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EAGLE Transition Training ISO 9001:2015

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ISO 9001:2015 Timeline

- Standard published on September 15, 2015
- EAGLE has submitted the ANAB Application – Accepted Plan
- EAGLE QMS Auditors become 2015 approved by January 31, 2016 (or prior to first 2015 audit)
- Transfers to 2008 will not be accepted after January 1, 2018, unless operations approved
- Transitions audits must occur no later than June 1, 2018

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Certificates

- No new certificates to 2008 after January 1, 2017
- ISO 9001:2008 certificates will become **obsolete** September 15, 2018
- EAGLE 9001:2008 certificates printed after September 15, 2015 will have an expiration date, no later than September 15, 2018

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Existing Clients

- Discuss with Certification Manager timing for when they want their transition audit
- Complete the **Transition Questionnaire**
- EAGLE office to help determine additional time needed for the transition based on the Questionnaire
- Audit Plans will include a Change/Follow-up note
- **Client must complete before transition audit:**
  - Internal Audit to ISO 9001:2015 or incorporated changes
  - Management Review covering implementation status of ISO 9001:2015

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Training

EAGLE Auditors and Clients

- On-line Transition Training (IAAR/Exemplar)
  - Focuses only on the changes in the standard
  - Training Link: www.iaar-training.org
- On-line EAGLE Training (this session)
  - Focuses on EAGLE process
  - Recording to post on EAGLE website October 16, 2015
  - Same session for both auditors, clients and staff

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Transition Audit Time –No major Changes

If a Gap Assessment to ISO 9001:2015 is completed and the current system is maintain without major changes:

- Off-Site
  - Add .25 day review to include the Gap Assessment results and risk documentation
- On-Site
  - At RE no additional time added
  - At SA additional .5 day added
  - Standalone = 1 day minimal

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Transition Audit Time –Major Changes

If **major changes** to documentation or system, rewrite to new format:

- Off-Site
  - Add .5 day review of documentation and changes
- On-Site
  - At RE or SA an additional .5-1 day will be added
  - If standalone an 1-2 days

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New ISO 9001:2015 Clients

- Audit time will be calculated the same as a 9001:2008 new client
- All new clients will be audited to 2015 as of January 1, 2017

Gap Assessments

- Gap Assessments are available for clients uncertain about their readiness
- May be done separately or concurrent with their scheduled assessments with additional time allocated
- Need to contact their Certification Manager if a client desires to schedule a Gap Assessment
- Minimal of 1 day on-site

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Templates Changes

- Minimal changes to the templates
  - Update Reg Plan and On-going SA plan
  - Adding Risk Box to Note Pages
  - Adding Note to Audit Plans
  - Transition Checklist Addendum

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ISO 9001:2015

New Terms & Key Changes

Harmonization Via “Annex SL”

- New “Common Core” for all ISO Management System Standards
- 10 Elements with identical sub-clause titles
  - Correlation Matrix available from ISO to map requirements from the current to the new version
- Common Vocabulary
- Ease in managing multiple certifications

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Elements of Annex SL

Section 1	Scope
Section 2	Normative References
Section 3	Terms & Definitions
Section 4	Context of the Organization
Section 5	Leadership
Section 6	Planning for the QMS
Section 7	Support
Section 8	Operation
Section 9	Performance Evaluation
Section 10	Improvement
Annex A	Clarification of Structure
Annex B	Quality Management Principles
Annex C	Portfolio of QM Standards (ISO 10000)

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Strategies for Understanding ISO 9001:2015

- **First, read the definitions -** purchase a copy of ISO 9000:2015, they are no longer in ISO 9001:2015. Understanding the terminology is critical to understanding the standard.
- **Second, read the Foreword, Annex A then 0.1-0.4.** These must be read BEFORE reading the requirements to fully understand the context and intent of the requirements.

Some Key New Terms

- **Risk**: The effect of uncertainty on an expected result.
- **Documented Information**: Information required to be controlled and maintained by an organization AND the medium on which it is contained.
- **Performance**: Measurable result.
- **Involvement**: Engagement in, and contribution to, shared objectives.
- **Organizational Knowledge**: Knowledge specific to an organization, gained by experience, that is used and shared to achieve the organization's objectives.

