ISO 9001:2015 FAQ

The focus of this FAQ is to provide answers to questions that have been received to date, and asked at the ISO 9001:2015 Revision Training webinar held on October 29th, 2014.

A1. Where can the current DIS draft of ISO 9001:2015 be found?

The current DIS draft of ISO 9001:2015 can be purchased from numerous organizations, including ISO and ASQ. Additional information may be obtained at.

http://iso.org/iso/iso9001_revision.html
http://asq.org/standards-iso-9001-2015.html

A2. What is the auditor certification process for ISO 9001:2015?

Since the requirements of ISO9001:2015 are fundamentally different than ISO9001:2008, UL DQS Inc. auditors will be going through extensive training in 2015 after the release of the FDIS. Following the training, all auditors will be tested to validate their knowledge and understanding of the new requirements prior to them performing any audits.

In particular, we will assess our program to ensure that our auditors and other relevant personnel demonstrate knowledge and understanding of:

- The requirements of the latest ISO 9001: 2015 Standard;
- The new "risk based thinking" as part of the requirements of the revised standard;
- Definition of certification scope in light of the changed exclusion requirements;
- Performance of system document reviews in light of the reduced emphasis on mandatory requirements for documented procedures in the new standard.

A3. Can you certify to 2008 version after 2015 has been released?

After publication, there will be a three-year period during which certificates against the current standard will still be valid. All such, these certificates will expire on the third anniversary of the date of publication of ISO 9001:2015.

On request of a client, UL DQS may still issue new certificates against the current standard version (ISO 9001:2008) within a period of 15 months after the publication of the revised standard. However, clients shall note that these certificates get a restricted validity period, expiring on the third anniversary of the date of publication of ISO 9001:2015. To allow time for the positive certification decision, all upgrade audits will be required to be done at least 3 months prior to the expiration of the certificate (33 months from the issuance of the standard).

A4. For a company with recertification in December 2015, will they be able to go to the 2015 Standard?

For registered clients, the most cost-effective way of transitioning will be to use their scheduled recertification audit for assessment against ISO 9001:2015. This is possible within the three year transition period announced by ISO. Should a registered organization wish to be assessed against ISO 9001:2015 prior to or after its scheduled reassessment, it may arrange a special audit for that purpose. The number of audit days for the special audit will be equivalent to a Triennial audit.

A two-stage approach will be used for all upgrades, and will be composed of "readiness review" and "system audit". Additional information concerning the tranisiton process will be announced by May 1, 2015.

A5. Our triennial is in late 2015. Is it preferable to wait, and not transition right away in late 2015?

Please refer to A4. The most cost-effective way is to do the transition during the Triennial audit. However, a client may decide to transition to the new standard during a regularly scheduled surveillance audit (or at any other time independent of any scheduled surveillance or recertification audit). In such cases, the number of audit days shall be equipvalent to a recertification audit. After a positive certification decision, the client will receive a new certificate with a validity of three years.

A6. How will ISO 9001:2015 affect an organization that is certified as an Integrated Management System (ISM)?

Conformance with the requirements of ISO9001:2015 is independent of the company's registration to any other quality management system standard. As such, clients with multiple registrations will have to show evidence that the requirements of ISO9001:2015 were effectively implemented and compliance with the requirements of the other standards is concurrently maintained.

A7. If your quality manual is currently written to reflect the ISO 9001:2008 standard, does it have to be re-written to reflect the now 10 instead of 8 sections?

No, assuming that the Quality Manual does not provide any contradictory information concerning the requirements of ISO9001:2015. However, the requirements of the two standards are significantly different. Upgrading the Quality Manual to comply with the requirements of the new standard may be a valuable effort to better identify the deficiencies within the organization and to have them addressed prior to the upgrade audit. Renumbering of the pages and/or sections is not essential as the new standard does not even require that a Quality Manual be maintained.

A8. Does the ISO 9001:2015 revision require a Quality Manual?

Please refer to A7.

A9. If a company has a manual based on standard requirements, won't they need to update to reflect process approach?

