



EAGLE Certification Group
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AS9100:2016 Key Changes

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January 27, 2017



- EAGLE Transition Process for AS9100
- High Level Summary
- Key ISO9001:2015 Changes
- Key AS9100:2016 Changes
- Transition Summary – Upcoming events
- OASIS Next Gen
- Deployment Support Material
- Questions



- Detailed in From the Nest dated 30 Nov 2016
 - Transition completed with Gap Assessment
 - Surveillance Audit – add 1 day
 - Recertification Audit – add .5 day
 - Transition completed with complete system rewrite
 - Surveillance Audit – add 1.5 days
 - Recertification Audit – add 1 day
- Gap assessment checklist was provided in January 2017 From the Nest
 - Also available at:
<http://www.sae.org/iaqg/organization/9100.htm>



- Clause 1 – Scope
 - New process model
 - Added PDCA model
 - Added Risk-based Thinking
 - Emphasis on defining the QMS and context of the org
- Clause 2 – Normative reference
 - ISO 9000:2015 referenced
- Clause 3 – Terms and definitions
 - ISO9001 terms and definitions moved to ISO9000
 - AS9100 added product safety and counterfeit parts



- Clause 4 – Context of the Organization
 - Requires determination of internal/external issues, relevant interested parties and their requirements
 - Documented information is required to be maintained
 - 9100 added – can be named a Quality Manual
 - Justified exclusions not limited to Realization/Operation processes
 - Explicit requirement that QMS processes have performance indicators

- Clause 5 – Leadership
 - QMS compatible with strategic direction
 - QMS requirements integrated into business processes
 - QMS processes have performance indicators



- Clause 6 – Planning for the QMS
 - When planning the QMS, determine the actions needed to address opportunities and risk (prevention)
 - Increases the requirements for planning of changes

- Clause 7 – Support
 - Determine knowledge management requirements
 - 9100 – Awareness on product conformity, product safety, ethical behavior



- Clause 8 – Operations
 - 9100 – Planning for product obsolescence
 - 9100 – Plan activities needed to assure product safety
 - 9100 – Prevention of counterfeit parts
 - 9100 – Process to validate test reports for raw materials based on risk
 - ISO – Release of products and services

- Clause 9 – Performance Evaluation
 - Assess performance of QMS processes
 - 9100 – Added note to evaluate performance indicators on internal audits



- Clause 10 – Improvement
 - 9100 – Consider human factors in nonconformity/corrective action



- Clearer understanding of the organization's context (Clause 4.1)
 - Determine external and internal issues that are:
 - relevant to it's purpose and strategic direction
 - affect its ability to achieve intended results
- Things to consider:
 - External context – legal, technological, competitive, market, cultural, social and economic environment
 - Internal context – values, culture, knowledge, and performance

- Clause 4.3 - Determining the scope of the QMS
 - The term exclusion(s) is no longer used – now requirements that are not applicable to the QMS

- Current registrations:
 - Audit plans will still indicate Rev C exclusions
 - We are asking auditors to verify the “non-applicability” of the requirement and indicate the new clause on the audit plan
 - Clients – need to be aware of and justify requirements determined to be not applicable.



- High Level Structure and Terminology
 - No requirement for documentation to reflect structure and terminology of the standard
 - Consider structuring QMS documentation around you business processes.

- Risk-based thinking
 - Concept of preventive action now addressed throughout the standard by risk identification and mitigation
 - Always implicit in ISO9001 – this edition builds it into the whole management system



- Implementation Considerations
 - Used throughout your organizational processes
 - Risk-based thinking for QMS (business) - clause 6.1
 - Identify and prioritize
 - Plans to address the risk
 - Implement the plan
 - Check for effectiveness
 - Learn from experience
- Outcome – Prevention
 - Minimize risk to the organization and Customers!



- Strengthened with integration of the QMS into business processes
 - Systemic management of processes and their interactions to achieve planned results
 - Plan
 - Set objectives/build processes necessary to deliver results
 - Do
 - Implement what was planned
 - Check
 - Monitor and measure results against the objectives
 - Act
 - Take action to improve results



- Clause 4.4.1 requirements
 - Determine processes needed for the QMS
 - Determine inputs and outputs for these processes
 - Determine the sequence and interaction of these processes
 - Determine and apply criteria and methods needed to ensure effective operation and control of these processes
 - Determine resources needed and ensure availability
 - Assign responsibility and authority for these processes
 - Address risk and opportunity
 - Evaluate these processes and implement changes
 - Improve the processes and the QMS



- Addressed in several clauses
 - Planning/implementing changes to the QMS – 6.3
 - Organizational Knowledge – 7.1.6
 - Controlling operational changes – 8.1
 - Appropriate actions are taken about changes related to requirements of products and services – 8.2.4
 - Managing changes related to design and development – 8.3.6
 - Changes affecting production/service provision- 8.5.6



- Organizational Knowledge – knowledge specific to the organization gained by experience
 - Tribal Knowledge
 - Safe guard from loss
 - Encourages acquiring and sharing of knowledge



- Clearer understanding of the organization's context
- Aligning QMS policy and objectives with the strategy of the organization
- Explicit performance evaluation requirements
- Greater flexibility with documentation
- More compatible with services



