The organization should define and implement a planning Process, which includes consideration of changing external trends and interested parties needs.	Plus: Business objectives should address customer expectations and be achievable within defined timescales. Positive trends exist on many measures. A balance between the plans and the availability of resources can be demonstrated. Risks and opportunities are fully evaluated and considered before plans are confirmed. Structured and periodic reviews of planning processes are in place. Measurement of progress towards achievements of the organisation strategic objectives is undertaken.	X				
5.4.2	Quality management system planning							
5.4.2-1	Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and b) the integrity of the qualitys management system is maintained when changes to the quality management system are planned and implemented.							
5.5	Responsibility, authority and communication							
5.5.1	Responsibility and authority							

5.5.1-1	Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.	Plus: Responsibilities and authorities are documented and updates are communicated through the organization.	Plus: Responsibilities and authorities are clearly defined at all levels, documented, updated and promptly communicated through the organization.					
5.5.1-2	Ownership, authorities and responsibilities for all Processes shall be defined. Interfaces with the customer shall be identified and communication channels described and communicated.	Plus: Ownership, authorities and responsibilities for all Processes are documented, including Special Processes according to IRIS GUIDELINE 6:2014 SPECIAL PROCESSES. Process owners / coordinators are empowered with sufficient authority.	Plus: Process ownership / coordination is reviewed at least annually. Knowledge is shared between process owners / coordinators and the organization.					
5.5.1-3	Each employee shall have the responsibility to raise any issue and (or) deviation from the requirement to his and (or) her manager for appropriate action.	Plus: Deviations are managed systematically and in a documented way.	Plus: Lessons learnt are fed back into the relevant Processes.					
5.5.2	Management representative							

5.5.2-1	Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes a) ensuring that Processes needed for the quality management system are established, implemented and maintained, b) reporting to top management on the performance of the quality management system and any need for improvement, c) ensuring the promotion of awareness of customer requirements throughout the organization, and d) the organizational freedom to resolve matters pertaining to quality or stop development and (or) production and (or) delivery and (or) Field Support Activities, if critical requirements are not met.							
5.5.3	Internal communication							

5.5.3-1	Top management shall ensure that appropriate communication Processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system. The organization shall establish a communication system from management to its personnel and vice versa, giving consideration to, as a minimum: -mission and vision, -policy, -organization performance and -customer related issues.	Plus: An extensive communication of the organization's performance using KPI's (see annex 3) is in place. The organization should also define and implement a Process for external communication (see 7.2.3).	Plus: Dashboards with KPI's are exhibited throughout the company and updated. Communication is supported by tools (1).	X				
5.5.4	Customer relationship management							
5.5.4-1	Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes: a) ensuring that Processes needed to satisfy customer requirements are established, implemented and maintained, b) reporting to top management on the performance of these Processes and any need for improvement and c) ensuring the promotion of awareness of customer satisfaction throughout the organization and related training.							
5.6	Management review							
5.6.1	General							

5.6.1-1	Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained (see 4.2.4). Planned intervals shall not exceed 12 months.	Plus: Planned intervals for management reviews are suitable to the management systems needs. Systematic reviews of key performance indicators and related objectives are regularly undertaken (see 5.6.2-2). Where adverse trends are identified they are acted upon. Reviews give an indication of whether adequate resources have been provided.	Plus: The frequency of management reviews is adapted to operational needs (potentially much shorter than one year). Internal comparisons are made to identify and share good practices. The review and analysis systems are activity oriented. Results coming from reviews demonstrate that the actions taken are effective.				X	
5.6.2	Review input							

5.6.2-1	The input to management review shall include information on a) results of audits, b) customer feedback, c) Process performance and Product conformity, d) status of preventive and corrective actions, e) follow-up actions from previous management reviews, f) changes that could affect the business management system, and g) recommendations for improvement, h) key issues from previous Project reviews, i) results of previous Process reviews and k) analysis of actual and potential field-failures and their impact on Safety and environment.							
5.6.2-2	During the management review the following KPI's shall be reviewed: - All mandatory KPI's (see annex 3), - customer on time delivery performance (1) and - nonconformities raised by the customer throughout the entire Project Life Cycle (2).	Plus: During the management review the following KPI's should be reviewed: - all recommended KPI's listed in annex 3, and in addition KPI's which state information about - internal and supplier nonconformities throughout the entire Project Life Cycle (3), - supplier on time delivery performance (4), - response time on nonconformities raised by customer (5), and - Quality Deficiency Costs (6).	Plus: additional KPI's defined by the organization to improve business performance.			X		
5.6.3	Review output							

5.6.3-1	The output from the management review shall include any decisions and actions related to a) improvement of the effectiveness of the quality management system and its Processes, b) improvement of Product related to customer requirements, c) resource needs, d) integration of business Processes, e) business objectives achievement, and f) customer satisfaction.	Plus: Action plans for improvement are submitted for management approval. A Multidisciplinary Approach exists.	Plus: additional actions defined by the organization to improve business performance.					
6	Resource management							
6.1	Provision of resources							
6.1-1	The organization shall determine and provide the resources needed a) to implement and maintain the quality management system and continually improve its effectiveness, and b) to enhance customer satisfaction by meeting customer requirements.	Plus: The organization should define and implement a Process for the planning of resources, including their identification, provision and monitoring. Dedicated resources for all identified Processes are planned and budgeted systematically. The risks of the potential scarcity of resources are evaluated.	Plus: The organization can demonstrate that it has regular and effective measurement of the approaches it uses to manage resources. Resource planning includes short term and long term objectives.	X				
6.1-2	A documented Procedure shall be in place to ensure the appropriate capacity regarding personnel, equipment, etc. taking into consideration the current order book and the forecast orders on a mid and long term basis.				X			
6.2	Human resources							

6.2.1	General							
6.2.1-1	Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience (1).	Plus: The organization should define and implement human resource management Processes within the business management system.	Plus: The organization should measure and review human resource management Processes within the business management system.	X				
6.2.2	Competences, training and awareness							
6.2.2-1	The organization shall a) determine the necessary competence for personnel performing work affecting conformity to Product requirements.	Plus: All mandatory competences for all personnel performing work affecting product quality are systematically documented (1).	Plus: All mandatory competences for all personnel performing work affecting Product quality are periodically reviewed.					
6.2.2-2	The organization shall b) where applicable, provide training or take other actions to achieve the necessary competence, c) evaluate the effectiveness of the actions taken, d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and f) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the Safety objectives.	Plus: The organization should define and implement an appraisal Process for systematically identifying training needs.	Plus: The organization has reviewed its training materials regularly and is continually improving the quality of the training.	X				
6.2.2-3	The organization shall e) maintain appropriate Records of education, training, skills and experience (see 4.2.4).						X	

6.2.2.1	Product design skills							
6.2.2.1-1	The organization shall ensure that personnel with responsibility for Product design have the necessary competence to achieve design requirements and are skilled in applicable tools and techniques.	Plus: Job descriptions and qualifications are regularly reviewed.	Plus: Skills on tools and techniques are maintained.					
6.2.2.1-2	Applicable tools and techniques shall be defined by the organization.							
6.2.2.2	Employee motivation and empowerment							
6.2.2.2-1	The organization shall motivate employees to achieve business, quality and Safety objectives, to make continual improvements and to create an environment to promote innovation.	Plus: A motivation system stimulates employees to make continuous improvements.	Plus: The motivation system is based on rewarding initiatives and creates an environment to promote innovation. A suggestion scheme system is working effectively throughout the entire organization.					
6.2.2.3	Training							
6.2.2.3-1	The organization shall establish and maintain documented Procedures for identifying and planning training needs in order to achieve and maintain the necessary competence of personnel performing activities affecting Product quality and Safety at all levels of the organization.				X			
6.2.2.3-2	Output of knowledge management activities (see clause 4.3) shall be taken into consideration as an input for training planning.							

6.2.2.3-3	Personnel performing specific assigned tasks (1) shall be competent and qualified, as required, with particular attention to the satisfaction of customer, local, statutory and regulatory requirements.	Plus: The organization has evaluated the training effectiveness through the impact on Product quality .	Plus: The efficiency of the training is measured, analyzed and action plan is implemented.					
6.2.2.3-4	A system shall be in place to maintain and upgrade the qualifications of such personnel.	Plus: The system includes as well the upgrade and the evaluation of the effectiveness of the qualifications of personnel that is performing critical or Special Processes.	Plus: Performance of the system is measured, analyzed and action plan is implemented.					
6.2.2.3-5	Critical activities affecting the Product quality and Safety shall be identified and Records of skilled personnel able to undertake these activities shall be maintained and regularly updated.						X	
6.2.2.3-6	Personnel, whose work can affect Product quality and Safety, shall be informed about the possible consequences to the customer if quality and Safety requirements have not been met.	Plus: Quality and Safety aspects are an integral part of Product quality and Safety related formal training.	Plus: The possible consequences to the customer of nonconformity of quality and Safety requirements are part of a global quality and Safety training plan and so are regularly refreshed.					
6.2.2.3-7	Appropriate induction shall be performed for temporary workers and newcomers, covering as a minimum Product quality and Safety.							
6.2.2.4	Performance management							
6.2.2.4-1	A system shall be established to regularly set individual objectives linked with business objectives and review the individual performance.							

