AEROSPACE QUALITY MANAGEMENT SYSTEMS

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Internationally Agreed Implementation Processes

AS/EN/JIS Q 9100

Int’l Rqmts & Company Rqmts

Quality System Requirements - International Standard ISO 9001

Common Aerospace Quality System Requirements - International Requirements 9100

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Aerospace Quality Standards
Numbering System

- **International Standards - 91xx**
  - Are planned for harmonization across all 3 aerospace sectors and are recognized globally

- **Americas Standards - 90xx**
  - Are published for use by AAQG, may become an 91XX standard at a later date

- **“AS” Standards - Americas**
  - Published by Society of Automotive Engineers

- **“EN” Standards - Europe**
  - Published in Europe by AECMA

- **“JIS Q” or “SJAC” is the Japan / Asia Equivalent**
Aerospace Quality System Standards

- INTERNATIONAL STANDARDS
  - 9100 - Quality System for Aerospace Manufacturers
  - 9102 - First Article Inspection
  - 9103 - Management of Key Characteristics
  - 9104 – Requirements for Registration of AQMS
  - 9110 - Quality System for Aerospace Repair Stations
  - 9120 - Quality System for “Pass-Through” Distributors
  - Special Process Approval
Why 9100?

- To standardize Aerospace quality expectations on a global level
- To achieve improvements in quality and reduce costs throughout the value stream
- ISO 9000 model for quality does not capture regulatory requirements or importance of safety, reliability or maintainability
- Captures aerospace supplements agreed to at an international level
9100:2001 conforms to 9001:2000
Model of a process based quality management system

Continual Improvement of the Quality Management System

CUSTOMER

Requirements

Management Responsibility

Management Responsibility

Product Realization

Value added activities

Information Flow

Product

output

Satisfaction

CUSTOMER

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9100 Specifics (where ISO 9001 implies – 9100 requires)

ISO 9001:
• Generic quality management system standard - applicable to anvils to airplanes

9100: (9100:2001)
• Includes all ISO 9001 requirements
• Adds the expectations of the aerospace industry for a robust quality management system for aerospace products

Continuous Improvement:
• Continuous improvement processes shall include provision for using the quality policy, quality objectives, audit results, measurement and analysis of data, variability reduction, corrective and preventive action, and management review (all but variability reduction are part of 9001:2000 requirements)
ISO9001 versus 9100

- 9100 version is formatted to match ISO 9001:2000 and added “requirements” that provide for -
  - Regulatory organizations interfaces
  - Configuration Management
  - Design and Development V& V., & V&V testing
  - Control of changes in Production Process
  - Control of production equipment, tools, NC machines
  - Control of work in outside facilities
  - Control of service operations
  - First Article Inspection
  - Inspection documentation

- These added requirements enables a standardized approach to supplier flow down requirements
• Requirements of regulatory authorities must be included in documentation
  – Including access by authorities to the records, documentation and change approval (as req’d)

• Must show relationship of 9100 standard to lower level procedures

• Documented procedure for records control

• Requires Configuration Management for the product / process
9100: Product Realization (ISO Clause 7)

- **Design and Development output includes:**
  - Identification of Key Characteristics (FMECA)
  - All necessary data to manufacture the product
  - Gated Design Reviews
  - Documentation of both Design Verification and Design Validation (reports / calculations / etc.)
  - Design Verification and Validation testing

- **Design Change Control**
  - Includes customer and regulatory approval as necessary
9100: Product Realization (ISO Clause 7)

- **Purchasing**
  - Responsible for all suppliers (incl. customer designated ones)
  - Must have a list of suppliers
  - Supplier performance review process
  - Control of special process sources
  - Whoever approves a supplier, can disapprove them as well
  - **Stringent flow down requirements - sub-tier**
    - Notification of nonconformance / process change
    - Right of access by customer and regulatory personnel
9100: Product Realization (ISO Clause 7)

- **Planning for Production and Service:**
  - Control plans and process controls
  - In-process verification for hidden features
  - Design of tooling for variable measurements

- **Controlled Production**
  - Accountability of product during manufacture
  - Evidence all operations are complete
  - FOD control
  - Monitoring of environmental influences
  - Criteria for workmanship
  - Use of approved data and specified tooling with instructions

Note: AS9000 / 9100 section 2 phase out December 15, 2003
Certificates are expected to expire in line with ISO 9001 requirements
Does NOT mean that “approvals” are invalid

