Updates to Standards

AEROSPACE | AUTOMOTIVE | ENVIRONMENTAL | FOOD SAFETY | IT SERVICES | MEDICAL DEVICES

Quarter 1, 2018

Topics covered in this issue:

ISO 20000-1:2017, ISO 45001 FDIS, IATF Transition Planning, and ISO 9001 Update

ISO 20000-1:2017 - What to Expect?

Update to ISO/IEC 20000-1:2011 is long overdue. ISO/IEC JTC1/SC40 has released the Draft Internal Standard of the new version ISO/IEC DIS 20000-1:2017 in September 2017. Voting process ended in December, 2017. The Final Draft International Standard (FDIS) is expected in next couple of months. It is expected that we will get the new standard in 2018.

As expected, the standard will follow Annex SL format, the same format used in ISO /IEC 27001:2013, ISO 9001:2015 etc. Expected new format of the standard:

4.0 Organization and its context (new section)

5.0 Leadership (old section 4.1 with more focus on accountability)

6.0 Plan the service (new section)

6.1 Action to address risk and opportunities

6.2 Plan to achieve service management objectives

7.0 Support (old sections 4.3, 4.4 with some changes) with new requirements

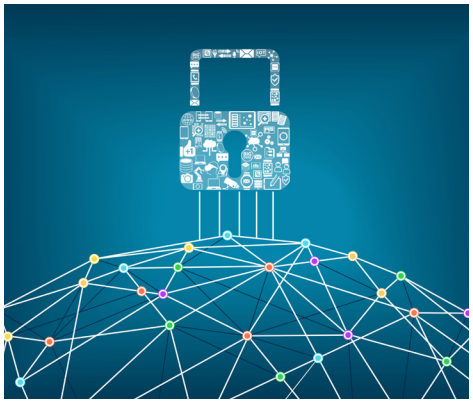
- Knowledge management
- Communication management
- Organizational change management

8.0 Service delivery (old sections 6, 7, 8, 9)

9.0 Performance evaluation (old sections 4.5.4 with increased focus on measurements)

10.0 Improvement (old section 4.5.5)

High level changes in requirements are summarized below:



- Risk management requirement will be more explicit.
- Mandatory policies and procedures removed, instead using the term "Documented information".
- Only mandated policy is Service Management Policy
- Introduced new requirements on
    - Knowledge Management
    - Demand Management
    - Asset management
    - Communication
- Separated Availability and Service continuity management. Service request and Incident management.
- Does not mandate Capacity plan, availability plan instead used generic term service planning.
- Service reporting is not a separate section – it is integrated with service delivery.
- Removed requirements for "Management representative".

Plan the SMS was addressed in the 2011 version of the standard. However, 2017 version provides more specific requirements for planning as a) what will be done; b) what resources will be required; c) who will be responsible; d) when it will be completed; e) how the results will be evaluated. It is expected to see an operational plan.

Measurement requirements were implicit in the 2011 version of the standard. It is expected to see more specific requirements on measurements as a) what needs to be monitored and measured; b) the methods for monitoring, measurement, analysis and evaluation; c) when the monitoring and measuring shall be performed; d) when the results from monitoring and measurement shall be analyzed and evaluated.

Please note the information above are based on DIS version of the standard. It is expected to see some changes in the final version when it comes out.

IATF Transition Planning & Follow Through: Top Issues

Let me start by saying congratulations to those of you who have made it through the transition. It hasn't been an easy process for anyone. We are about 30% through the process. There have been a few items that really seem to hang people up. It's not the issuance of majors or minors that are the concern. The show stoppers seem to be in the planning stage and corrective action stage. Let's talk about planning.

The auditors are sending out a CF167 form with required information for organizations to send in. The form is not for you to complete, but a list of items that need to be sent to the auditor. The auditor will review the completeness of the information. This information is critical to determining the readiness for transition. If items are missing, you are not ready and the audit will not start. You will lose your certificate and be required to go through the registration process all over again.

If there are remote locations that support your site, you must, at a minimum, have a gap assessment performed for each individual remote location. Combined gaps for 2 locations or more because they do the same activities is not acceptable and will be rejected. Gaps are only required if the remote location has not transitioned to IATF 16949. If no gap assessments or reports showing evidence to IATF 16949 then the audit shall not start. You will lose your certificate and be required to go through registration all over again.

You must have had a full system internal audit to IATF or full system audit to ISO/TS with a gap assessment which was reported in management review. Evidence of both of these is required to proceed with the transition audit. These are identified in the CF167 transition readiness document.

Risk and objectives must be identified for each process in your process interactions. No exceptions.

Objectives for each process include 1 efficiency metric and 1 effectiveness metric.

Don't be surprised if majors are written against your system. Few audits have gone without major concerns. You have 90 days to implement and close major items. An on-site follow up is required within 90 days when majors are issued against the system.