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More New Terms

- **Context of the Organization**: Business environment, specifically the combination of internal and external factors and conditions that can have an effect on an organization's approach to its products, services, investment, and interested parties.
- **Interested Party**: Person or organization that can affect, be affected by, or perceive themselves to be affected by a decision or activity.
- **Performance Indicator**: A performance metric evaluating a characteristic having significant impact on the realization of the output and customer satisfaction.

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Key Changes

- Focus on **addressing risk** (16 mentions of “risk” in IS!)
- Emphasis on **adding value** (to company and customers)
- Increased **flexibility** regarding documentation and records (no use of “procedure” in IS, no stated requirement for a quality manual, 42 uses of “documented information”)
- **Controlling changes** – 27 mentions of requirements dealing with “change”
- **Easier implementation** in non-traditional applications (i.e., services)
- **No** stated requirement for “**Management Representative**”
- Standard requires a mechanism to define the system boundaries and justify any areas of non-applicability (use of the term **“exclusion” is no longer permitted**)

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Details of the 2015 Changes

Details of the Changes by Clause (new layout)

- The intentions of the following pages are to show **key requirements** where they are changed or new, and to **clarify EAGLE audit criteria** and expectations for verification of implementation.

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4. Context of the Organization (Revised)

- 4.1 The Organization's Top Management and it's representatives must understand the "big picture" of the company and both the external and internal issues that influence it.
- Management must use this knowledge to develop and implement its long range business strategies.
- In this clause, there is no requirement for "documented information" therefore, records are desired to demonstrate conformity but interviews with top management can be adequate.

4.2 Needs of Interested Parties (New)

- The organization **shall** determine the interested parties that are relevant to the quality management system and their related requirements as well as monitor and review information about these interested parties.
- Includes: Customers, End Users, Suppliers, Action Groups, Competitors, Distributors, Retailers, Industry/Trade Groups, Statutory Bodies, Regulatory Authorities, Local Community, Unions, Employees & Families, etc.
- While documented information is not specified, the implications are that this is part of management review, (reference 9.3.2.b)

4.3 Determining the Scope of the QMS (Revised)

- Must consider internal & external issues and relevant parties
- No exclusions, must **justify** any clause deemed non-applicable

➢ **NOTE:** Auditors will be looking for evidence of the definition of the company's QMS, it's scope, justifications for anything deemed "non-applicable, and the issues surrounding the QMS.

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4.4 Quality Management System and its Processes (Revised)

- Identify processes, interactions, inputs, outputs, metrics, objectives, resources, responsibilities, risks, and improvements FOR EACH KEY PROCESS
- All companies already certified to ISO 9001:2008 must have a **schematic representation** of their processes and how they interact, and be able to show how they are monitoring the effectiveness of their processes. Now, additional evidence must be provided that the ***risks*** are identified and mitigated as appropriate.
- Management review notes, process picture maps, turtle diagrams and FMEAs are some examples of where such evidence may be located.

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5.1 Leadership – General (Revised)

- Persons in top management and other relevant management roles throughout the organization shall demonstrate leadership with respect to the QMS
  - NOTE: This can be shown, for example, by motivating and empowering persons to contribute to the effectiveness of the quality management system.
- No longer a reference to “Management Representative, but then who is responsible?

TOP MANAGEMENT

Duties may be delegated, but responsibility for the QMS and it’s effectiveness remain with Top Management!

6.1 Actions to Address Risks & Opportunities (New)

"..the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to…"

- Assure the QMS can achieve its intended outcome(s), prevent undesired effects & continually improve
- The organization **shall** plan:
  - Actions to address these risks and opportunities and how to:
    - integrate and implement these actions into its QMS processes (see 8.1)
    - evaluate if the actions have been effective (see 9.3.2).

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“Risk Based Thinking” is Hotly Debated –What to consider?

- The TC176 is adamant that “Risk Based Thinking” is **NOT** Risk Management (as in FMEA, HACCP, or similar formal approaches)
- Any means of risk identification, prioritization, mitigation, and effectiveness review is allowed
- Multiple, different approaches may (should) be used
- Must be verifiable (9.3.2 requires Management Review to verify the effectiveness of these actions)
- Must encompass key processes within the QMS (Remember, support processes maybe a source of risk)
- Client must be able to defend how their approach(es) to risk meet requirements

6.2 Planning for the Quality Management system (was 5.4)

- While the requirements in this version are more clearly defined, they are not substantively different than the 2008 version.
- 6.3, while new, simply defines issues to be considered when making changes to the system itself. This is fairly straightforward and should not be burdensome to organizations already effectively controlling their QMS.