6.3	Infrastructure							
6.3-1	The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to Product requirements. Infrastructure includes, as applicable, a) buildings, workspace and associated utilities, b) Process equipment (both hardware and software), c) supporting services (such as transport, communication or information systems), d) planned Maintenance activities, e) packaging, storage and preservation and (or) condition checks of equipment and (or) tools and (or) fixtures and measurement equipments, f) availability of spare parts and consumables for key manufacturing equipment, and g) documenting, evaluating and improving Maintenance objectives.	Plus: The organization should utilize predictive Maintenance methods to continually improve the effectiveness and the efficiency of Production equipment. The organization should periodically review the infrastructure and related processes with the future in mind.	Plus: Risks for the infrastructure are identified and preventive actions are in place. The Maintenance plan is based on a risk analysis.					
6.4	Work environment							
6.4-1	The organization shall determine and manage the work environment needed to achieve conformity to Product requirements.	Plus: The organization should define and implement Processes to ensure that the work environment complies with all applicable statutory or regulatory requirements. A periodic assessment of the effectiveness of the work environment takes place.	Plus: Data review shows that the work environment encourages productivity, creativity and the well -being of people. The Processes implemented for the development of the work environment supports competitiveness and compares well with similar organizations.	X				

6.4-2	Product Safety and means to minimize potential risks to employees shall be addressed by the organization, especially in the design and development Process and in the Production Process activities.	Plus: Effectiveness of the Product safety and the means to minimize risk are measured and improved. Multidisciplinary Approach.	Plus: An Occupational Health and Safety management system compliant with OHSAS 18001 is implemented.					
6.4-3	The organization shall maintain its premises in a state of order, cleanliness and repair consistent with the Product and Production Process needs.	Plus: Cleaning instructions are available in all areas.	Plus: Systematic use of the methods including visual management showing achieved results against targets (1).					
6.5	Contingency plan							
6.5-1	The organization shall prepare contingency plans to mitigate the event of an emergency such as utility interruptions, interruptions in the Supply Chain, labour shortages, key equipment failure and field returns, taking into account the output of the resources analysis including a succession plan.	Plus: Contingency plans are validated and periodically tested.	Plus: Contingency plans are regularly reviewed and improved.					
7	Product realization							
7.1	Planning of product realization							

7.1-1	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the business management system (see 4.1). The output of this planning shall be in a form suitable for the organization's method of operations.	Plus: The organization investigates possibilities for improving planning and product realization. The organization should define, implement and manage Key Processes, such as those related to Product realization and customer satisfaction. The organization, when applicable, deploys Special Processes, in the planning of product realization, and treats them according to IRIS GUIDELINE 6:2014 SPECIAL PROCESSES.	Plus: The organization is monitoring the performance of Processes and has improvement programs in place. Improvements in agility, flexibility and Processes innovation can be demonstrated. The effectiveness of the Product realization planning Process is systematically measured and acted upon.					
7.1-2	In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish Processes and documents, and to provide resources specific to the Product; c) required verification, validation, monitoring, measurement, inspection and test activities specific to the Product and the criteria for Product acceptance; d) Records needed to provide evidence that the realization Processes and resulting Product meet requirements (see 4.2.4).			X			X	
7.2	Customer related Processes							
7.2.1	Determination of requirements related to the Product							

7.2.1-1	The organization shall determine a) requirements specified by the customer, including the requirements for delivery and post -delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements applicable to the product, and d) any additional requirements considered necessary by the organization.	Plus: The organization has determined : -experience from similar products / projects -requirements resulting from a market analysis -use-cases out of discussions with the customer, and -obsolescence requirements.	Plus: Systematic innovation management is in place.					
7.2.1-2	A detailed internal total cost breakdown shall be determined.	Plus: The cost breakdown should be supported by past experience from operation and supplier offers.	Plus: The internal cost breakdown is continually improved by validation of the initial cost breakdown versus series costs and by past experience into new products.					
7.2.2	Review of requirements related to the Product							

7.2.2-1	The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that a) Product requirements are defined, b) contract or order requirements differing from those previously expressed are resolved, and c) the organization has the ability to meet the defined requirements. Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).	Plus: Issues that could not be resolved immediately are tracked. A feasibility analysis is conducted.	Plus: All risks are covered by mitigation actions.				X	
7.2.2-2	Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.							

7.2.2-3	Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.	Plus: The organization should define and implement a change Process, which includes a change control board. The change Process involves customers and suppliers. A formal change Process, that involves customers and suppliers, is defined and implemented including a change control board.	Plus: The changes are managed via an information system.	X				
7.2.2-4	A Multidisciplinary Approach (including suppliers when appropriate) shall be used. Project Management and design and development shall be appropriately represented in all requirements' reviews.							

7.2.2-5	The organization shall have a Process to ensure that identified requirements are: a) individually checked for compliance (e.g. clause by clause), b) negotiated and updated with impact on the offer identified, c) evaluated and taken into account, d) properly transferred, understood, acknowledged and committed to by everybody involved, and e) complete, clear, precise, unequivocal, verifiable, testable, maintainable and feasible. The Process shall be applied for all the phases: submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders.	Plus: Process is supported by templates, checklists, … Customer is involved in the Processes to ensure that the requirements are appropriately managed. The performance of this Process should be measured by a KPI (see annex 3) (1).	Plus: Internal best practice examples are adopted across the site(s).	X		X		
7.2.2-6	This Process shall also control contract variation including liaison with customers.	Plus: Revisions of contract variations are maintained.	Plus: Contract variations are reviewed and joint action plans are agreed with customers.					
7.2.2-7	Deficiencies identified during the Process shall be managed and corrected by the organization.							

7.2.2-8	In order to avoid risks and to allow a smooth Project and (or) Product realization, reviews shall cover as a minimum the aspects (see clause 7.7): Critical Product characteristics; customer, statutory and regulatory requirements; scope; time; cost; quality; resources; communication; risk; changes.	Plus: The review covers as well the Product maturity levels. Reports should be issued to senior management and regular reviews should be held with them (allowing proactive activities).	Plus: Review by top management should cover at minimum: -actual situation vs. planned situation in terms of time, -forecast (time to complete), -contingency activities, mitigation plans, -actualization of risk assessment, and -follow-up of open issue list.					
7.2.2-9	Risks shall be identified, monitored and mitigated when applicable.							
7.2.2-10	Risks shall be communicated internally and to the customer, if applicable.	Plus:	Plus: Action plan and joint risk mitigation with the customer.					
7.2.3	Customer communication							
7.2.3-1	The organization shall determine and implement effective arrangements for communicating with customers in relation to a) product information, b) enquiries, contracts or order handling, including amendments, and c) customer feedback, including customer complaints. The organization shall define and implement effective arrangements for communicating any information related to the delivery in accordance with of the customers' contractual requirements in the Value Chain.	Plus: Regular and appropriate meetings are initialized to share performance details and to decide jointly improvement needs. The organization should also define and implement a Process for external communication (see 5.5.3). A KPI is established to measure response time on nonconformities raised by the customer (1).	Plus: There is evidence that communication processes meet the needs of interested parties (see also 5.5.3).	X		X		
7.2.4	Tender management							

7.2.4-1	In addition to the requirements related to the Product (see clause 7.2.2), the organization shall have a Process to ensure that requirements identified during the tender phase are: a) individually checked for compliance (e.g. clause by clause), b) negotiated and updated with impact on the offer identified, c) evaluated and taken into account, d) properly transferred, understood, acknowledged and committed to by everybody involved and e) complete, clear, precise, unequivocal, verifiable, testable, maintainable and feasible. The performance of this Process shall be measured by a KPI (see annex 3) (1).	Plus: In addition to the requirements related to the Product (see clause 7.2.2), the organization should have a documented Procedure to ensure that requirements identified during the tender phase are: a) individually checked for compliance (e.g. clause by clause), b) negotiated and updated with impact on the offer identified, c) evaluated and taken into account, d) properly transferred, understood, acknowledged and committed to by everybody involved and e) complete, clear, precise, unequivocal, verifiable, testable, maintainable and feasible. Process is supported by templates, checklists, … Process effectiveness is analyzed on a regular basis.	Plus: Efficiency and continual improvement of the requirement management Process or through benchmarking.	X	X	X		
7.2.4-2	Prior to the submission of the quotation, the organization shall use a Multidisciplinary Approach (including suppliers when appropriate) to investigate customer and statutory and regulatory requirements.	Plus: Records of tender management are available.	Plus: Information from past experience / earlier Projects are considered during tender reviews.					
7.2.4-3	Also the organization shall confirm and document the feasibility of the proposed Products in the tender.							

