

AS9100C



Rod Bothwell
Executive Vice President



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Outline



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Biography



- Rod Bothwell has worked for a Fortune 100 company for many years. His functional responsibility included operations management, manufacturing, purchasing and materials, core process redesign, and most recently quality management.
- Technically, Rod enjoys mathematics and statistics. His green belt and black belt projects include: hardware reliability, feature churn, product safety / product liability, performance excellence, and core process redesign to list a few.
- He has published and presented papers at the 1996 Annual Reliability and Maintainability Conference in Las Vegas. In 1992, he presented at the Thirteenth IEEE / CHMT International Electronics Manufacturing Technology Symposium in Baltimore. In 1985, he published in Quality magazine a basic computer program for calculating the area under a normal curve.
- Within the American Society for Quality, Rod is a Fellow. He maintains a Certified Quality Engineer and a Certified Quality Manager certifications.



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The DESARA Group



We do:

- Business Improvement / Project Management
- Training
- Consulting
- MRP Implementation Project Management
- Supplier Management Assistance
- 6 σ Training, Coaching, Implementation

Business Performance

- Operational Improvement
- Scorecards
- Change Management
- Green / Black Belt Projects
- Strategy Planning
- Quality Strategy Planning
- Core Process Redesign
- Detail Process Maps for MRP Implementation

Our partners have over 100 years experience in quality, auditing, training, and consulting!



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Grant Funding Services Provided by The DESARA Group



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Course Objectives and Learning Outcomes



- The course objective is to provide:
 - Details on the changes in AS9100C (from AS9100B)
 - Details on AS9100C implementation
- The learning outcome is:
 - A clear understanding of the changes



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AS9100C Details



- Published January 2009
- 33 Pages total
- AS9100C incorporates ISO 9001:2008
- AS9100C Revisions
 - 6 Additions
 - 8 Revisions/Relocations
 - 3 Deletions



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Associated Standards



AS9100 Rev C (Jan/09)

- Quality Management Systems - Requirements for Aviation, Space and Defense Organizations

AS9101C (Jul/06)

- AS9100 Quality System Assessment Checklist. The standard defines the content and the presentation of the Assessment Report for the AS9100 standard.

AS9102 (Jan/04)

- Aerospace First Article Inspection Requirement for AS9100 (FAI). This standard establishes documentation requirements for the First Article Inspection

AS9103 (Oct/01)

- Variation Management of Key Characteristics



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Associated Standards (Continued)



ISO 10007 (Jun/03)

- Quality management systems - Guidelines for configuration management

AS9110 (Jan/03)

- Aerospace Requirements for Maintenance Organizations. This standard specifies requirements for a quality management system for aerospace maintenance organizations.

AS9111 (Feb/05)

- Quality Management System Assessment for Maintenance Organizations

AS9120 (Oct/02)

- Aerospace Requirements for Stocklist Distributors. This standard specifies requirements for a quality management system for the aerospace industry applicable to Stocklist distributors.



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Associated Standards (Continued)



AS9121A (Sep/07)

- Stocklist Distributors Quality Systems Questionnaire Associated with AS9120. This standard defines the content and the presentation of the Assessment Report for the 9120 standard.

ISO 9001:2008

ISO 9004:2000

- Quality management systems - Guidelines for performance improvements (ISO 9004); Trilingual version EN ISO 9004

ISO 14001:2004 Standard (environmental)

- Environmental management systems - Requirements with guidance for use. Edition: 2nd



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Frequently Asked Questions



- Who is responsible for updating the AS9100 standard?
 - The International Aerospace Quality Group (IAQG) is responsible for the development and maintenance of the AS9100 standard. For further details contact AS9100 team via the IAQG website.
- How can you tell the difference between the ISO 9001:2008 text and the AS9100 text?
 - The bold, italic text represents the aviation, space and defense specific additions.
- Where can I find more information about the IAQG and the standards it has published?
 - The International Aerospace Quality Group website is located at <http://www.iaqg.sae.org/iaqg/>.