There is no requirement for a quality manual in the draft for 2015. The new standard also requires that the processes be identified and that their interaction be defined. The internal audit process must use the "process approach". The process approach requirement has not changed. However, although the "Process Approach" was noted in the ISO9001:2008 standard, the new standard explicitly requires the use of the "Process Approach" when implementing the Quality Management System. Furthermore, the new standard requires the top management to demonstrate leadership and commitment by promoting awareness of the "Process Approach" within the organization.

Since a Quality Manual is no longer required, the "documented information" required by the standard may be in any media or format.

A10. If we are concurrently certified to AS 9100, are there changes in ISO 9001:2015 that are not covered under the aerospace standard?

We have not performed a one to one analysis at this time with the first draft. The IAQG is developing revisions to the AS9100 standard concurrently with the ISO 9001:2015 development and is currently targeted for release in April 2016. They have proceeded with the intent to retain the ISO 9001:2015 requirements with additional AS9100 additions. The IAQG had over 60 inputs into the ISO 9001:2015 draft. Please refer to Q6 as well in regard to integrated management systems. Information about the AS9100:2016 development process is available here:

http://www.sae.org/aaqg/publications/9100_series_rev_overview.pdf

A11. For medical devices companies, if ISO 13485:2015 is going to align with ISO 9001:2008, how will that impact the transition to ISO 9001:2015?

If an organization that is certified to ISO 13485 intends to remain certified to ISO 9001, the requirements of the 2015 version must still be met. Or an organization that is certified to ISO 13485:2015 and does not want to upgrade to the ISO 9001:2015 version will lose ISO 9001 certification once ISO 9001:2008 becomes obsolete. UL DQS is prepared to audit to the additional requirements of ISO 9001:2015 in order to maintain both.

A12. How does the transition period affect companies not yet certified?

Please refer to A3.

A13. Will there be access to a gap analysis tool?

For most of our clients, the extent of the revision to the Quality Management System will be dependent upon the maturity and effectiveness of the current management system, organizational structure and practices. Therefore, a "Gap"-audit or "diagnostic" might be useful in order to identify realistic resource and time implications.

Such audits to verify the conformity status of organizations against the revised standard or

draft standard may be scheduled at any time, independent or together with a scheduled audit. The purpose of these audits is to show clients their conformity status and to identify any actions required to assure a successful transition. The audit time will be depend on the desired depth (sampling or full conformity verification). To ensure availabiity of adequate resources, please contact your Customer Service Representative well in advance if you will be interested in scheduling a " Gap" audit.

A14. You mentioned that a management representative is not required any more. How about MRM?

Although the requirement for having a management representative has been removed, the new standard now allows for multiple individuals to be responsible for different aspects of the quality management system (Process owners, instead of just one person for the entire system). Management is now required to identify the responsibility and authority of the personnel affecting quality. Section 9.3 of the Standard clearly defines the requirements for the Management Review Process. It is an essential part of the PDCA cycle for performance evaluation.

A15. What are some of the new requirements for Leadership and how will the new Standard be friendlier to service companies?

Section 5 of the new Standard outlines the requirements for "Leadership and Commitment" within the organization. By requiring fewer Procedures and other non-prescriptive requirements, the new standard is generic in nature and the requirements are intended to be applicable to all organizations, regardless of type, size and product provided.

A16. Are site extensions (process moved to a separate building, but still under the same management umbrella sharing the same QA manual, procedures QA manager, purchasing, shipping, etc.) allowed under the main location certificate?

Under ISO 9001:2015, yes. Each program, such as AS9100, has its own specific requirements for identifying the nomenclature and method for determining days and combinations of locations/buildings. Site extensions are not allowed if your organization is registered to TS16949.

ISO 9001:2015 Auditor Training

B1. Should auditors re-do external auditor training in regard to this change?

