UPDATES TO STANDARDS

from DQS Inc.

Special Edition- Transition to New Standards

At DQS Inc., we have been preparing for the expected changes to the standards for the last few years.

Now that the new standards have been published, and the deadlines are set, we are putting our preparations to use by helping our customers to prepare for their transition audits. We know that many of our customers have multiple standards they need to transition, and we want to make that transition as easy as possible.

We have recorded webinars and other resources available on our website. For those customers looking for a bit more guidance, we have some informational sessions offered as well.

You can read through some of the previous newsletters for additional information on the standard changes, but we are publishing this Special Edition as a quick reference guide.

How to prepare for the transitions

As with any other strategic decision, a well-defined transition plan should be developed to ensure effective implementation of the new requirements. Basic tasks may include:

- Obtain a copy of the standard
- Identifying any Gaps between old and new standards and implement needed changes
- Take actions (i.e. training) to become competent in the new standards
- Ensure the context of the organization is identified
- Identify the Process Owners for responsibility and accountability
- Track Completion
- Ensure top management is committed to the process
- Establish a timeline
- Take advantage of the DQS Informational Sessions or request a Gap Assessment
- Review life cycle of your products to ensure all potential risks are identified and planned for

Contact your Auditor or CSP to schedule your Readiness Review and Transition Audit now.
If your next audit is before 6/15/17, have your upgrade audit dates ready for your auditor as we expect heavy upgrade activity next year and want to ensure resources are available.

- Perform a full round of System Internal Audits of all processes in accordance with the new requirements followed by a formal Management Review

These are preparations you can make for all the transitions. Read on for more information on each standard and contact us with any questions.

ISO 9001:2015

Published 9/15/15

Key Changes

- New Structure to allow better integration with other management system standards
- Added focus on enhancing Customer Satisfaction while addressing risk
- Considering the Context of the organization and determining expectations of the Interested Parties
- Increased emphasis for top management commitment and involvement
- Increased focus on process output

How the transition takes place

1- As part of the Recertification Audit. Upon successful completion, a new certificate

of registration will be issued and good for 3 years.

2- As part of the Surveillance Audit, with days equivalent to a Recertification Audit. This option will reset the certification cycle, and a new certificate will be issued and be good for three years.

3- As a Special Audit anytime during the certification cycle. The number of days for this audit will be equivalent to a Recertification Audit. A new certificate will be issued and valid for a period of 3 years.

All upgrades will be conducted as part of a two stage process. Since the extent of the changes between the new standard and the previous version are significant, Stage 1 audits are intended to assist our clients in identifying the gaps in their quality management system so they could be addressed prior to Stage 2.

Resources Available

- FAQs, customer bulletin, and recorded webinars at https://dqsus.com/iso-90012015/

ISO 14001:2015 and RC 14001:2015

Published 9/15/15

Key Changes

- New Structure to allow better integration and inclusion of the PDCA approach
- Added focus on environmental performance while addressing risk
- Understanding context of the organization and needs, expectations of interested parties
- Increased requirements for top management commitment and involvement
- Requirements to manage or influence upstream and downstream processes, including outsources activities
- Consideration of a life cycle perspective
- More flexibility with the use of documentation

How the transition takes place

- A stage 1 audit will be scheduled to ensure the basic processes of the standard have been addressed. Where there are concerns or clarification needed, these items will be brought to the site's attention to allow for resolution prior to the Stage 2. The Stage 1 will also look at the context of the organization, identify processes and develop plans and agenda for the Stage 2.
- The Stage 2 upgrade will be a comprehensive review, designed to focus on the key philosophies and requirements of the revised ISO-14001:2015 standard.
- A site may opt to upgrade during a recertification audit, or if they choose to upgrade during their normal surveillance with 35% increase in time to allow for adequate evaluation of the new requirements.

Important Dates for ISO 9001:2015, ISO 14001:2015, RC 14001:2015 IATF 16949:2016, and AS9100:2016

- 6/15/17- All audits after this date must be scheduled as a transition audit
- 9/15/18-All existing certificates that have not completed the transition will expire

Resources Available

- Customer bulletin and recorded webinars at https://dqsus.com/iso-140012015/

IATF 16949:2016

Published 10/3/16

Key Changes

- All Changes listed in ISO9001:2015 including risk based analysis of all processes
- Increased requirements for Supplier development, evaluation and monitoring
- New Total Productive maintenance requirements
- New competency requirements for Internal Auditors
- Accountability for process owners

How the transition takes place

- The transition audit shall be the duration of a recertification audit according to the IATF Rules
- Table 5.2. A (new) subsequent audit cycle starts from the last day of the transition audit.
- The transition audit shall be a full systems audit equivalent to a recertification audit and shall comply with all requirements defined in the IATF Rules, section 6.8.
- An off-site documentation

review shall be conducted prior to the transition audit that shall include as a minimum a review of the client's quality management system documentation (i.e. quality manual and procedures), including the evidences about conformity to IATF 16949 requirements.

