Understanding the Key Changes to: ISO 9001:2015, AS9100D, and AS9101E – Auditing Standard
ABS Group Organizational Overview

ABS Group is a wholly-owned subsidiary of ABS, the world’s leading marine and offshore classification society, founded in 1862.
ABS Group Overview

ABS GROUP REGIONS
Americas / Europe / Middle East / West Africa / Asia Pacific / Australia

MARKET SECTORS
- Offshore
- Oil, Gas & Chemical
- Maritime
- Government
- Power

SERVICE LINES
- Technical Inspection
- Safety, Risk and Compliance
- Asset Performance Optimization
- Advanced Engineering
- Management System Certification
An Overview Of The Key Changes
Topics for Overview

- **ISO 9001:2015 & AS9100D:2016**
  - ISO9001 Background
  - ISO 9001 Revision Activities – Why Change?
  - ISO 9001 and AS9100 Relationship
  - Transition Timelines
  - AS9100D Revision Activities – Why Change?
  - Summary
ISO 9001 needs to change, to:

- Adapt to a changing world
- Enhance an organization's ability to *satisfy its customers*
- Provide a consistent foundation for the future
- Reflect the increasingly complex environments in which organizations operate
- Ensure the new standard reflects the needs of all *interested parties*
- Integrate with other management systems
Key Changes

- High level structure (HLS) and terms/definitions
- More efficient to address multiple management system requirements
- Standardized core definitions
- There is now greater emphasis on:
  - The customer
  - Risk-based thinking
  - Greater flexibility with documentation - The term documented information replaces the terms document and record
  - Preventive action is throughout the standard as risk identification and mitigation
  - Control of externally provided products and services replaces purchasing/outsourcing
ISO 9001:2015 Revision Activities

4 Context of organization
5 Leadership
6 Planning
7 Support
8 Operation
9 Performance and Evaluation
10 Improvement

8.1 Operational planning and control
8.2 Determination of requirements for products and services
8.2.1 Customer communication
8.2.2 Determination of requirements related to products and services
8.2.3 Review of requirements related to products and services
8.3 Design and development of products and services
8.3.1 General
8.3.2 Design and development planning
8.3.3 Design and development Inputs
8.3.4 Design and development controls
8.3.5 Design and development outputs
8.3.6 Design and development changes
8.4 Control of externally provided products and services
8.4.1 General
8.4.2 Type and extent of control of external provision
8.4.3 Information for external providers
8.5 Production and service provision
8.5.1 Control of production and service provision
8.5.2 Identification and traceability
8.5.3 Property belonging to customers or external providers
8.5.4 Preservation
8.5.5 Post-delivery activities
8.5.6 Control of changes
8.6 Release of products and services
8.7 Control of nonconforming process outputs, products and services
8.8 Determination of requirements for products and services
8.8.1 Customer communication
8.8.2 Determination of requirements related to products and services
8.8.3 Review of requirements related to products and services
8.9 Design and development of products and services
8.9.1 General
8.9.2 Design and development planning
8.9.3 Design and development Inputs
8.9.4 Design and development controls
8.9.5 Design and development outputs
8.9.6 Design and development changes
8.10 Control of externally provided products and services
8.10.1 General
8.10.2 Type and extent of control of external provision
8.10.3 Information for external providers
8.11 Production and service provision
8.11.1 Control of production and service provision
8.11.2 Identification and traceability
8.11.3 Property belonging to customers or external providers
8.11.4 Preservation
8.11.5 Post-delivery activities
8.11.6 Control of changes
8.12 Release of products and services
8.13 Control of nonconforming process outputs, products and services

ABS Group
ISO 9001:2015 Revision Timeline

2013

June 2013 CD
(Committee Draft)

2014

May 2014 DIS
(Draft International Standard)

2015

July 2015 FDIS
(Final Draft International Standard)

September 2015
Published International Standard
ISO 9001:2015 Transition Timeline

ISO 9001:2015 Timeline

- September 2015 start of 3 years transition period to September 2018
- Certifications to ISO 9001:2008 will no longer be valid after September 2018

September 2015
Published International Standard
AS9100D:2016 Transition Timeline

Follows the ISO9001:2015 transition timeline once released - mandatory transition date is September 2018
Partnership between ISO 9001 and AS9100?