That was planning. Now let's talk about corrective actions.

Corrective actions have been a struggle for many of you for years. The rules have not changed but the adherence to the rules has. Each organization will be held firmly to supplying well written, containment, systemic root cause, systemic corrective actions and verification of effectiveness.

In order to close a corrective action all of the above must be identified and evidence provided to the auditor within 60 days of the audit to close. Majors have a different timing. Your auditor will review at the closing meeting additional timing requirements. We have a maximum of 90 days to resolve any issues. The IATF is tracking this timing closely. This is a very strict requirement identified in rules 5th edition.

Containment: Containment must include immediate measures to contain the concern. It should also include timing and number of occurrences identified during containment so everyone understands how big or small the impact is to the system.

Root Cause: Root cause must be systemic root cause. What in the system failed to allow this to occur? Please do not write a root cause specific to the individual item identified in the objective evidence. Only systemic root causes will be acceptable.

System corrective action:

Actions taken only to resolve the item identified in the objective evidence of the non-conformance will not be accepted. That is containment not systemic correction. Please send in as much evidence to show the changes in the system.

Effectiveness Verification:

Issuing a procedure is not effectiveness verification. If you state that your verification of effectiveness is going to be an internal audit, then we would expect to see results of that audit in the 60 day submission along with any other evidence of implementation that you would send. If it is a layered process audit, do not just send in a blank layered process audit form with the change. Send in several audits with the results so the auditor can see the system is working.

Only when the above has been accomplished and provided can the auditor close the finding.

If the findings cannot be closed in a maximum of 90 days then the audit will be considered failed, certificate will be removed and you will have to start the registration process again. This is the requirement according to IATF rules 5th edition. If you do not have a rules book, get one immediately.

I hope everyone has a great year in 2018 and I wish everyone great success through the transition process and maintaining IATF 16949.

Cindy L Soltis

Director Automotive SBU

Gap Assessments Available to the FDIS ISO 45001

As we look forward to the highly anticipated release of the Occupational Health & Safety management system standard requirements in late February or March, 2018, DQS has begun making preparations to assist our customers in migrating from the former BS OHSAS 18001 to the new ISO 45001.

Our Lead Auditors have already begun offering gap assessments to the Final Draft International Standard and are beginning the qualification process to conduct upgrades.

Organizations who are currently registered to the OHSAS 18001 standard will have three years to come into conformance with the ISO standard, based on the date when ISO 45001 is published.

Why choose an Occupational Health and Safety standard?

The adoption of an occupational health and safety (OH&S) management system is intended to enable an organization to improve its OH&S performance to prevent work-related injury and/or ill health to workers and to provide safe and healthy workplaces.

The ISO 45001 standard has been developed to provide a framework for managing OH&S risks. It's designed to integrate and harmonize with ISO 14001:2015 and ISO 9001:2015.

This harmonized approach allows for the addition of OH&S specific text including requirements and notes to clarify and ensure consistent interpretation and implementation of the common text in the context of an OH&S management system.

According to the standard introduction, the intended outcomes of the OH&S management system are to prevent injury and/or ill health to workers and to provide safe and healthy workplaces; consequently, it is critically important for the organization to eliminate or minimize OH&S risks by taking effective preventive and protective measures.

Benefits of an OH&S Management System

When these measures are applied by the organization through its OH&S management system, they improve its OH&S performance. It can be more effective and efficient to take early action to address opportunities for improvement of OH&S performance. It is anticipated that an organization will improve its performance with the implementation of the ISO 45001 standard.

An OH&S management system can also assist an organization to fulfill its legal requirements and other requirements. ISO 45001, like other International Standards, is not intended to increase or change an organization's legal requirements.

Upon its release, anticipated late February or early March, the standard will be available for purchase on the ANSI web store (https://webstore.ansi.org/RecordDetail.aspx?sku=ISO%2FFDIS%2045001:2017&source=blog). If you would like to receive a quote for a Gap Assessment, please contact Sales (sales@dqsus.com) or your Customer Service Representative.

ISO 45001 Info Series- Volume 1 - Definitions

One feature of the ISO 45001 standard is that it includes some definitions that weren't present in the old standard.

A clear definition of "worker" is a person performing work or work related activities that are controlled by the organization. This definition opens it up to include top management, managers, non-managers, contractors, temporary, agency workers, part-time, seasonal, paid or unpaid.

Participation is defined as involvement in decision-making with further clarification as including engaging health and safety committees and workers' representatives, where they exist.

Consultation is defined as seeking views before making a decision including engaging health and safety committees and workers' representatives, where they exist.

One of the notes added to the definition of an objective (simply defined by the standard as "result to be achieved" is that an objective can be expressed in other ways, e.g. as an intended outcome, a purpose, an operational criterion, as an OH&S objective or by the use of other words with similar meaning (e.g. aim, goal, or target).