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Frequently Asked Questions (Continued)



- Why change the AS9100 standard?
 - Incorporate ISO 9001:2008 changes
 - Expand scope to include land and sea based systems for defense applications
 - Ensure alignment with IAQG strategy (on-time, on-quality performance)
 - Adopt new requirements based on stakeholder needs
 - Improve existing requirements where stakeholders identified need for clarification, including when a documented procedure is required.



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Frequently Asked Questions (Continued)



- **What is the difference between Key Characteristics, Special Requirements and Critical Items?**
 - **Special Requirements** are those requirements that have high risks to being achieved, hence requiring their inclusion in the risk management process.
 - **Critical Items, including key characteristics,** are those items that have significant effect on the product realization and use of the product, and hence require specific actions to assure they are adequately managed.
 - **Key Characteristics** includes an attribute or feature whose variation has a significant effect on product fit, form, function, performance, service life or producibility, that requires specific actions for the purpose of controlling variation.
- **How long will we have to transition to AS9100C?**
 - 30 months. Companies will be encouraged to upgrade during their scheduled audit cycle.



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AS9100C Changes



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Clause 1

Scope and Application



- Revision:
 - Scope extended to include Defense as well as Aviation and Space
 - Application guidance provided when AS9100, AS9110, and AS9120 are appropriate for use
- Rationale:
 - The AS9100 based QMS is applicable to other complex systems and would receive benefit from implementation including land based applications and sea based applications



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Clause 3.1 Risk



- Addition: Define new term “risk”
 - An undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.
- Rationale:
 - The understanding of risk is important for an organization to develop a proactive quality management system



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Clause 3.2 - Special Requirements



- Addition: Define new term “special requirements”
 - Those requirements which have high risks to being achieved thus, requiring their inclusion in the risk management process.
 - Factors used to determine special requirements include:
 - product or process complexity
 - past experience
 - product or process maturity.
 - Examples include:
 - performance requirements imposed by the customer that are at the limit of the industry’s capability
 - requirements determined by the organization to be at the limit of its technical or process capabilities