• Goal is for 90% of the tier 1 aerospace supply chain to be AS9100 certified
• It is recognized that lower tier suppliers do not always need the rigor of AS9100 based on their complexity of work
• Certification to AS9100 can be as a dual certification with ISO 9001
• Having ISO 9001 as the baseline to AS9100 helps maintain QMS continuity across the Aviation, Space & Defense (ASD) supply chain
• ASD Industry can and will add additional Industry requirements as needed in addition to ISO9001 when needed.
Why Revise AS9100?

AS9100 needs to change, to:

• Incorporate changes made by ISO TC176 to the embedded ISO 9001 standard
• Consider Aviation, Space and Defense stakeholders’ needs identified since the last revision
• Consider clarifications to 9100 series requests issued by IAQG since the last revision (Resolutions / Frequently Asked Questions)
Key Changes

- Product Safety added in carefully selected areas.
- Human Factors added as a consideration in Nonconformity / Corrective Action.
- Risk merged current 9100 requirements with the new ISO requirements and emphasis on Risks in Operations.
- Preventive Action current clause requirements absorbed into Risk & Opportunities and Nonconformance & corrective action clauses, 9100 additions reinforce prevention.
- Counterfeit Products enhanced in carefully select areas and limited new requirements.
- Configuration Management clarified and improved considerably to address stakeholder needs.
Key Changes

- Product Realization & Planning clarified and enhanced planning throughout the standard
- Post Delivery Support merged current 9100 requirements with the new ISO requirements
- Project Management & Work Transfer combined with Operation Planning clause to address user interpretation issues
- Design Development and Supplier Management gap analysis - ISO text has been added back in a few places to meet the IAQG needs
- Quality Manual note added pointing to the requirements that make up a Quality Manual or the equivalent
- Management Representative requirement added back in for QMS oversight
Organizations are recommended to take the following actions:

- identify organizational gaps which need to be addressed to meet new requirements,
- develop an implementation plan,
- provide appropriate training and awareness for all parties that have an impact on the effectiveness of the organization,
- update existing quality management system (QMS) to meet the revised requirements and provide verification of effectiveness,
- where applicable, liaise with your certification body for transition arrangements.

**NOTE:** users should be aware that at Draft International Standard (DIS) stage technical changes may still occur, therefore it is recommended that, while preparation can be carried out at DIS, significant changes should not be implemented until the Final Draft International Standard (FDIS) is issued and the technical content is finalized.
Implementation Benefits

- When implemented and managed well:
- Organization will produce and continually improve safe and reliable products
- Meet or exceed customer and regulatory requirements to ensure satisfaction
- Processes necessary to conduct day-to-day business are defined and managed
- Documentation accurately reflects the work to be performed and actions to be taken
- Focus on the complete supply chain and stakeholders
- Fewer customer unique documents
- Recognized by Regulatory Authorities
AS9101E
Auditing Standard
Changes Overview
AS 9101E (2013) Revision – Revision Overview

- Team Membership
- Why is 9101 important? Why do we care?
- 9101E Key Change Summary – What is different?
  - Changes to the methods for recording objective evidence
  - Changes to the NCR, PEAR and Process Evaluation Matrix forms
  - Definitions
IAQG 9101 Writing Team Member Companies

**Industry Representation**

- Rolls Royce
- PFW
- GKN Aerospace
- Safran
- Zodiac
- Lockheed Martin
- United Technologies
- Mitsubishi Heavy Industries

**CB Representation**

- *ABS Quality Evaluations*
- Bureau Veritas Certification
- Det Norske Veritas
- Japan Quality Assurance
- Lloyd’s Register Quality Assurance

*IAQG 9101 is a document of international consensus*
• Better alignment with ISO 17021 and the IAQG’s AS 9104-1 rule standard.