Since the requirements of the new standard are significantly different than ISO9001:2008, all Internal Auditors should be "deemed competent" in conducting these audits. Although no external training has been mandated, it may be beneficial to have the auditors trained in the new approach. Upon release of FDIS, UL DQS will be offering public seminars, webinars and customized auditor training. Details on the availability of the additional services will be announced by May 1, 2015.

B2. Does the Lead Auditor for an organization have to recertify?

Please refer to B1. Section 7.4 of the new Standard requires an organization to determine the necessary competence of person(s) doing work. As such, all auditors are required to be "deemed competent" by the organization.

If adequate auditing can be done at the current level of competency, then no additional training may be needed. However, if additional competency is needed to ensure effective implementation of the requirements and for better understanding of the concept of the new standard, then external training may be beneficial. Inadequate coverage of the requirements, lack of understanding of "process approach", and unfamiliarity with the organization's requirements may indicate the need for additional training of the auditors.

B3. What will be the auditor training requirements?

Please refer to B2. Competency requirements will have to be defined by the organization, and may be unique.

UL DQS will be offering auditor training, and additional information concerning this service will be provided by May 1, 2015. Should you be interested in receiving Auditor Training from UL DQS, please notify your Customer Service Representative so you could be kept advised of the training sessions as soon as they are announced.

Risk Based Approach

C1. The concept of risk management is raising concerns in our organization. If no risk register or formal assessment is required, could you describe what would be required? What would the risk based thinking process look like for a small company?

The concept of "Risk Based Thinking" is noted in section 0.5 of the Standard. Risk is defined as the effect of uncertainty on an expected result. Every organization has risks to consider in order to fulfill its commitments to its stakeholders and to ensure customer satisfaction.

C2. What is the number of risk documents you suggest we review?

ISO 31000 Risk Management will be helpful but not mandated.

C3. Can you give an example of a risk based approach and how it would work in practice?

An excellent example of "Risk" in ISO9001:2015 is provided in Document N1222 (July 2014) published by ISO/TC 176/SC2. A link to the document and related N1221 Risk Based Thinking presentation is provided below. Under section 1, please select "A paper on ISO9001 and Risk" for more information.

http://isotc.iso.org/livelink/livelink/open/tc176SC2public

C4. Can you give an example of what risk might mean in a manufacturing setting?

Examples include availability of skilled labor, limited resource materials, union conditions, unemployment rate, transportation conditions, seasonal natural events and outdated equipment. Risk based thinking occurs at all levels in all processes. Please refer to C3 as well.

C5. Without a risk registry, how will the auditors be able to determine if we have identified and addressed risks?

The new standard does not require the use of a risk registry. However, that may be an effective way of demonstrating that the risks have been considered. Other methods will be equally acceptable if all applicable Risks are clearly identified.

C6. Does risk analysis have an acronym rule of thumb, i.e. plan, act, do, check?

None has been identified at this time. However, this International Standard makes risk-based thinking more explicit and incorporates it in requirements for the establishment, implementation, maintenance and continual improvement of the quality management system. Essentially, risk can be associated with all aspects of the PDCA cycle.

C7. Will there be any recommended tools for conducting a risk analysis?

ISO 31000 Risk Management will be helpful but not mandated. Also, please see C3.

C8. Is there a note on how long you have to maintain risk based approach in your organization before you are considered ready to get a 3rd party audit?

No specific timing requirements have been identified for evidence of risk based thinking / approach. Evidence will need to demonstrate that risks and opportunities have been identified, actions have been planned and implemented to minimize the most significant risks and that the effectiveness of these actions has been checked.

C9. Are PEARs a good way to deal with the proof of risk analysis?

PEARs are an evaluation of the process effectiveness and do not address risk, risk assessment or any actions taken to mitigate risk.

TS 16949 and ISO 9001:2015

D1. When will the TS 16949 standard be revised and will the auto industry follow ISO 9001:2015 changes or stick with ISO 9001:2008?

The following was posted on the IATF website on December 5, 2014

"The IATF has established a work team consisting of IATF member organizations to develop a design specification for the revision of ISO/TS 16949 to align with the ISO 9001:2015 based structure and requirements."