Aerospace Supply Chain

**Tier 1**
Vehicle / Airframe / Propulsion Manufacture

**Tier 2**
Integrators / Source Control / Software Dev. / Major Assemblies

**Tier 3**
Integrators / Source Control / Specialty Electronics / Wiring / Components

**Tier 4**
Make to Print / Machine Shops / Processors

**Tier 5**
Distributors (Fasteners, Raw Materials, Commodities, Adhesives, Special Materials)

**Tier 6**
Raw Materials (Castings, Forgings, Sheet, etc)

Variation Reduction

Special Processes

9100

9102

9103

9110

MR&O

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9100 Introduces Two important Concepts for Aerospace

• First Article Inspections
  – **Always required**
  – 9102 is mentioned for Guidance
  – 9102 is only mandatory when specifically required in contracts

• Key Characteristics
  – **When specified**
  – 9103 is referenced for guidance
  – 9103 is only mandatory when specifically required in contracts and key characteristics are identified
• FAIs apply:
  – to assemblies and all levels of parts within an assembly, including castings and forgings
  – **Suppliers responsible for ensuring that characteristics conform to Customer requirements**
  – Sub-tier suppliers and processors of parts and materials for suppliers
What is Included in First Article Inspection?

• **Verification of All Design Characteristics:**
  - Dimensional Verification via Marked-up (or “Ballooned”) Drawings that Correlate Characteristic Number from FAI to the Drawing.
  - Part Marking

• **Material and Special Process Certifications**
  - Including Operator Certs (e.g. NDT, Welding)

• **Manufacturing Process Verifications**
  - Manufacturing Routing Sheets.
  - Referenced Exhibits Supporting the FAI (e.g. CMM Data Printouts, Test Data, Acceptance Test Procedures, Process Certifications, etc.).
  - Process Capability Studies, As Applicable.
  - Gauge Correlation, As Applicable.
  - Tooling Traceability, If Tooling Is Used to Verify Design Characteristics

• **Nonconformance Resolutions**
9102 First Article Inspection

• Any 9100 compliant organization in absence of a contractual requirement to use 9102 or other specific FAI customer requirement, can devise any methods and processes it chooses to meet the requirements of this clause and the "extent" of an FAI is also at the discretion of the organization as along as it is applied to each "new part" and subsequent changes thereto.

• New part means – Parts, sub-assemblies and assemblies, however FAI’s are progressive
Variation Management of Key Characteristics will provide a common standard for expectations for KC’s within the aerospace industry.

Key Characteristic (9100): The features of a material or part whose variation has a significant influence on the fit, performance, service life, or manufacturability.

- Dimensional features - thickness, diameter, length, etc.
- Chemical concentrations
- Time, Pressure, speed, rates, temperature, etc.
Intent to drive the improvement of the manufacturing processes through adequate planning and effective management of Key Characteristic variation.

- Methodology for component/process proving focused on Key Characteristics.
  - Understanding processes
  - Using appropriate tools
  - Demonstrating acceptable process capabilities
  - Guidelines for reporting process capability data to primes.
Process Based Variation Management of Key Characteristics (9103)

1. Understand Key Characteristics
2. Plan a manufacturing process
3. Operate the process
4. Analyze data

Continue to monitor performances

Is a process change required?

No

Yes

Take action from study

Output for each stage.
Report to a common form.
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Variation Reduction
9102
9103

Special Processes
9110
MR&O

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9120 Distributor Quality System

- 9120 developed and implemented for “pass through” stockists / distributors that handle parts and supplies that are used in aerospace products
  - Checklist 9121 is also available
  - Based on 9100, but only applies necessary system requirements.
  - Expected flow-down requirement
  - Registration plans are available (just begun)
Aerospace Supply Chain

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Variation Reduction
9102
9103

9110
MR&O

Special Processes

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9110 Repair Station Quality System

• Why 9110?
  – Manufacturers want a Quality Management System flow-down requirement for their MR&O activity
  – Manufacturers want reputable suppliers that have repair station approvals and a defined quality system
  – There is a need to put all of the expectations in one document for Maintenance, Repair and Overhaul organizations
  – Military is very interested in having defined Quality System requirements for MR&O
9110 Repair Station Quality System

- 9110 developed and implemented in facilities that perform maintenance & repair of aerospace products
  - Based on 9100 requirements and FAA / JAA - 145 requirements (new version)

- Corresponding 9111 checklist has also been developed

- Registration plans are in development and expect full implementation in 2004
Aerospace Supply Chain

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• 7.5.2 Validation of processes for production and service

• ...processes ...where the resulting output cannot be verified by subsequent monitoring or measurement.