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Clause 3.3 – Critical Items

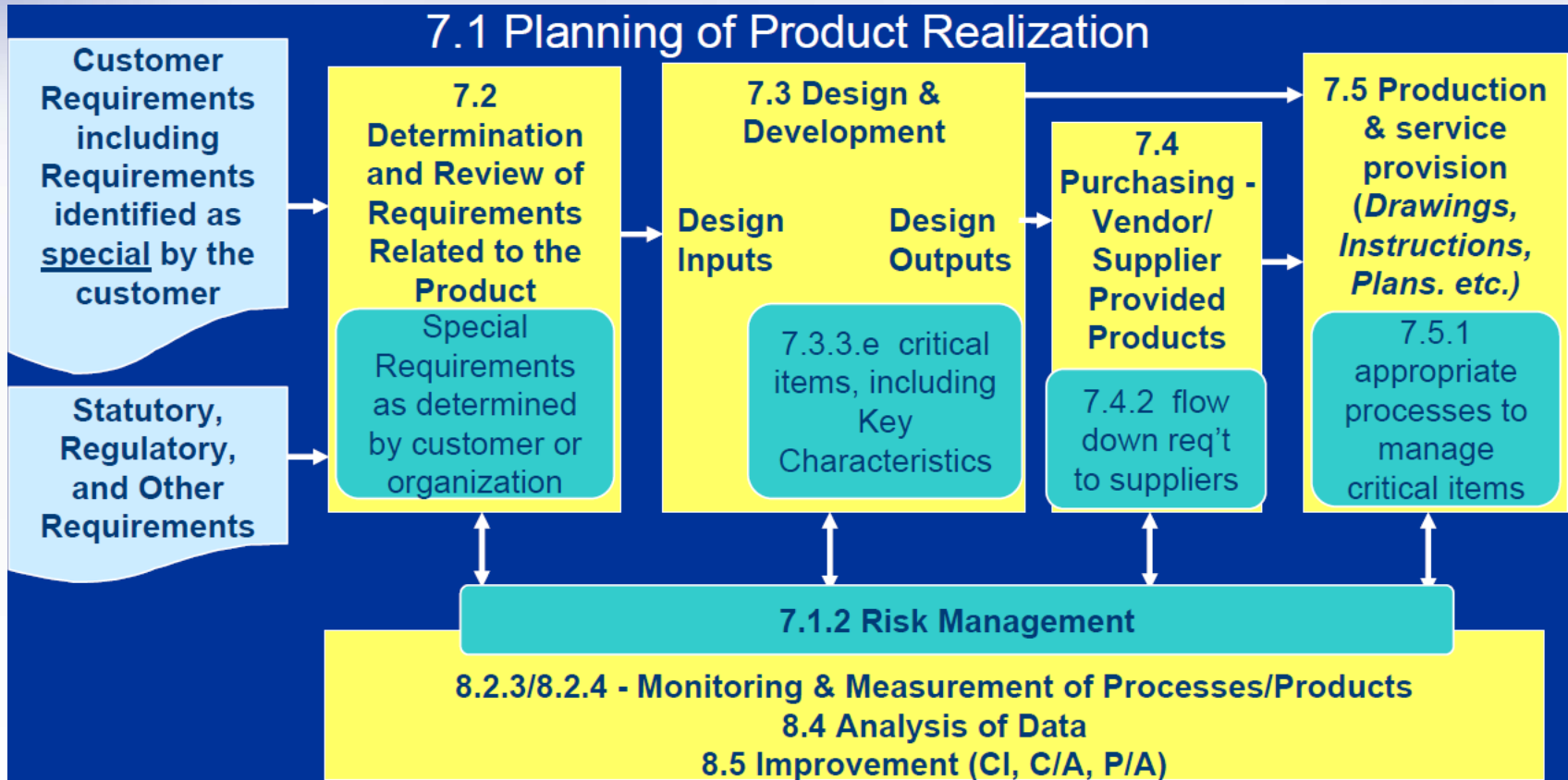


- Addition: Define new term “critical item”
 - Those items (e.g., functions, parts, software, characteristics, processes) having significant effect on the product realization and use of the product; including safety, performance, form, fit, function, producibility, service life, etc. that require specific actions to ensure they are adequately managed.
 - Examples of critical items include:
 - safety critical items
 - fracture critical items
 - mission critical items
 - key characteristics



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Requirements, Critical Items, Key Characteristics, and Risk Management process:



Clause 4.1 – QMS General requirements



- Revision/Relocation:
 - The organization's QMS shall address customer and applicable statutory and regulatory QMS requirements
- Rationale:
 - Clarify that the requirement is placed at the QMS level and not only at the documentation level



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Clause 4.2.2 – Quality Manual Relationships



- Deletion:
 - Requirement to create a document showing the relationship between AS9100 requirements and the organizations documented procedures
- Rationale:
 - Requirement adds no value to assuring product quality.
 - Requirement was viewed as prescriptive in that it specifies a particular method of assuring the requirements of the standard have been met.



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Clauses 5.2 / 8.2.1 – Customer Focus /Satisfaction



- Addition:
 - Top management shall ensure that product conformity and on-time delivery performance are measured and that appropriate action is taken if planned results are not, or will not be, achieved. (5.2)
 - Information to be monitored and used for the evaluation of customer satisfaction shall include, but is not limited to:
 - product conformity
 - on-time delivery performance
 - customer complaints
 - corrective action requests
 - Organizations shall develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results. (8.2.1)



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7.1.1 – Project Management



- Addition:
 - New requirement for planning and managing product realization in a structured and controlled way to meet requirements at acceptable risk, within resource and schedule constraints.
- Rationale:
 - Most aviation, space and defense products are complex and involve multi-tier partners and suppliers
 - This clause provides additional focus on upfront planning and the management of project plans throughout product realization



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7.1.2 - Risk Management



- Addition:
 - New requirement to implement a risk management process applicable to the product and organization covering: responsibility, criteria, mitigation and acceptance.
 - The concept of risk is integrated within the revised AS9100.
- Rationale:
 - Risk Management was placed in clause 7.1.2 to provide additional focus on product risk during product realization.