7.2.4-4	During the tender review the organization shall approve the offer including planning, resources and pricing.							
7.2.4-5	As a minimum, Project and (or) Product requirements as well as risks and opportunities shall be identified, controlled and validated.							
7.3	Design and development							
7.3-1	The organization shall establish and maintain a Process for design and development. The performance of this Process shall be measured by a KPI (see annex 3) (1).	Plus: The organization should document it in a Procedure. The organization should define and implement an innovation Process for new Products and Processes, which is able to identify changes in the organization's business environment, and to plan innovations.	Plus: Innovations are prioritized, based on the balance between their urgency, the availability of resources, and the organization's strategy. Suppliers and partners are involved in the innovation	X	X	X		
7.3-2	Every new technology and (or) new Product shall fulfil the design and development requirements described in clause 7.3.							
7.3-3 KO	The principles applied in developing high integrity systems shall be in line with the IEC (CENELEC) standards or other agreed equivalent models. The software design Process shall explicitly implement the appropriate requirements (e.g.: IEC 62279 (EN 50128)) related to the Safety Integrity Level of the intended IRIS scope of certification.							

7.3-4	Documentation and training related to the application of the Product shall be considered as integral part of the system to be designed and developed, especially in a Safety critical environment. The organization shall have the capability to provide this where required for safe use.	Plus: The organization actively promotes training for safe use of the Products.	Plus: The organization systematically evaluates problems with the application of the Product or system by the customer and uses this information to improve the documentation and training.					
7.3.1	Design and development planning							
7.3.1-1	The organization shall plan and control the design and development of product.	Plus: Objectives to shorten design phases are defined and activities occur simultaneously in detailed design and manufacturing stages.	Plus: Process indicators defined and regularly reviewed (with countermeasures, if necessary) to follow-up the implementation of the design and development policy.					
7.3.1-2	During the design and development planning, the organization shall determine a) the design and development stages, b) the review, verification and validation that are appropriate to each design and development stage, and c) the responsibilities and authorities for design and development.	Plus: Design and development stages identified as significant to meet objectives are determined. Maturity level of the product with regard to its application and integration is assessed for the design object (1). If Special Processes are inputs to the design, risk assessment is part of the design and development process according to IRIS GUIDELINE 6:2014 SPECIAL PROCESSES.	Plus: During the review, verification and validation activities the past experiences of previous Projects and field data are taken into account.					

7.3.1-3	The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.	Plus: The organization should define and implement a collaboration Process and indicators to measure its efficiency.	Plus: Risk idenfication and risk mitigation is part of the collaboration Process.	X				
7.3.1-4	Planning output shall be updated, as appropriate, as the design and development progresses.	Plus: Deviations are identified and corrective actions are implemented.	Plus: Improvements of design and development planning Process are implemented.					
7.3.1-5	The organization shall determine task sequence, mandatory steps, significant stages and method of configuration control.	Plus: Updates of determined topics are carried out. Planning of quality engineering is carried out.	Plus: Updates of determined topics are carried out on specific milestones or in case of major changes and Records are maintained.					
7.3.1-6	Where appropriate, due to complexity, the organization shall give consideration to the following activities: -structuring the design effort into significant elements, and -for each element, analyzing the tasks and the necessary resources for design and development.	Plus: This analysis should consider an identified responsible person, design content, input data, planning constraints and performance conditions.	Plus: Design concepts (1) should be investigated and applied where appropriate.					
7.3.2	Design and development inputs							

7.3.2-1	Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include a) functional and performance requirements, b) applicable statutory and regulatory requirements, c) where applicable, information derived from previous similar designs, and d) other requirements essential for design and development.						X	
7.3.2-2	The inputs shall be reviewed for adequacy.							
7.3.2-3	Requirements shall be complete, unambiguous and not in conflict with each other.							
7.3.2-4 KO	The organization shall ensure that new technologies and (or) new Products (designed to meet market needs) are validated before introduction into a customer Project.							
7.3.2-5	RAMS / LCC shall be considered as design inputs (1).	Plus: RAMS and LCC requirements are translated into technical specifications. End of life of Products should be considered as design input. Design for Maintenance (2) is considered as design input. Obsolescence requirements (3) are considered as design input.	Plus: RAMS and LCC requirements are compared with field data (past experience). A Process is in place covering end of life of the Product as design input. Customer and suppliers are integrated into RAMS / LCC activities during the design phase.					

7.3.3	Design and development outputs							
7.3.3-1	The outputs of design and development shall be in a form suitable for verification against the design and development input.	Plus: Outputs of design and development ensure the traceability of requirements and that a validation plan is defined. If Special Processes are outputs of design and development, a qualification and validation plan is defined for Special Processes and associated critical material and services with the elements listed in IRIS GUIDELINE 6:2014 SPECIAL PROCESSES.	Plus: Output requirements are continually improved.					
7.3.3-2	The outputs of design and development shall be approved prior to release (1).	Plus: The organization should define and implement a Process, which ensures that approval is carried out by sufficient competent staff (2).	Plus: Approval is carried out according to a Process, which defines skills, roles and responsibilities, acceptance criteria, escalation steps and ensures independence of staff with authorities for approval. Customer is integrated into design output reviews.	X				
7.3.3-3	Design and development outputs shall a) meet the input requirements for design and development, b) provide appropriate information for purchasing, production and service provision, c) contain or reference Product acceptance criteria, and d) specify the characteristics of the Product that are essential for its safe and proper use.							

7.3.3-4	The design and development output shall be expressed in terms that can be verified against production Process input requirements.							
7.3.4	Design and development review							
7.3.4-1	At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1) a) to evaluate the ability of the results of design and development to meet requirements, and b) to identify any problems and propose necessary actions. c) to authorize progression to the next stage. Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).	Plus: The organization should define and implement a design review Process. Design and development reviews are conducted at each applicable level of detail in accordance with the system architecture (1). Measurements at specified stages of design and development should be defined, analysed and reported as an input to management and (or) Project review (2). Customer is informed about design and development reviews.	Plus: Design reviews are part of, or an input to Project management phase reviews. Customer is integrated into design and development reviews.	X			X	
7.3.4-2	Reviews shall also involve other functions as appropriate to review the Product characteristics (e.g. costs, RAMS and serviceability).							
7.3.5	Design and development verification							

7.3.5-1	Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).	Plus: Design and development verification are conducted on each level of detail (1). A verification plan is defined.	Plus: Design and development verification is in accordance with the dedicated maturity level of the Product with regard to its application and integration.				X	
7.3.6	Design and development validation							
7.3.6-1	Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4) (1).	Plus: A design and development validation plan is defined. Root cause analysis of failed Product validation (2). Customer is informed about design and development validation plan and results.	Plus: Design and development validation is in accordance with the dedicated maturity level of the Product with regard to its application and integration. Customer is integrated in design and development validation.				X	
7.3.6-2	Wherever practicable, validation shall be completed prior to the delivery or implementation of the Product.							

7.3.6-3 KO	Design and development validation shall be demonstrated for all identified operational conditions. The organization shall apply the validation concepts, organization and methods as mandated by applicable standards (e.g. IEC 62278 (EN 50126), IEC 62279 (EN 50128), IEC 62425 (EN 50129)).							
7.3.6-4	A documented Procedure shall be in place in the event that tests are necessary for validation. These tests shall be planned, controlled, reviewed and documented to ensure and prove the following: a) test plans or specifications identify the Product being tested and the resources being used, defining test objectives and conditions, parameters to be recorded and relevant acceptance criteria, test conditions and reproducible environment, b) test Procedures describe the method of operation, the performance of the test and the Recording of the results, c) the correct configuration of the Product is submitted for the test, d) the requirements of the test plan and the test Procedures are observed and e) the acceptance criteria are met.	Plus: Customer is informed about design and development validation plan and results.	Plus: Customer is integrated in design and development validation.		X			
7.3.7	Control of design and development changes							

7.3.7-1	Design and development changes shall be identified and records maintained. Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4)	Plus: The organization should define and implement a design and development change Process. Associated actions are regularly followed up.	Plus: The design and development change Process ensures full traceability of changes. Progress status for follow-up actions is available.	X			X	
7.3.7-2	The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.	Plus: The effects of changes on constituent parts and Product already delivered are assessed and actions in order to minimize the impact of change are planned accordingly. Root cause analysis of design and development changes and follow up of corrective and preventive actions. Labor hours and material costs due to design and development changes are considered as part of Quality Deficiency Cost and continually reduced. Update of maturity level and risk analysis are conducted.	Plus: The design change Process includes the impact analysis on constituent parts and product already delivered, and effective action plans are implemented to minimize the number of design and development changes. Labor hours and material costs due to design and development changes are collected at Site and in the field, analyzed, assigned to causers and continually reduced. Joint work on corrective and preventive actions with customer / suppliers is performed, as applicable.					
7.3.7-3	The organization shall have a Process to control deferred and Abnormal Work in design and development.	Plus: This process includes an assessment of the risk/impact of Abnormal Work.	Plus: Abnormal work is analyzed on a regular basis and company is prepared for Abnormal Work. Internal best practice examples are adopted across the Site(s).	X				
7.3.8	Design approval							

7.3.8-1 KO	In the case that IEC 62279 (EN 50128) in conjunction with a Safety Integrity Level is required, the organization shall provide a documented Procedure defining the Safety Case and approval in line with IEC 62425 (EN 50129).				X			
7.4	Purchasing							
7.4.1	Purchasing Process							
7.4.1-1	The organization shall ensure that a Process for purchasing of Products is in place. The performance of this Process shall be measured by a KPI (see annex 3) (1).			X		X		
7.4.1-2	The organization shall provide a documented Procedure covering purchasing Process activities that affect Product conformity to requirements.				X			
7.4.1-3	The organization shall ensure that purchased product conforms to specified purchase requirements. The organization shall implement a system to ensure the quality of all - Products purchased from suppliers, - Products purchased from customer designated suppliers.	Plus: The system requires - Detailed FAI or appropriate incoming / outgoing inspection (documented) on all parts, - Evaluation of maturity level of Products (ready to use)	Plus: Evidence of Process capability on all critical characteristics is obtained by additional on Site assessment.					