ASD Industry learned valuable lessons:

- Previous AS9101 version changed the focus from *conformance* to *effectiveness*; AS9101E attempts to create a balance
- The Industry was looking for a more efficient way to record objective evidence
- There was a need to remove “hidden” requirements from AS9101 forms instructions
Why Are Audits Important To Your organization?

- Defined processes and sequencing offers better repeatability and predictability
- Processes measurements can be used to:
  - Determine health of QMS processes
  - Identify waste and improvement opportunities
  - Manage consumer and producer risks
- AS9101E defines how these processes will be assessed by third party auditors in a standardized manner
- This is how we will all be measured by our auditors and customers
  It is good to be knowledgeable of the auditing requirements to support the conduct of the audit
- Understanding the requirements can help organizations understand what their certification body auditors are looking for
AS9101E Key Changes

- Specific call out of ISO/IEC17021 requirements by clause number e.g.
  - 4.2.2.4 Audit Conduct - “The requirements of ISO17021 clauses 9.1.9.3 thru 9.1.9.5 apply. In addition, the audit shall be conducted ………”

- Incorporation of AS9104/1 requirements including the new certification structures (single site, multiple site, several sites, campus, and complex)

- Defined audit approaches

- General improvements to Audit Reports
Updated the methods for recording of objective evidence:

- Objective Evidence Report (OER) no longer required
- Objective Evidence is recorded on PEAR reports for QMS processes that are directly related with Product Realization
- Objective Evidence is recorded on QMS Matrix for QMS processes audited that are not directly related with Product Realization
- Completed audit forms will be posted on OASIS – can be implemented by all organizations (not just a third party audit process)
Now structured into (4) Sections

- Section 1 - Process Details: Inputs, Activities, Outputs and Interactions
- Section 2 – Process Results includes the identification of performance measures and KPIs.
- Section 3 - Process Realization summarizes audit trails and sources of evidence (formerly recorded on the OER).
- Section 4 – Process Effectiveness includes an evaluation matrix (to be used after a process has been assessed).
AS9101E Key Definitions

- **Effectiveness?**
  - Extent to which planned activities are realized and planned results achieved

Source: ISO 9000-2005
AS9101E Key Definitions

• **Planned Activities?**
  - The means, methods and internal requirements by which an organization intends to achieve planned results of a given process to meet customer requirements

Planned activities include conformity to process requirements and procedures.

• **Planned Results?**
  - The intended performance of a process, as defined and measured by the organization

Planned results include product conformity (Quality) and On-time delivery (OTD) to meet customer requirements, and may include other elements as defined by the organization.
Process Evaluation Matrix (PEM)

**Table 3 - Process Evaluation Matrix**

<table>
<thead>
<tr>
<th>Process Realisation (a)</th>
<th>Planned activities fully realised</th>
<th>Planned activities not fully realised</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONFORMANCE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EFFECTIVENESS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PERFORMANCE</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Designed to aid the auditor in determining process effectiveness level.
- Understanding if appropriate action is being taken is key.
Summary

• The OER is no longer a mandatory form to be completed by the auditor: Objective Evidence will be recorded on the PEAR and the QMS Process Matrix
• The definitions of planned activities and planned results are added to support the definition of effectiveness
• PEM added to standardize and add clarity to effectiveness levels
• Forms will no longer be part of the standard and will appear online
Questions?

Please stop by our booth for additional literature or if you have additional questions from today’s presentation.

Thank you all very much for attending this presentation!
Understanding the Key Changes to: ISO 9001:2015, AS9100D, and AS9101E – Auditing Standard

Paul Dionne, Manager, Global Aerospace Programs
ABS Quality Evaluations
pdionne@abs-qe.com