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7.1.3 – Configuration Management



- Revision/Relocation:
 - Moved from Clause 4.3 to 7.1.3.
 - Structured in line with ISO 10007 requirements
- Rationale:
 - Focuses configuration management on the product and how it is sustained throughout product realization
- Implementation/Audit Considerations:
 - Some level of configuration management is expected for all products at all levels of the supply chain in compliance with exclusion criteria (see clause 1.2).



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7.1.4 – Work Transfer



- Revision/Relocation:
 - Moved from clause 7.5.1.4 (Production) to clause 7.1.4
 - The organization must have a process to plan and control the transfer activities
 - Expanded to cover permanent transfer (e.g. from one organization to another, from one organization to supplier, from one supplier to another).
- Rationale:
 - Work transfer can occur at anytime during product realization
 - Addresses problems that often occur during work transfers



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Clause 7.4.1 – Recognition of Supplier Quality Data



- Revision:
 - Added note to recognize that one factor that may be used during supplier selection and evaluation is objective and reliable data from external sources
- Rationale:
 - Recognition that the industry trend is to use externally provided supplier performance data (e.g. Online Aerospace Supplier Information System –OASIS, Nadcap)



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Clause 7.4.1 – Approval status for suppliers



- Revision:
 - Added and provided examples of “approval status”(e.g. approved, conditional, disapproved) and examples of “scope of approval”(e.g. product type, process family).
 - The organization must define the process for suppliers approval status decisions or changes.
- Rationale:
 - Clarify that the conditions for using a supplier depends on its approval status



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Clause 7.4.3 – Validation of Test Reports



- Deletion:
 - Where the organization utilizes test reports to verify purchased product, the data in those reports shall be acceptable per applicable specifications. The organization shall periodically validate test reports for raw material.
- Rationale:
 - Misunderstood concept that was frequently misapplied
 - Requirement was prescriptive, not applicable to all stakeholders (especially small organizations) and for all types of products, and was subject to varying interpretation.



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Clause 7.5.1.1 – Production Process Verification



- Revision/Relocation:
 - Moved from 8.2.4.2 (measurement) to 7.5.1.1 (production)
 - Requirement to verify the production processes, documentation and tooling are capable of producing parts and assemblies that meet requirements. This process shall be repeated when changes occur that invalidate the original results(e.g. engineering or manufacturing processes changes, tooling changes).



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Clause 8.2.2 – Detailed Tools and Techniques



- Deletion:
 - “Detailed tools and techniques shall be developed such as check sheets, process flowcharts, or any similar method to support audit of the quality management system requirements.
 - The acceptability of the selected tools will be measured against the effectiveness of the internal audit process and overall organization performance.”



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Clause 8.2.4 – Sampling Inspection



- Revision:
 - When the organization uses sampling inspection as a means of product acceptance, the sampling plan shall be justified on the basis of recognized statistical principles and appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability).
- Rationale:
 - Numerous requests were received to improve clause 8.2.4. The comments ranged from that it was statistically inaccurate, to that it was too prescriptive.



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Proposed AS9100C Implementation Schedule



Maximum 30 month Implementation from Publication



AS9101D
expected to be
published July
2009.

Recommended Next Steps



- Get copies of AS9100C
- When AS9101D is published, get copies
- Evaluate compliance and effectiveness of the requirements that changed



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Feedback on This Presentation



- Feel free to send comments on the presentation and material to info@DesaraGroup.com
- How was the:
 - Presenter?
 - Material (content)?
 - Audio / video / internet?



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Q & A



Thank you very much



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