7.4.1-4	The type and extent of control applied to the supplier and the purchased Product shall be dependent upon the effect of the purchased Product on subsequent Product realization or the final product.	Plus: Escalation levels for controlling activities exist in order to improve efficiency	Plus: Past experience is considered in impact analysis.					
7.4.1-5	The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).	Plus: The organization should define and implement a Process to select, evaluate, re-evaluate and rank suppliers. This Process covers: -appropriate rules for assessing competency of suppliers, -execution of risk assessment, -check if product maturity and integration readiness levels (ready to use) are evaluated by the supplier, -existence of appropriate inspection / testing procedures, -check of process capability on all critical characteristics, -availability of necessary suppliers qualifications in terms of certificates. Unless otherwise specified by the customer, suppliers to the organization should be certified according to ISO 9001:2008 by an accredited third party certification body. Action plans in place are regularly followed up.	Plus: There is evidence that the supplier evaluation, selection and re-evaluation Process also covers feedback to supplier and regular joint performance reviews. Suppliers to the organization are certified according to IRIS based on impact analysis.	X			X	

7.4.1-6	The organization shall: a) maintain and use a register of approved suppliers which includes the scope of their approval.	Plus: The organization should: a) periodically review supplier performance; the results of these reviews should be used as a basis for establishing the level of controls to be implemented, and b) define the necessary action to be taken when dealing with suppliers that do not meet technical and (or) performance targets.	Plus: The organization defined the necessary action to be taken when dealing with suppliers that do not meet technical and (or) performance targets. Progress status for follow-up actions is available.					
7.4.1-7	The organization shall: b) ensure that customer requirements are cascaded down through the Supply Chain and especially that both, the organization and its suppliers, use customer approved Special Processes, where required.	Plus: Customer approved Special Processes which are subcontracted to suppliers are validated by the organization. Relevant requirements are cascaded down to specific suppliers.	Plus: Regular follow-up of customer approved Special Processes is performed.					
7.4.1-8	The organization shall: c) ensure that the function having responsibility for approving supplier quality systems has the authority to reject the use of sources.							
7.4.1-9	The organization shall: d) assess and manage the risks for supply of Critical Products throughout the Supply Chain (1).	Plus: Product criticality is identified on purchase orders. Communication given to supplier about potential risks associated with their Products. Product maturity level and integrational readiness are checked.	Plus: Suppliers provide feedback on the associated risks to enhance overall understanding. Periodic and formal review sessions were held. Available market information and external benchmark is considered in the risk analysis					

7.4.1-10	The organization shall develop suppliers with the goal of improving supplier operational performance.	Plus: An improvement plan is in place for key suppliers covering joint targets, time schedule and measurements. Regular joint reviews with suppliers are performed. Key suppliers are identified according to strategic needs or risks. The organization should define and implement a relationship Process to develop key suppliers.	Plus: Open communication of needs and strategies occurs with those key suppliers Relationships with key suppliers are undertaken with a view to creating value for both . Evidence can be shown, that key suppliers are engaged and contributing to the organization's successes.	X				
7.4.2	Purchasing information							
7.4.2-1	Purchasing information shall describe the Product to be purchased, including, where appropriate, a) requirements for approval of Product, Procedures, Processes and equipment, b) requirements for qualification of personnel, and c) quality management system requirements.							
7.4.2-2	The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.	Plus: In the reviews, subject matter experts from procurement, quality, engineering are participating, if appropriate. Joint review with supplier, if appropriate. Systematic approach is used and improved based on past experience.	Plus: Knowledge management is established.					

7.4.2-3	Purchasing information regarding the Product shall include, where appropriate d) the name or other identification, applicable issues of specifications, drawings, Process requirements (including special ones), inspection instructions, appropriate details from the organization's quality plan and other relevant technical data, e) requirements for design, test, examination, inspection and related instructions for acceptance by the organization, f) requirements for test specimens (e.g. production method, number, storage conditions) for design approval, inspection, investigation or auditing, l) requirements for all Deliverables associated to the Product.							
7.4.2-4	Purchasing information regarding the Product shall include, where appropriate g) requirements relative to -supplier notification to organization of nonconforming Product and -arrangements for organization approval of supplier nonconforming material.							

7.4.2-5	Purchasing information regarding the Product shall include, where appropriate h) requirements for the supplier to notify the organization of changes in Product and (or) Process definition and, where required, obtain organization approval, i) right of access by the organization, their customer and regulatory authorities to all facilities involved in the order and to all applicable Records, k) requirements for Supply Chain logistics.							
7.4.2-6	Purchasing information regarding the Product shall include, where appropriate j) requirements for the supplier to cascade to its suppliers, the applicable requirements in the purchasing documents, where required.	Plus: Organization has agreed with the supplier to forward these requirements to their suppliers.	Plus: Organization has checked whether the supplier forwarded these requirements to their suppliers. The performance of the Supply Chain logistic is measured with an KPI and continually improved.					
7.4.2-7	The organization shall ensure that the supplier's offer is selected only after thorough analysis prior to negotiation. The negotiation shall take into account: - the level of compliance with the purchasing information, - the total cost requirements (including LCC) and - previous Product quality, costs and delivery performances.	Plus: A detailed total cost analysis is carried out (1). Product maturity levels are taken into consideration.	Plus: Quality, costs and delivery performance indicators are taken into account, including a risk analysis prior to the final offer selection.					
7.4.3	Verification of purchased product							

7.4.3-1	The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased Product meets specified purchase requirements.	Plus: The organization should define and implement a Process for verification activities, like inspection or audit at supplier's premises, which is supported by checklists and templates. For material critical to Special Processes, a reception control plan is established as specified in IRIS GUIDELINE 6:2014 SPECIAL PROCESSES.	Plus: The performance of the Process is measured.	X				
7.4.3-2	Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of Product release in the purchasing information.							
7.4.3-3	Verification activities of the organization shall include: a) obtaining objective evidence of the quality of the Product from suppliers (e.g., accompanying documentation, certificate of conformity, test reports, statistical Records, Process control), b) review of the required documentation and c) inspection of Products upon receipt.	Plus: Verification activities of the organization should also include inspection and audit at supplier's premises. The verification activities includes also supplier Special Processes, if applicable.	Plus: Joint assessments of verification activities take place at least once per year.					

7.4.3-4	The organization shall define activities accordingly in case of delegation of verification to the supplier or supplier certification. Where the organization delegates verification activities to the supplier, the requirements for delegation shall be defined and a register of supplier delegations maintained.	Plus: Regular review of requirements for delegation of verification activities are carried out.	Plus: Delegation is reviewed after subsequent changes.				X	
7.4.3-5	The purchased Product shall not be used or Processed until it has been verified as conforming to specified requirements or unless it is released under authorized customer Concession (see clause 8.3.2).							
7.4.3-6	Where the organization utilizes test reports to verify purchased Product, the data in those reports shall be acceptable per applicable specifications.	Plus: Periodically verification activities are applied to identified most relevant critical materials.	Plus: Periodically verification activities are applied to identified all critical materials.					
7.4.3-7	The organization shall periodically verify test reports for raw material.							
7.4.4	Supply chain management							
7.4.4-1	Supplier deliveries shall be scheduled in order to meet the purchase requirements.	Plus: Formal acknowledgement is required to suppliers. There is evidence that changes in delivery are communicated by updated supplier deliveries schedules. A KPI is established to measure supplier on time delivery performance (1).	Plus: Agreement on maximum lead times. Suppliers committed to a target for the			X		

7.4.4-2	Ordering shall be supported by an information system which: -covers the supply, -permits access to customer, supplier and Production information at key stages of the purchasing Process and -is order driven.	Plus: Data of the information system is updated on each event / change after purchase order.	Plus: KPI's for continual improvement of the whole ordering process along the Supply Chain are established.					
7.4.4-3	The organization shall communicate regularly a forecast to its supplier so that they can manage their capacity accordingly.	Plus: The organization appoints a contact person who communicates forecasts as well as every request for change in delivery with suppliers.	Plus: Joint activities in place to improve scheduling and capacity planning.					
7.4.4-4	Supplier shortages shall be identified, communicated to the organization, controlled and actions shall be established to recover the delivery schedule.	Plus: Regular check of delivery schedule progress takes place. Follow-up of actions.	Plus: Early warning policy agreement with supplier available (1). Joint corrective / improvement actions are defined.					
7.5	Production and service provision							

7.5-1	The organization shall ensure that the Production Process inputs are expressed in terms that can be verified against design and development output requirements, including: -specifications and drawings, -information on materials, -Production Process flow chart and (or) layout, -control plan, -work instructions, -Process and Product approval acceptance criteria, -data for quality, measurement, reliability, maintainability, -results of error prevention activities (e.g. FMEA), as appropriate and -methods of rapid detection and feedback of Product and (or) Production Process nonconformities.	Plus: Production Process Failure Modes and Effects Analysis (FMEA) or alternative suitable methods are applied for relevant Processes in order to identify and mitigate production risks. Actions to prevent recurrence of past problems are considered (1).	Plus: All Production Processes are systematically reviewed for the need to conduct Process FMEA. Continual improvement based on past experience.					
7.5.1	Control of production and service provision							

7.5.1-1	The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable, a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring equipment, e) the implementation of monitoring and measurement, and f) the implementation of product release, delivery and post-delivery activities. Controlled conditions shall include for all shifts: g) accountability for all Products during manufacturing (e.g. parts quantities, split orders, nonconforming Product), h) evidence that all manufacturing and inspection operations have been authorized and completed as planned in the Production schedule or as otherwise documented.	Plus: Conditions needed are regularly reviewed and updated. Risks evaluation is carried out at an early stage of the Process. Evidence that all shifts produce outputs of the same quality.	Plus: Conditions needed are subject to efficiency analysis and improvement.					