We all know risk is the 'effect of uncertainty' at this point. In the ISO 45001 standard, where the terms "risks and opportunities are used together, that means OH&S risk, OH&S opportunities to the management system.

Occupational health and safety risk is the combination of the likelihood of occurrence of a work-related hazardous event or exposure and the severity of injury and ill health that can be caused by the event or exposure.

Injury and ill health is defined as adverse effect on the physical, mental or cognitive condition of a person. These adverse effects include occupational disease, illness and death.

Stay tuned to our website and newsletters for future volumes and updates.

ISO 9001:2015 Transition Update

When the availability of ISO9001:2015 Standard was first announced in September of 2015, the three year transition time frame seemed like a reasonable window. Today, with less than six months left in that window, more and more organizations are gearing up to make the necessary enhancements and the task of upgrading for some is becoming rather urgent.

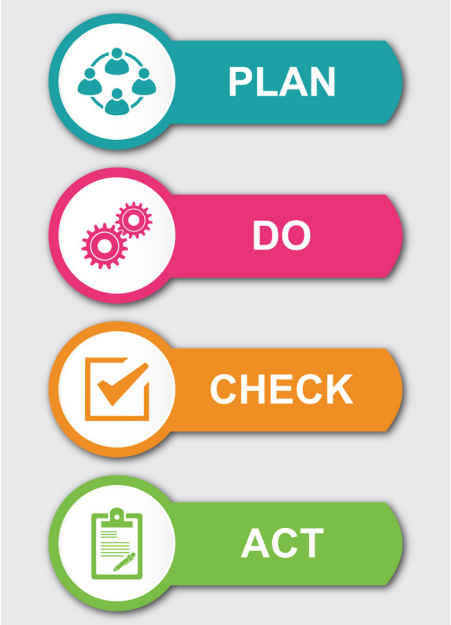
Our transition plan has been available on our website (www.dqsus.com) since the announcement of the Standard and has not changed much. We continue to offer upgrades to all our registered clients as part of a two stage upgrade process. Stage 1 is to determine the organization's readiness and Stage 2 is the actual upgrade audit to assess effectiveness of the ISO9001:2015 requirements.

Although upgrading early on is always a thrill to be sought, upgrading later in the transition window may have some benefits as well. Far more additional information is currently available regarding the wording and intent of the various requirements. The sense of uncertainty is no longer a factor as the requirements are very well known and explained. DQS has offered several webinars on the various sections of the Standard that are still available, free of charge, on our website. Also, a complete ISO9001:2015 checklist and a checklist containing the new requirements are also available for our clients as a self-assessment tool. These checklists may be obtained from the assigned Customer Service Professionals upon confirmation of the Stage 1 assessment.

From what has been observed so far, organizations tend to have varying levels of compliance when it comes to the following topics:

1. Identification of Processes:

Clause 4.4.1 requires all processes to be identified. ISO 9000:2015 (3..4.1), defines "Process" as "set of interrelated or interacting activities that use inputs to deliver an intended result". Often, the first struggle it to have the processes identified as defined by ISO9001:2015. After all, the tasks will have to be interrelated or interacting. One may find it difficult to justify inclusion of Purchasing and Warehousing under a larger process, say "Fulfillment". In most organizations, both Purchasing and Warehousing have well defined inputs and expected outputs, with very little in common. Therefore, having both under the same umbrella may not be adequate. However, if a justification could be made that, say for a Distributor, Purchasing and Warehousing are related activities to ensure adequate stock levels at all times, then that may make it perfectly fine for the two "distinctly different" activities to be merged into one.



Based on what has been seen so far, for smaller organizations, ten or so processes may be sufficient to meet the intent of the requirements. Mid-size companies may have a bit more – perhaps 15 or so. For larger organizations 20-25 may be the right subscribed number. Anything more or less will have to be evaluated for adequacy. It will continue to be up to the client to identify the processes. The very same identified processes will be used when planning our audits. So, it is not always the number of processes that may matter but their adequacy in ensuring effective and predictable result.

2. Identification of Risks :

For the identified processes, clause 4.4.1 also requires that the risks be identified and managed. "Risks" should include factors that may prevent the organization from achieving its intended targets in meeting their Interested Parties' expectations and objectives. Risks need to be clearly identified and managed. Most organizations find the use of FMEAs suitable in addressing this requirement but its use is not mandatory.

3. Establishing Goals and Objectives for all Processes:

Also in 4.4.1, the need to monitor the process by use of process indicators is included as well. Please note that this requirement is not just related to the "Key Processes", but all processes of the organization.

As we are getting closer to the end of the transition window, we would like to encourage our ISO9001:2008 registered clients to schedule their Stage 1/Stage 2 audits and have an open dialogue with their assigned Lead Auditor concerning any aspect of their audit or to seek clarification of the new requirements.

Good luck with the transition process. Just remember, we are here to help!