- Old – Products;
 - New – Products and Services
- Old – Exclusions;
 - New – Scope of the QMS to be formally defined and all requirements are applicable if they are in the scope
- Old – Documentation, records, documented procedures;
 - New – Maintain (documents/procedures) and Retain (records) documented information
- Old – Purchased Product;
 - New – Externally provided products and services
- Old – Supplier;
 - New – External provider



- As a consequence of the new ISO 9001 structure:
 - 9100 additions have been relocated into appropriate ISO sections
 - The requirements are better organized and clarified
 - Notes and examples added to enhance understanding



- Added as a separate clause (8.1.3) and in selected areas
 - 7.3 – Awareness: personnel aware of their contribution to product safety
 - 8.1 – Operational planning and control: consideration of personnel and product safety
 - 8.4.3 – Information for external providers: ensuring persons are aware of their contribution to product safety
- Activities to consider:
 - Assessment of hazards and mitigation of associated risks
 - Management of safety critical items
 - Analysis and reporting of occurred events affecting safety
 - Communication of these events and training of personnel



- Added in a separate clause (8.1.4) and in selected areas
 - 8.4.2 - Type of Control for External Providers: These shall include inspection or period testing when there is high risk of nonconformities including counterfeit parts.
 - 8.4.3 – Information for External Providers: the need to prevent the use of counterfeit parts.
 - 8.7 – Control of nonconforming outputs: Counterfeit or suspect counterfeit parts shall be controlled to prevent reentry into the supply chain
- Activities to consider:
 - Training – awareness of design (parts obsolescence), procurement (parts acquisition), inspection (detect) and traceability (to OEM or authorized manufacturer)
 - Reporting – Monitoring reporting from external sources and quarantining and reporting incidences in appropriate reporting systems.



- Separate clause added (8.1.1)
 - Clause 6.1 – related to risk in “QMS of the organization”
 - Clause 8.1.1 – related to risk in Operational Processes
- Implement a formal process to manage risk
- Adapt the process to the organization and the product
- Deploy the risk analysis with the operation activities
- Requirements:
 - Assign of responsibilities
 - Definition of risk assessment criteria
 - Identification, assessment and communication of risks
 - Implementation and management of mitigation actions
 - Acceptance of risk remaining after implementation of mitigation



- Clause 7.3 The organization shall ensure that persons doing work under the organization's control are aware of:
 - Policy, quality objectives, contribution to effectiveness and implications of not conforming with QMS requirements
 - AS Additions
 - Relevant QMS documented information and changes
 - Their contribution to product or service conformity
 - Their contribution to product safety (remember flow down of this requirement from product safety discussion?)
 - The importance of ethical behavior



- Awareness activities:
 - Direct communication of expectations
 - Communication campaigns: posters, fliers, newsletters, video
 - Formal training
- What is expected?
 - Individuals should be able to explain their role
 - Quality basics (follow instructions, report events, records)
 - Know the use of product and potential impact of failure



- Included as a controlled condition under Control of Production and Service Provision – Clause 8.5.1 g
- Included as a consideration in the root cause analysis of nonconformities – Clause 10.2.1 b. 2
- Examples
 - Stress
 - Human Error and Reliability
 - Situational Awareness
 - Human-Machine Interaction
 - Teams and Communication



- Implementation Considerations
 - Determine the human factors to be considered according to the products, workplaces, equipment and people
 - Include elements to be reviewed during the root cause analysis of nonconformities
 - Capitalize with lessons learned on occurred human errors



- Organizations submit Transition plan to EAGLE by 1 Feb 2017
 - EAGLE must have signed agreement with each organization documenting acceptance of additional audit time
- Jan – Jun 2017 – Authenticated Auditor Upgrade Training
- June 15, 2017 – All Certification, Surveillance and Recertification audits must be to 2016 version of applicable standard
 - Transfers audits and special audits to close NCRs can still be conducted to old version of applicable standard
 - Audits to 2016 version of standards must use AS9101:2016



- All current Exclusions will be updated as part of the Transition audit.
 - The auditor will confirm applicability and reference the new section (e.g. Design 7.3. now 8.3)
 - All data bases will be updated as part of the report review process
 - EAGLE's EMIS system
 - OASIS system
- September 15, 2018 – All 9100/9110/9120:2009 certificates are no longer valid
- All Transition audits Shall use the OASIS report system for the audit



- Phase 1 released December 5, 2016
 - Auditors and clients need to log in and change password
 - Password requirements have changed

- Auditors (AS9100:2016 audits)
 - Cert Manager sets up audit in OASIS
 - AS9101 required forms will be completed in OASIS
 - NCR actions are now accomplished in OASIS
 - Only lead auditor can close NCRs
 - Lead Auditor must approve audit and submit to EAGLE



- Clients (AS9100:2016 audits)
 - Required to have database admin to approve access requests
 - Should be completed ASAP to avoid issues during audit planning
 - Will receive notice to check/verify site info when audit set up is complete
 - NCR response and closure completed in OASIS
 - Review reports on OASIS



- Available on IAQG website
 - <http://www.sae.org/iaqg/organization/9100.htm>
- Includes
 - Clause by Clause Presentation
 - Correlation matrices between 9100:2009 and 9100:2016
 - Frequently Asked Questions
 - Gap Assessment Worksheet
 - 9100 Evaluation Guidance Material



Questions

Thank You.