- If the organization does not provide the required information, the audit plan shall include a minimum of 0.5 additional audit days on site to collect and review the missing information prior to the one hour on site meeting.
- All supporting functions on site or remote shall be included in the transition process in line with the current ISO/TS 16949:2009 audit cycle and shall be included at the transition audit.

Resources Available

- Transition planning information at https://dqsus.com/certification/ts16949/

AS9100:2016

Published in September 2016

Additional Deadline: 6/15/18- All currently certified organizations must have completed the transition audit

Key Changes

- Those listed under ISO 9001:2015
- Clause 3: added product safety and counterfeit parts
- Clause 7: awareness on product conformity, product safety, and ethical behavior
- Clause 8: planning for product obsolescence; plan activities needed to assure product safety; prevention of counterfeit parts; process to validate test reports for raw material based on risks
- Clause 9: added note to evaluate performance indicators on internal audits
- Clause 10: consider human factors in nonconformity/ corrective action

How the transition takes place

- A readiness review will be performed a minimum of 3 months before the transition audit
- All transition audits require an increase in audit duration per SR-003
- If transition audit is done during a surveillance audit, the certificate cycle will not be reset and the existing 3 year cycle will remain in place.
- If the transition audit is done during a recertification audit, the certification cycle will be reset for another 3 year cycle.

Resources Available

- Transition information at https://dqsus.com/certification/aviation-space-and-defense/
- Free webinars from IAQG and support material at http://www.sae.org/iaqg/organization/9100.htm

ISO 13485:2016

Published 3/1/16

Deadlines

- 12/1/17- All audits after this date must be a transition audit
- 2/28/19- All existing certificates that have not completed the transition will expire

Key Changes

- More prescriptive inclusion and clarification of risk-based approaches applying to the overall QMS and not just to product design controls and product realization processes. More emphasis is placed on outsourced processes to ensure a risk-based management and control approach is applied. Additionally clarification is provided that risk is considered in the context of the safety and performance of the medical device that is to be placed in the global marketplace.
- More specific linkage with regulatory requirements, especially in relation to particular regulatory documentation.
- Increased emphasis on application to organizations throughout the lifecycle of the medical device as well as in relation to the supply chain for medical devices.
- More specifically outlines applicability and requirements for software validation of different software applications.
- More emphasis on ensuring an appropriate infrastructure, especially in relation to production of sterile medical devices and for validation of sterile barrier properties.
- Inclusion of additional requirements in design and development in relation to consideration of use of external standards, usability and safety requirements, planning for verification and validation, transfer of outputs, as well as more emphasis on design records

UPDATES TO STANDARDS

and maintaining a design and development file.

- Increased emphasis on complaint handling and reporting to regulatory authorities in accordance with regulatory requirements, along with increased focus and consideration of post-market surveillance feedback and activities including ensuring appropriate methods are in place for incorporating that feedback into the risk management program.
- Increased emphasis on planning and documenting of corrective and preventive action, ensuring that implementation of corrections / corrective actions are taken without undue delay.

How the transition takes place

- Transitions may take place during regularly scheduled audits or a special audit
- Stage 1 assessments are not required but optional Stage 1 or Gap assessments can be performed as requested
- Certificate renewal date will not be reset upon renewal unless done during a recertification audit
- Number of audit days required for the transition audit are as follows:
  - Recertification audit- recertification days with no reductions
  - Surveillance audit or special audit: Annual surveillance time with no reductions plus one day
  - If conducted at the same time as an ISO 9001:2015 S1/S2 upgrade/ recertification audit with same scope and same or lower employee count, no additional time for ISO 13485:2016 upgrade is required. Scopes that differ only by clarifying it is "for the medical device industry" or similar wording with same or lower employee count will also not require additional time for ISO 13485:2016 upgrade. Other scenarios will be reviewed on a case by case basis to determine if additional time is needed.

Resources Available

- Information at https://dqsus.com/certification/iso-13485/ and recorded webinar at https://dqsus.com/information-center/recorded-webinars/

Important Note for Organizations Currently Certified to Both ISO 13485 and ISO 9001

- The structure of ISO 13485:2016 does not follow the same structure introduced within ISO 9001:2015. The ISO 13485:2016 structure continues to align with ISO 9001:2008 with some adjustments introduced to the sub-clause numbering. The structural differences between ISO 13485:2016 and ISO 9001:2015 are likely to complicate an organization's effort and ability to demonstrate compliance for medical device manufacturers who are currently certified to both ISO 13485 and ISO 9001.
- The primary rationale behind maintaining the same was to maintain alignment with the classification system for observations described by the Global Harmonization Task Force (GHTF) … now known as IMDRF … as well as to ensure continued alignment with the Medical Devices Single Audit Program (MDSAP) that a number of global regulatory authorities have adopted.
- For organizations who elect to maintain compliance and certification with both standards, Annex-B is included in the revised ISO 13485 standard (ISO 13485:2016) to provide a cross-references with the clause structure that is now represented in ISO 9001:2015.