*NOTE: These processes are frequently referred to as special processes.*

• ...demonstrate the ability of these processes to achieve planned results.

• ...establish arrangements for these processes including, as applicable

• a) defined criteria for review and approval of the processes,

  *qualification and approval of special processes prior to use,*

• b) approval of equipment and qualification of personnel,

• c) use of specific methods and procedures,

  *control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto,*

• d) requirements for records (see 4.2.4), and

• e) revalidation.
Special Process Approval

Objectives

- **To put in place industry controlled process for meeting requirements of 9100 clause 7.5.2**
  - Supplier processes are an extension of the OEM processes

- **To reduce redundant audits for the special process at suppliers and improve the global quality level**
  - Common requirements (auditors and audit questionnaires)
  - Harmonized assessment process
  - Data exchange
  - Demonstrated industry managed process
  - Process oversight
  - Mutual system recognition
Each geographic region or area is establishing a system, based on a set of agreed criteria, which defines how 9100 will be implemented.

The IAQG will have agreed and compatible systems acceptable to all, which allows sharing of audit results and approvals resulting in multiple assessment reduction and process improvement.
What is the Goal of the System?

The goal of the system is for a supplier to receive one aerospace quality systems approval that will be acceptable to all aerospace OEMs throughout the world.

The key element in this is **confidence**. The aerospace OEMs must have confidence in the approvals being performed on a global basis.

All Aerospace organizations will be able to take advantage of the system for supplier control purposes.
International Requirements for Certification / Registration

- Oversight/control by IAQG and Sectors
- Single global standards 9100
- Harmonised systems of application
- Inter-National Accreditation control
- Approved Cert. Bodies & Registrars
- Approved Aerospace Auditors
- Inter-National Aviation Authority endorsement
- One audit accepted by all Primes
- Active Industry participation
- Data easily available to all participants
- Global acceptance by supplier base

International Aerospace Supplier Quality System Evaluation/Certification

Oversight/control by IAQG and Sectors

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Important Considerations about Certification / Registration

- Industry Controlled Process
  - Includes requirements for AB’s and CRB’s
  - Includes requirements for auditors
    - Training requirements are stated
  - Includes requirements for reporting results of audits
  - Includes minimum audit times and guidelines

- Industry involvement
  - Must require suppliers to notify OEM’s of status of Registration and any changes thereto
  - Must report problems with Registrars
  - Track suppliers vs. Registrars vs performance
O.A.S.I.S. - Database

- **On-line Aerospace Supplier Information System**
- **Went “Live” 1 July 2003**
  - Assessments are entered by CRB’s
- **Assessment results are to be entered when performed or can be entered now for assessments prior to 1 Jul 03**
- **Organizations can access information now**
- **Restricted access to data**
The database is essential to provide independent verification of the status of certification, thereby validating the entire other party process to stakeholders.

Enables the acceptance of a single assessment globally thus preventing multiple visits / audits by multiple stakeholders.

Without the database OEMs would have to independently verify each auditor, CRB and assessment results.
OASIS Benefits

- **Customers / OEM’s / Suppliers**
  - Provides Up-to-date and complete information on Aerospace QMS approvals, with data on Who, How, When and What is Approved, including results.

- **AB’s / CRB’s / Auditors**
  - Current information on Who is Approved and for What by the Aerospace Industry

- **NAAs / DoD’s and Space Agencies**
  - Complete oversight information available in one source with no conflicting information (i.e. multiple data entries)
OASIS Benefits

• **OASIS should be part of the OEM / Supplier’s process of supplier management**
  - The database should allow a supplier to be added to an ASL without additional showing of QMS approval
  - OEMs need to insist that suppliers be listed in OASIS
  - Available to entire Aerospace Supply Chain

• **Fee for every INITIAL certification/registration into the IAQG-OASIS database – invoiced via the CRB.**
  - The recurring fee for reassessment (normally in 3 years) – WILL BE LESS

“If a database entry saves 1 Day of an OEM / supplier’s time in a QMS audit it will be worth the fee”
Industry Leaders are Listening

- Agreed to improve the overall approach to quality
- Major Aerospace Companies have agreed upon Quality Management System approval approaches
- A key objective is to improve performance and reduce the number of audits
- There are significant benefits to the entire Aerospace Industry supply chain
- International approach is based on agreed standards, harmonization of system application and shared information