7.5.1-2	The organization shall have a Process to control deferred and Abnormal Work in Production.	Plus: This process includes an assessment of the risk impact of deferred work and ensures that work is carried out as quickly as possible.	Plus: Abnormal work is analyzed on a regular basis and, where appropriate, this is incorporated into the next contract specification. Efficiency and continuous improvement of the control Process. Approach of the IRIS GUIDELINE 7:2014 PROBLEM SOLVING is applied.	X				
7.5.1.1	Production scheduling							
7.5.1.1-1	Production (including test equipment) shall be: - scheduled (short-, mid- (MPS = Master Production Schedule) and long-term (SOP = Sales and Operation Plan)) in order to meet the customer purchase requirements, - supported by an information system that permits access to Production information at key stages of the Process, and -order driven.	Plus: Data is updated on each event / change of customer contract.	Plus: Continual improvement of Production scheduling.					
7.5.1.1-2	The organization shall use customer forecasts and orders to plan, measure capacity and adjust regularly its resources according to its workload, taking into account risks (e.g. extra order at the last minute, supplier failure.).							
7.5.1.1-3	Bottlenecks in Production shall be identified and an improvement action plan established.	Plus: The improvement action plan is also based on past experience and efficiency measurements.	Plus: The improvement action plan is also based on risk analysis. Preventive actions are in place.					

7.5.1.2	Production documentation							
7.5.1.2-1	Production operations shall be carried out in accordance with approved data. This data shall contain when necessary: a) drawings, parts lists, Process flow charts including inspection operations, Production documents (e.g.: manufacturing plans, traveller, router, work order, Process cards) and inspection documents (see clause 8.2.4) and b) a list of tools and numerical control (NC) machine programs required and any specific instructions associated with their use.	Plus: Feedback to design / engineering is regularly provided.	Plus: Continual improvement of production documentation.					
7.5.1.3	Control of production process changes							
7.5.1.3-1	The organization shall establish, document and maintain a Process to control Production Process changes. Persons authorized to approve changes to Production Processes shall be identified.	Plus: This Process includes impact analysis on requirements prior to acceptance.	Plus: This Process includes a systematic multidisciplinary impact analysis on requirements prior to acceptance.	X				
7.5.1.3-2	The organization shall identify and obtain acceptance of changes that require customer and (or) regulatory authority approval in accordance with customer contracts and (or) statutory and regulatory requirements.							

7.5.1.3-3	Changes affecting Processes, Production equipment, tools and programs (software) shall be documented.	Plus: The results of changes to Production Processes should be reviewed to confirm that the desired effect has been achieved without adverse effects to Product quality.	Plus: Analyses of changes affecting Processes, production equipment, tools and programs (software) are also documented.					
7.5.1.3-4	The organization shall maintain a Record of the date and (or) serial number of each change which is implemented in Production.						X	
7.5.1.4	Control of equipment and tools							
7.5.1.4-1	The organization shall have a documented Procedure for providing adequate manufacturing equipment and tools to produce Products according to the design output.	Plus: The organization should apply the design and development Process (see clause 7.3) for manufacturing equipment (1) (2).	Plus: Efficiency of the control of equipment and tools process is continually improved	X	X			
7.5.2	Validation of processes for production and service provision							
7.5.2-1	The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.	Plus: The organization should define and implement a Process for validation of Processes for Production and service provision. Qualification, requalification and validation for Special Processes changes including Special Processes transfer are considered, as stated in IRIS GUIDELINE 6:2014 SPECIAL PROCESSES.	Plus: Continual improvement of the validation activities.	X				

7.5.2-2	Validation shall demonstrate the ability of these processes to achieve planned results. The organization shall establish arrangements for these processes including, as applicable, a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures, d) requirements for records (see 4.2.4), and e) revalidation.							
7.5.2-3 KO	Special Processes shall be managed according to the contractual and (or) internal requirements.							
7.5.2-4	The organization shall establish a Process for the control of Special Processes, including qualification and approval of the Special Processes prior to use and in accordance with documented specifications and any subsequent changes thereto. All personnel performing Special Processes shall be identified, trained and authorized.			X				
7.5.3	Identification and traceability							
7.5.3-1	Where appropriate, the organization shall identify the Product by suitable means throughout Product realization.							

7.5.3-2	The organization shall identify the Product status with respect to monitoring and measurement requirements throughout Product realization.							
7.5.3-3	Where traceability is a requirement, the organization shall control the unique identification of the Product and maintain records (see 4.2.4).	Plus: Serialization (serial numbering) is applied for required parts of the unit / system. Required parts (of the Product) are traceable from their origin up to customer delivery.	Plus: Required parts are traceable from their origin up to at least the end of warranty.				X	
7.5.4	Customer property							
7.5.4-1	The organization shall exercise care with customer property while it is under the organization's control or being used by the organization.	Plus: Traceability of customer property is documented up to delivery / return to customer.	Plus: Regular status report to customer.					
7.5.4-2	The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product.							
7.5.4-3	If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.4).	Plus: Root cause analyses are performed and required actions are taken.	Plus: Dedicated person / function to solve such cases jointly with the customer.				X	
7.5.5	Preservation of product							

7.5.5-1	The organization shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.	Plus: Preservation of Product should also include, in accordance with Product specifications and (or) applicable regulations, provisions for: a) cleaning, b) special handling for sensitive Products, c) marking and labelling, d) shelf life control and stock rotation, e) special handling for hazardous materials. Guidelines are in place to cover all internal processing, till delivery to the intended destination, that have impact on Product conformity / preservation.	Plus: Continual improvement of handling, packaging, storage and protection. Factors having impact on Product conformity are identified, recorded and actions are taken as needed (including update of guidelines).					
7.5.5-2	The organization shall ensure that Product documentation required by the contract and (or) order is present at delivery and is protected against loss and deterioration.							
7.6	Control of monitoring and measuring equipment							
7.6-1	The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of Product to determined requirements.							

7.6-2	The organization shall establish Processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.	Plus: Process effectiveness is monitored.	Plus: Continual improvement of the control Process.	X				
7.6-3	Where necessary to ensure valid results, measuring equipment shall a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.4); b) be adjusted or re-adjusted as necessary; c) have identification in order to determine its calibration status; d) be safeguarded from adjustments that would invalidate the measurement result; e) be protected from damage and deterioration during handling, maintenance and storage. Measurement equipment shall f) be recalled in accordance with a defined method when requiring calibration.						X	
7.6-4	In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements.	Plus: The organization should define and implement a Process, how to react when monitoring and measuring equipment is found not to conform to requirements (1).	Plus: Continual improvement of the Process.	X			X	

7.6-5	The organization shall take appropriate action on the equipment and any Product affected.							
7.6-6	Records of the results of calibration and verification shall be maintained (see 4.2.4).						X	
7.6-7	When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.	Plus: Computer software is validated by the organization in accordance with IEC 62279 (EN 50128).	Plus: Continual improvement of the validation Process.					
7.6-8	The organization shall maintain a register of this monitoring and measuring equipment and define the Process employed for its calibration or verification, or both, including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.	Plus: Analysis of measurement equipment capability is regularly conducted and updated.	Plus: Application of a central database.					
7.6-9	The organization shall ensure that ambient conditions are suitable for the carrying out calibration, inspection, measurement and testing.							
7.7	Project management							

7.7-1 KO	The organization shall implement a Project Management Process or new Product development Process, addressing the applicable areas of Project Management, describing roles and responsibilities, integrating all relevant functions of the organization into a multidisciplinary team. The performance of this Process shall be measured by a KPI (see annex 3) (1).			X		X		
7.7.1	Integration management							
7.7.1-1	An integrated Project plan shall be developed, reflecting the specific rules to follow whilst executing a Project (e.g. multi-Site Project, consortium) throughout the entire Project Life Cycle, including Project plan change control.	Plus: During the project launch phase the entire Project plan is harmonized between the participating functions, Sites and/or consortium partners (1). The multidisciplinary Project team is formally in charge as appropriate.	Plus: The Project plan is approved by the customer.					
7.7.2	Scope management							
7.7.2-1	The organization shall ensure that the entire scope of work is identified, subdivided into work packages, controlled and verified. Scope changes shall be controlled and consistency guaranteed throughout the Project and reflected in the Project plan.	Plus: Scope changes are managed in a Multidisciplinary Approach and communicated to all stakeholders.	Plus: A standardized work break down structure is in place.					
7.7.3	Time management							