7.1 Resources (was Section 6, Revised)

- Outsourcing & purchasing represent uses of external providers
- Change management controls must be in place for new or additional resources
- Infrastructure includes supporting services: communication, transport, IT (no change from 2008)
- Calibration moved to this clause (reduced language, but no substantive changes)
- Organizational Knowledge (New Term) Must be determined and includes; current & additional knowledge to operate processes effectively.

8.1 Operational Planning & Control (was section 7)

*"The organization **shall** plan, implement and control those processes needed to address the risks and opportunities determined in 6.1 and to meet requirements, by…":*

- **Establishing criteria** for those processes
- **Implementing control** of these processes in accordance with the criteria
- Keeping **documented information** to demonstrate that the processes have been carried out as planned

In practical application, this is what most 9001 certified companies should already be doing.

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8.2 Determination of Requirements

- Requirements related to the product … including regulatory, other parties, & risks
- Evidence of the review of the requirements must be documented
- Customer communications shall include contingency plans (where required)
- Changes to requirements must be identified, communicated, and relevant “documented information” updated accordingly

8.4 External Processes/Products

- “Purchasing” clause rebranded, minimal changes
- Higher expectations of outsourced processes to include a determination of the controls needed
- Organization is responsible for defining requirements and verifying that requirements are fulfilled
- Records must be kept, including risk assessments

8.5 Production and Service Provision (was 7.5)

- 8.5.1 Control of production and service provision
  - Reorganized and expanded, but no substantively changed requirements
- 8.5.3 Property belonging to customers or external providers.
  - Expanded concept beyond customer property to external provider property

8.5.6 Operational Planning & Control…

Change Control Criteria:

- "The organization **shall review and control changes** for production or service provision, to the extent necessary to ensure continuing conformity with requirements."
- Understood in Aerospace, Automotive and Medical Industries and expanded upon from 7.2.2 (2008) review of requirements related to the product.
- Earlier drafts included language about avoiding unanticipated consequences. While dropped, this is still good advice and highly recommended to be part of the review of potential changes.

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8.6 Release of Products

- While new to 9001 this paragraph is in most other QMS Standards: products may not be released for shipment until **completion of verification** by competent authority that all requirements have been fulfilled.
- Records of the review must be retained and must show who authorized release as *documented information.*

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9.1 Monitoring, Measurement Analysis and Evaluation

The organization **shall** determine:

- What needs to be measured and monitored
- The methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results
- When the monitoring and measuring, analysis and evaluation shall be performed
- Action(s) necessary to address adverse trends or results before a nonconformity occurs
- Monitor customer perception

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9.2 Internal Audits

- Not much changed, but includes considerations for risks, management objectives, other opportunities in scheduling and planning audits
- Remember that audit nonconformities must be addressed “without undo delay”

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9.3 Management Review

- Shall be timely and relevant to operational outcomes
- Consider risks & determine the effectiveness of risk mitigations
- Consider changes in external and internal issues that are relevant to the quality management system
- Consider customer satisfaction ***and*** feedback from relevant interested parties
- Consider the extent to which quality objectives have been met
- Consider the performance of external providers

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10.2 Nonconformity and Corrective Action

"When a nonconformity occurs, the organization **shall**:

a) react to the nonconformity, and as applicable take action to control and correct it, and deal with the consequences;

b) evaluate the need for action to eliminate the causes of the nonconformity, in order that it does not recur or occur elsewhere, by

- reviewing the nonconformity
- determining the causes of the nonconformity, and
- determining if similar nonconformities exist, or could potentially occur;

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10.2 Nonconformity and Corrective Action

c) implement any action needed;

d) review the effectiveness of any corrective action taken; and

e) make changes to the quality management system, if necessary."

10.2 Nonconformity and Corrective Action

- Again, **actions must be appropriate** to the effects of the reported failure (system or product).
- **Documented information** must be retained including the event, the investigation of the cause(s) and consequences, and actions taken.

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Summary

- Changes are not significant; keep what works, but consider streamlining documentation
- ISO 9001:2015 is not a complicated document to read
- Annex A offers clarifications
- Avoid waiting until year 3 to start your transition
- Gap Assessments are a good benchmarking tool
- ISO TC website offers useful tools and information
  - http://isotc.iso.org/livelink/livelink/open/tc176SC2public

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