7.7.3-1	The organization shall ensure timely completion of the Project through the identification of: -specific activities to produce the Project Deliverables, -interdependencies of the work packages including those of suppliers, -activity sequences, resource requirements and duration and -the critical path.	Plus: Standardized tools for Project scheduling and activity tracking are in place (1).	Plus: Past experience and feedback is appropriately used into Project scheduling.					
7.7.3-2	These integrated activities (e.g. Project schedule) shall be regularly reviewed, controlled and recorded.	Plus: Regular reporting of Project progress to upper management. The reviews are conducted with a Multidisciplinary Approach and functional line managers are involved as necessary.	Plus: An early warning system is effective. Cross-Project learning approach led by functional line managers.				X	
7.7.3-3	In any case of an imminent deviation the organization shall identify and implement appropriate counter measures to avoid any impact on customers.	Plus: Regular reporting of status of counter measures to upper management.	Plus: An early warning system is effective. Cross-Project learning approach led by functional line managers.					
7.7.3-4	The organization shall not change the delivery schedule unless authorized by the customer.							
7.7.3-5	Project schedules shall be regularly updated with regard to: - development activities with suppliers (major milestones with suppliers) and - the identification and management of long lead time items.	Plus: Long lead time items are identified and managed jointly with suppliers.	Plus: Optimization activities of long lead time items are initialized and followed up over the Supply Chain.					
7.7.4	Cost management							

7.7.4-1	A cost management Process shall be in place: - to plan all Project related costs during the whole Project Life Cycle (1), - to regularly follow the cost progress on each work package and on each item of the total cost breakdown, including the identification of the estimate to completion (2). The performance of this Process shall be measured by a KPI (see annex 3) (3).	Plus: Cost savings (4) should be identified in order to recover the budget in case of deviation. The reviews are conducted with a Multidisciplinary Approach. Regular reporting to senior management.	Plus: Efficiency and continual improvement of the cost management process. An early warning system is implemented.	X		X		
7.7.5	Quality Management							
7.7.5-1 KO	The organization shall ensure that a Process is in place to manage Project Deliverables (1).			X				
7.7.5-2	As a minimum (1), the Project Deliverables shall be managed with regard to: - identification, clarification, fulfilment and control, - validation and delivery on time, - approval by the customer (e.g. customer product acceptance points), where required and - management of the suppliers within the Project (e.g. listing, criticality, innovation, actions, Sites).	Plus: The Project quality management plan is regularly updated during the entire Project life.	Plus: The Project quality management plan is continually improved based on feedback of past experience.					
7.7.5-3	Open issues shall be controlled and the appropriate resources put in place to manage the associated activities.							
7.7.5-4	Documented Project reviews shall take place at regular intervals throughout the entire Project life.	Plus: Systematic	Plus: An escalation Process is in place.					

7.7.5-5	Phase reviews shall take place at predefined Project phases and (or) milestones to assess the Project compliance, the availability of work package Deliverables and to authorize the start of the next phase.	Plus: Systematic	Plus: An escalation Process is in place.					
7.7.5-6	The organization's risk and opportunity management Process shall be employed to rectify any issue and (or) deviation arising from these reviews in order to maintain the Project plan and schedule.	Plus: The reviews are conducted with a Multidisciplinary Approach and functional line managers are involved as necessary. Regular reporting of status of counter measures to senior management.	Plus: An early warning system is effective. Cross-Project learning approach led by functional line managers.					
7.7.5-7	Assessment of the Project performance shall be established to monitor the Project progress and efficiency through performance indicators (1).	Plus: On main Projects formal Project closing reports, including lessons learned exist. Final review with the customer / main suppliers is conducted, including assessment and SWOT (Strengths, Weaknesses, Opportunities, Threats) analysis. A KPI is established to measure internal and suppliers nonconformities throughout the entire Project Life Cycle (2).	Plus: Quality Deficiency Costs are analyzed and actions are taken to avoid recurrence of issues in other Projects.					
7.7.6	Human resources management							

7.7.6-1	Requirements described in clause 6.2 of this standard with regard to competence, awareness and training, motivation and empowerment and performance management shall be deployed at Project team level.	Plus: All Project managers are trained in additional skills like: -Product technologies, -communication and leadership, -Project management tools, -management of Project financials, -quality assurance (advanced level).	Plus: The whole Project management team is trained in additional skills like: -communication, -Project management tools , -quality assurance (advanced level).					
7.7.6-2	It shall cover as a minimum: - identification, documentation and assignment of Project roles, responsibilities and reporting relationships, - acquisition of appropriate resources assigned to and working until Project completion and - development of individual and team competencies to enhance Project performance.	Plus: Project managers have adequate empowerment (1).	Plus: Project specific mandates are defined (2).					
7.7.7	Communication management							
7.7.7-1	The organization shall ensure that the Project team determines and communicates needs of the stakeholders (e.g. communication plan). This information, including performance information, Product specific requirements, defect reporting and Rail Industry Risks, shall be made available to Project stakeholders in an adequate timely manner.	Plus: A detailed communication plan is put in place. Adequate periodic reporting of status, essential results, performance and actions to stakeholders, including customers.	Plus: An up-to-date communication system is in place (1).					
7.7.8	Risk and opportunity management							

7.7.8-1	The organization shall ensure that a Process is in place to identify, analyse (quantitatively and qualitatively) and when necessary decide upon the risk response (e.g. acceptance, mitigation, transfer, avoidance).	Plus: The Process should be documented in a Procedure and should include methods such as documented risk assessment, FMEA and control of counter measures (1). Failure Modes and Effects Analysis / FMECA for safety and function critical items are also included.	Plus: The risk analysis is triggered out of an assessment of the criticality of the components based on maturity and failure with the input from all stakeholders.	X	X			
7.7.8-2	The risk response or opportunity enhancement shall be recorded and reported to all stakeholders as appropriate. The effectiveness of the response plan shall be assessed on a regular basis (e.g. during the Project reviews). The output of the risk assessment shall be regularly reviewed and updated throughout the Project Life Cycle.	Plus: The output of the risk assessment should be extracted and communicated for the purpose of lessons to be learnt throughout the organization.	Plus: An up-to-date risk management information system is in place.				X	
7.7.8-3	The organization shall demonstrate - appropriate awareness of the Criticality of the Product and the function and risks of a Product within the system and (or) vehicle of which it forms a part, - assurance of appropriate Production control Procedures to implement risk mitigation.	Plus: Periodic and formal internal reviews of risk assessment are carried out. Appropriate personnel demonstrate awareness of mitigation measures.	Plus: Periodic and formal reviews of risk assessment carried out with members of the Supply Chain.					
7.8	Configuration management							

7.8-1	The organization shall establish, document and maintain a configuration management Process appropriate to the Product.	Plus: The organization should have a documented Procedure for configuration management.	Plus: A software is used to manage the configuration management Process.	X	X			
7.8-2	The organization shall: a) at the beginning of the contract, define a list of Products - at least Safety critical ones - including their Component parts, which shall be managed with regard to their configuration; this list shall be approved by the customer, b) address the change management Process within the configuration management Process (see clause 7.13) and c) maintain traceability during Production and operations.	Plus: Configuration audits are systematically performed. For software development and software Production a configuration management for applied tools should be available.	Plus: Suppliers configuration management system is integrated in the organisations' system. Consistency with the changing requirements during Product life cycle is maintained.					
7.9	First Article Onspection (FAI)							
7.9-1 KO	The organization shall provide a documented Procedure covering the inspection, verification, documentation and update of Records with results of a representative item from the first series Production run of a new Product or major upgrade of an existing Product, following: - the verification of the Production Process or - a change that invalidates the previous First Article Inspection result.				X		X	

7.9-2	The organization shall ensure that a Process is in place to plan, initiate and conduct a First Article Inspection.	Plus: The IRIS GUIDELINE 2:2012 FAI is considered (for internal and suppliers' FAI), including a) a matrix is defined in order to identify the Products of the Project to be subject to the FAI b) Criteria are stated to define in which cases the FAI is to be repeated c) Pre-conditions to perform the FAI are to be evaluated by the organization prior to begin the FAI d) A typical list of participants to the FAI, depending on the product, is defined e) Criteria and conditions for releasing or not realizing the serial Production, are defined f) Specific forms and templates, to assure punctual and complete gathering of the FAI results, are utilized. The performance of this Process should be measured by a KPI (see annex 3) (1).	Plus: Efficiency and continual improvement of the FAI Process (both for internal and suppliers' FAI).	X		X		
7.9-3	This FAI Procedure and Process shall be applied to suppliers according to defined and agreed criteria.	Plus: FAI data is systematically analyzed including tools are identified, trained and used. Application of methodology is ensured.	Plus: The FAI Process and Procedures are applied at suppliers premise and include a review of the suppliers Production Process with focus on critical and Special Processes.					
7.10	Commissioning / Customer service							

7.10-1 KO	For customer service and commissioning (when commissioning is a contractual requirement) a Process shall be in place. This Process shall include a) actions to be taken when problems are identifiedafter delivery, including investigation, reporting activities and actions on service information.			X				
7.10-2	This Process shall include b) the control and updating of technical documentation and its publication, c) the approval, control and use of repair schemes, d) the management of Consignment Stock.	Plus: The commissioning / Customer Service Process ensures -prompt control and updating of technical documentation and its publication, -Knowledge of complaints (1) are input for Review of Design in sense of return of experience, and -prompt issue of repair schemes and their proper implementation.	Plus: Efficiency and continual improvement of the commissioning / Customer Service Process. Customer Service information is input for systematical design rules.					
7.10-3	The organization shall demonstrate that adequate customer support is provided: -during commissioning, -until Product validation is complete, -during warranty, -until final customer acceptance.							
7.10-4	Suitable resources shall be available to provide customer support in accordance with the agreed requirements, for all the after sales activities including supply of spare parts.	Plus: A dedicated company organization is in charge of after sales activities including supply of spare parts.	Plus: Evidence that the after sales organization provides adequate feedback from the field to all stakeholders and gets all the support from other functions needed to satisfy the customer.					

7.10-5	Maintenance contracts shall be managed in accordance with the requirements defined in clause 7 “Product realization”.							
7.11	RAMS / LCC							
7.11-1	The organization shall have a documented Procedure in place to cover all the aspects of RAMS activities, including: - calculation and documentation, - data collection, analysis and improvement action plan set up, - implementation of defined tasks of the action plan. Resources shall be in place to address the RAMS requirements.	Plus : If unexpected results, root cause analysis and follow up of action for improvement are existing. Dedicated and skilled internal staff using adequate tools. Internal best practice examples are adopted across the Site(s).	Plus : Efficiency and continual improvement of the RAMS activities. Best practice is set and generally available for external benchmarking. Involvement of customers.		X			
7.11-2	Maintainability of the Product shall be an integrated part of the design and development Process. Standardized routines for the Maintenance of software shall be established and recorded according to IEC 62278 (EN 50126), IEC 62279 (EN 50128), IEC 62425 (EN 50129) or other agreed equivalent models in accordance with the design and development Process.	Plus: The organization systematically evaluates Product maintainability field data (1).	Plus: The organization systematically uses field data to improve the design for Maintenance.				X	

7.11-3	The organization shall have a Process in place to manage LCC. Resources shall be in place to address the LCC requirements.	Plus: The organization should document it in a Procedure.. If unexpected results, root cause analysis and follow up of action for improvement are existing. Dedicated and skilled internal staff using adequate tools. Internal best practice examples are adopted across the Site(s).	Plus: Efficiency and continual improvement of the LCC activities. Best practice is set and generally available for external benchmarking. Involvement of customers.	X	X			
7.11-4	RAMS / LCC data collection and analysis shall be supported by past experience from operation, during warranty period and continually improved (see clause 8.5.1).	Plus: After sales function is engaged in RAMS / LCC data collection. Root causes analysis based on failure category and component allocation and impact (remedy and severity).	Plus : Data collected and analyzed to reassess RAMS / LCC performances. Feedback for design and development improvement provided.					
7.11-5	RAMS / LCC data collection and analysis shall be supported by past experience from operation, after warranty period and continually improved (see clause 8.5.1).	Plus: An agreement with the maintenance organization is effective that ensures that RAMS / LCC data are collected and provided. Root causes analysis based on failure category and component allocation and impact (remedy and severity).	Plus: Data collected and analyzed to reassess RAMS / LCC performances. Feedback for design and development improvement provided.					
7.12	Obsolescence management							

7.12-1	The organization shall establish a Process to ensure, for the defined and agreed Product life cycle, the availability of the supplied Products and spare parts.	Plus: Obsolescence management plan in place, covering: -second source strategy, -storage approach, -form, fit and function compatibility approach. Proactive communication with customer.	Plus: Monitor and review potential risk of obsolete parts. Control and mitigate potential risk derived from obsolete Products.	X				
7.13	Control of changes							
7.13-1	The organization shall establish a Process and a documented Procedure to implement, execute, control and react to changes that impact Product realization, including the definition of which changes need to be referred back to the customer for authorization in line with local and customer requirements.			X	X			

7.13-2	The effects of any change, including those changes caused by any supplier (e.g. changes of subcontractor, location, Production Process, standard) and by customers (e.g. for new Product introduction) shall be assessed and verified (1).	Plus: Changes are registered in an information system. Changes should be analysed regarding the impact of testing and side effects. Their root cause is analysed as well as. Follow up of corrective actions are performed. Cost due to changes (requested to solve nonconformity issues in design and development, production Processes, during commissioning / Customer Service, purchasing and/or Project execution) are considered as part of Quality Deficiency Costs. Changes in terms of Maintenance (2) are considered in the change management Process.	Plus: Costs due to changes are collected from all stakeholders analyzed, assigned to causer and continually reduced.					
7.13-3 KO	Validation and approval activities shall be defined to ensure compliance with customer requirements before implementation.							
7.13-4	The organization shall have controls in place which prevent changes from external origin being implemented without prior authorization from all appropriate stakeholders (1).							

7.13-5	The impact of change on form, fit and function of proprietary designs (including performance and (or) durability) shall be reviewed with the customer so that all effects can be properly evaluated.							
8	Measurement, analysis and improvement							
8.1	General							
8.1-1	The organization shall ensure that a Process for measurement, analysis and improvement is in place.			X				

8.1-2	The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed a) to demonstrate conformity to product requirements, b) to ensure conformity of the quality management system, and c) to continually improve the effectiveness of the quality management system (1). This shall include determination of applicable methods, including statistical techniques, and the extent of their use.	Plus: Strategic plan includes follow up of actions, measurements, analysis and update of objectives. Generally, for each KPI deployed a target is set in accordance with the strategic plan. The achievement of objectives is regularly reviewed and counter actions are taken, if necessary. Internal best practice examples are adopted across the Site(s) (2). Process level objectives, are related to key performance indicators. The main conditions for success are identified and tracked by suitable, practical indicators. Management decisions are adequately supported by reliable data from the measurement systems.	Plus: All company KPI's are adjusted. Targets relating to quality, time and cost are balanced. Efficiency and continual improvement of the measurement, analysis and improvement Process. Best practice is set (3) and generally available for external benchmarking. Data is available to show progress on key performance indicators over time and how the organization's performance compares with that of other organizations. It is possible to monitor efficiently the timely deployment of the strategy and objectives. The results of the measurements are made available inside the organization and are widely used. Systematic analysis of comprehensive data allows future performance to be predicted with confidence.					
8.2	Monitoring and measurement							
8.2.1	Customer satisfaction							

8.2.1-1	As one of the measurements of the performance of the business management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements.	Plus: The organization should define and implement a monitoring Process, which is performed in a systematic and planned way, and includes cross checks with external data sources. Resource requirements are assessed in a systematic and planned way, over time. Feedback from employees and customers is gathered through professionally conducted surveys and other mechanisms such as focus groups. Feedback from key suppliers and partners is gathered in a planned manner. The organization should define and implement Processes for tracking statutory and regulatory requirements.	Plus: Regular review of customer satisfaction with senior management. Efficiency and continual improvement of customer satisfaction. The monitoring Process delivers trends and reliable data. The focus is on trends within the organization's activity sector, technologies, and labour situation, with optimization of the use and development of resources. Changes taking place or expected in economic policies, product demands, technologies, environmental protection, or in social and cultural issues, that could have an impact on the organization’s performance, are monitored in planned way.	X				
8.2.1-2	The methods for obtaining and using this information shall be determined.							
8.2.1-3	The organization shall implement a Process for obtaining and evaluating customer satisfaction data.	Plus: The performance of this Process should be measured by a KPI (see annex 3) (1). Root cause analysis of the main issues should be done with special emphasis on customer related issues. Internal best practice examples are adopted across the Site(s).	Plus: Regular reviews of incident reports to understand trends and develop action plans to improve Products. Efficiency and continual improvement of the Process. Best practice is set and generally available for external benchmarking.	X		X		

8.2.2	Internal audit							
8.2.2-1	The organization shall conduct internal audits at planned intervals to determine whether the business management system a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the business management system requirementsestablished by the organization, and b) is effectively implemented and maintained. An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. The audit program shall cover all Production shifts, if applicable.	Plus: All business Processes are audited at least once within a period of 3 years. Root cause analysis of non conformities is conducted. A Multidisciplinary Approach ensures that the number of internal audits is optimized and redundancies are avoided. The organization should define and implement a Process for data gathering (see clause 8.4). When necessary, qualifying studies are conducted to verify the data, particularly when the data is derived from judgements, opinions, etc. Audits ensure the accuracy of data and the effectiveness of the management system. Self-assessments are regularly conducted.	Plus: Efficiency of continual improvement of audit Processes. Supporting tools exist. The data gathering Processes are continually evaluated and their effectiveness and efficiency improved. Sources of data are comprehensive and reflect the performance of all strategic and operational areas of the organization. Approaches to audit are integrated. Joint audits (with other interested parties) provide opportunities for partners to identify improvements. Self-assessment outcomes are integrated into the strategic planning Process and are compared with other organizations.	X				

8.2.2-2	Internal auditors of relevant functions shall be qualified to ensure that rules of auditor behaviour are applied and IRIS requirements of relevant chapters are understood (1). The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.	Plus: Monitoring of -internal audit results, and -performance of internal auditors is in place.	Plus: Frequency of auditor training is adapted in accordance with changes to standards, at least once in a 3 years period.					
8.2.2-3	A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results (1). Records of the audits and their results shall be maintained (see 4.2.4).	Plus: Internal best practice examples are adopted across the Site(s)	Plus: Efficiency and continual improvement of the audit Process. Best practice is set and generally available for external benchmarking.		X		X	
8.2.2-4	The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes (1). Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).	Plus: Evidence, that -root cause analysis of nonconformities is conducted, and -actions are established to increase responsiveness. Standardized tools and techniques are implemented to support audit Process.	Plus: Responsiveness is measured by an indicator and continually improved. Tools and techniques are capable to measuring the effectiveness of the internal audit Process and overall performance of the organization.					

8.2.2-5	The organization shall audit all Processes (1) of its management system to verify compliance with all requirements (including any external requirements).	Plus: Critical Projects and (or) Products as well as production Processes (2) are audited in order to verify the effectiveness of the necessary controls.	Plus: Audits are generally used for governance of all management tasks.					
8.2.3	Monitoring and measurement of Processes							
8.2.3-1	The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate (1). Mandatory KPI’s shall be established as listed in annex 3 to measure and monitor Processes.	Plus: Root cause analysis and follow up of actions for improvement. Recommended KPI’s should be established as listed in annex 3 to measure and monitor Processes.	Plus: Efficiency of actions is demonstrated by performance improvement of affected Processes. KPI's are established to measure and monitor all mandatory Processes as listed in annex 3.					
8.2.4	Monitoring and measurement of Product							

8.2.4-1	The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met (1). This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained.	Plus: Implementation of quality plan Customer feedback validates compliance. As much as possible measurements are moved upstream to the earliest possible Production stage (2), At appropriate stages, the Product maturity level is checked	Plus: Customer feedback used to further enhance the product conformity. Efficiency of continual improvement of Product monitoring and measurement.					
8.2.4-2	Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).						X	
8.2.4-3	The release of product and delivery of service to the customer shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.							

8.2.4-4	Measurement requirements for Product or service acceptance shall be documented. This documentation may be part of the Product documentation, but shall include: a) the criteria for acceptance and (or) rejection, b) where in the sequence measurement and testing operations are performed, c) a Record of the measurement results and d) the type of measurement instruments required and any specific instructions associated with their use.	Plus: Objective acceptance criteria are maximized (1).	Plus: Monitoring and analyzing of these criteria during the complete Product realization. Efficiency of continual improvement of acceptance activities by review and update of the criteria.					
8.2.4-5	Test Records shall show actual test results data when required by specification or acceptance test plan.							
8.3	Control of nonconforming Product							
8.3-1	The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.				X			

8.3-2	Where applicable, the organization shall deal with nonconforming product by one or more of the following ways: a) by taking action to eliminate the detected nonconformity; b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer; c) by taking action to preclude its original intended use or application; d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.	Plus: IRIS GUIDELINE 7:2014 PROBLEM SOLVING is applied. In case alternative methods are used, they include root cause analysis, corrective and preventive actions and the follow-up of actions status. A KPI is established to monitor the criticality of backlog of problems (1).	Plus: Labor hours and material costs due to nonconforming Product are collected at site and in the field, analyzed, assigned to causer and continually reduced. A KPI is established to measure Quality Deficiency Costs (2).					
8.3-3	When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.	Plus: Verification frequency is adopted in accordance with risk level in order to prevent nonconforming Product being shipped (1).	Plus: Poka Yoke methods are applied where appropriate to prevent nonconforming Products.					
8.3-4	Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).	Plus: A KPI is established to monitor the resolution time of problems (1).	Plus: A KPI is established to monitor the quantity of problems (1).				X	
8.3.1	Control of nonconforming Process							

8.3.1-1 KO	The organization shall establish, document and maintain a Process to manage business management Process variation, which includes: a) identification, Recording and analysing of the root causes of the variation and if the business management Process is non conform, taking appropriate action to correct the nonconforming Process, b) evaluation whether the business management Process variation has resulted in Product nonconformity and c) identification and control of the nonconforming Product in accordance with clause 8.3.			X				
8.3.2	Customer Concession							
8.3.2-1	The organization shall obtain a customer Concession or Deviation Permit prior to further Processing, whenever the Product or Production Process differs from what has been approved. The organization shall maintain a Record of the expiration date of such a Concession and (or) quantity authorized.	Plus: The organization should define and implement a customer Concession Process. Penalties due to Concessions and Deviation Permits should be collected, analyzed and assigned to causers.	Plus: Penalties due to Concessions and Deviation permits are considered as part of Quality Deficiency Cost.	X			X	
8.3.2-2	The organization shall also ensure compliance with the original or superseded specification when the authorization of the customer Concession expires.							

8.3.2-3	Material shipped, which is subject to such a Concession, shall be appropriately identified. This applies equally to purchased Products.	Plus: Regular review of Process application.	Plus: Methods for packaging, delivery and expediting of deliveries with customer Concession are standardized and agreed with customer.					
8.3.2-4	The organization shall ensure that Concessions requested by any supplier are agreed before submission to the customer.	Plus: The register to control Concessions also includes Concessions requested by suppliers.	Plus: Efficiency and joint continual improvement of the control Process with the suppliers.					
8.4	Analysis of data							
8.4-1	The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made (1). This shall include data generated as a result of monitoring and measurement and from other relevant sources (2).	Plus: The organization should ensure that a Process for the analysis of data is in place (see clause 8.2.2) The analysis process is supported by the wide use of statistical software. Effective decisions and actions are based on the analyses of data and information.	Plus: Risks and opportunities that could impact the achievement of long and short term objectives are identified, based on analysis of data and trends. The performance of this Process should be measured by a KPI (see annex 3) (3).			X		

8.4-2	The analysis of data shall provide information relating to a) customer satisfaction (see 8.2.1), b) conformity to product requirements (see 8.2.4), c) characteristics and trends of processes and products, including opportunities for preventive action (see 8.2.3 and 8.2.4), d) suppliers (see 7.4), e) external incident reports associated with the organization's Products and f) Product Safety.	Plus: The analysis investigates trends and correlations between different aspects / Processes. Results of analysis of data are shared with defined stakeholders. The analysis of data has provided information relating to service and Maintenance.	Plus: KPIs integrate analysis of internal or external customer and supplier specific data. Joint actions with stakeholders and interested parties are performed (internal / customers / suppliers).					
8.5	Improvement							
8.5.1	Continual improvement							
8.5.1-1	The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.	Plus: The organization should define and implement improvement Processes, based on corrective and preventive actions (see clause 8.5.2 and 8.5.3). Improvement Projects are launched, Challenging targets concerning continual improvement are set.	Plus: Follow-up of improvement Projects is performed, Efficiency of continual improvement is regularly evaluated, Set targets concerning continual improvement are met.	X				
8.5.2	Corrective action							

8.5.2-1	The organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.	Plus: Root cause analysis of nonconformities and follow up of corrective actions. Results are shared with customers on demand. The organization should define and implement a corrective action Process, which is regularly reviewed in a multidisciplinary assessment (see clause 8.5.1) and has used problem solving methods. Application of IRIS GUIDELINE 7:2014 PROBLEM SOLVING in terms of customer complaints. In case alternative methods are used, they include root cause analysis, corrective and preventive actions and the follow-up of actions status.	Plus: Labor hours and material cost due to corrective actions are collected at Site and in the field, analyzed, assigned to causer and continually reduced. Joint work on corrective actions with customer / suppliers, as applicable.	X				

8.5.2-2	A documented procedure shall be established to define requirements for a) reviewing nonconformities (including customer complaints), b) determining the causes of nonconformities, c) evaluating the need for action to ensure that nonconformities do not recur, d) determining and implementing action needed, e) records of the results of action taken (see 4.2.4), f) reviewing the effectiveness of the corrective action taken, and g) documenting the effectiveness and close out of corrective action.				X		X	
8.5.3	Preventive action							

8.5.3-1	The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.	Plus: The organization should define and implement a preventive action Process (1), which is regularly reviewed in a multidisciplinary assessment (see clause 8.5.1). Preventive actions are used to improve the operational performance. Appropriate tools supporting the identification of preventive actions are identified, trained and used. Application of IRIS GUIDELINE 7:2014 PROBLEM SOLVING. In case alternative methods are used, they include root cause analysis, corrective and preventive actions and the follow-up of actions status.	Plus: Quality Deficiency Cost are used to evaluate the effectiveness of preventive actions and to improve the effectiveness of risk management. Joint work on potential nonconformities with customer / suppliers, as applicable.	X				
8.5.3-2	A documented procedure shall be established to define requirements for a) determining potential nonconformities and their causes, b) evaluating the need for action to prevent occurrence of nonconformities, c) determining and implementing action needed, d) records of results of action taken (see 4.2.4), and e) reviewing the effectiveness of the preventive action taken.				X		X	