D2. If we are certified to TS 16949, should we wait to make changes and do training until the TS update comes out?

If your organization is dual registered to ISO 9001 and ISO/TS 16949, system upgrades will be needed to meet the ISO 2015 requirements for your ISO registration. There is no information on when TS will change.

D3. Would it be possible / recommended for TS companies to upgrade to new ISO certifications before TS upgrades, or just wait?

It is not definite when TS will be updated. All ISO9001 registered organizations, regardless of their registration to other standards, will be required to meet the requirements of ISO9001:2015 as noted in A3.

D4. How will current TS 16949 customers be audited in the transition time between ISO 9001:2015 and TS revision?

If you are not dual certified with ISO 9001, there will be no concerns until TS decides to adopt any changes. If you are certified to ISO 9001 and wish to maintain that certification, please see D3.

This document will be updated periodically.
Please email your questions to ISO9001_2015_Questions@us.dqs-ul.com and we will provide an answer as part of the next update.

Updates will be available at : http://ul-dqsusa.com/iso-90012015/

February 18, 2015 Webinar Questions

Q1. What is the current difference between element approach and process approach?

Explanation of Process Approach was included in slides 30-49. ISO9001:2015 requires all Processes (value-added activities of the organization) be identified and managed as a process. Element-based standards just outline the requirements.

Q2. What do you mean by the standard now requires min 17 "documented information"

"Retain Documented Information" appears 17 times in the Standard. Namely, in sections 4.4, 6.2.1, 7.1.5, 7.2, 8.1.e), 8.2.3, 8.3.5, 8.3.6, 8.4.1, 8.5.2, 8.5.6, 8.6, 8.7, 9.1.1, 9.2.2, 9.3.2 and 10.2.2.

This is equivalent to the current Quality Records requirement, where the information can be in any media or format. For clarification, please note that "Maintain documented information" is equivalent to the current "Documented Procedure" requirement.

Q3. What does PDCA stand for?

Plan-Do-Check-Act. Please refer to slides 15-19.

Q4. How do I obtain training in Risk Management? Where do I go to learn more? Will the ISO9000:2015 numbering align with ISO14k and the OHSAS18k?

We will be covering Risk Management as part of our March 25 Webinar. Yes, the numbers will align for all ISO standards, but not necessarily for some industry based standards such as TS16949 and AS9100 at this time. Those changes are made by the governing organizations of those standards. Please refer to slides 54-55. All new ISO standards will be utilizing the same High Level Structure that is noted in Annex SL. Actual clause numbers may vary but core definitions and structure will be consistent.

Q5. Sessions on April 19th or April 29th?

The next webinars have been scheduled for March 25, April 29 and May 26. Also, the final webinar will be held after the issuance of FDIS, on August 19, 2015. Please register on our website once more for access to the next four free webinars.

Q6. What will be the deadline to update documentation to the 2015 standard after release? If we just got re-certified, will we have to do it again, or can we do it at the next 3 year cycle?

Please refer to slides 56-63 and FAQ question A5.

Q7. The ISO 176 link is no longer valid. Can you supply the new link?

http://isotc.iso.org/livelink/livelink/open/tc176SC2public . As of February 24, 2015, the link is still active.

Q8. Can you provide the FAQ location again?

http://ul-dqsusa.com/iso-90012015/

Q9. I missed the link to the Risk based thinking document. What is it ?

Please refer to slide 53. The correct link is
http://isotc.iso.org/livelink/livelink/open/tc176SC2public

Q10. How is transition audit schedule affected for those clients duel certified by other standards such as ISO/TS 16949 if those standards haven't been modified yet? Don't the changes to this standard put you in a noncompliance with the other standard before they are changed?

There don't seem to be any contradictory requirements between ISO/TS16949:2009 and ISO9001:2015. Nonetheless, the additional requirements in ISO9001:2015 will have to be addressed. Please refer to FAQ questions D1, D2, D3 and D4.

As of 2-22-2015, the following was posted on the IATF website :

"The IATF assigned work team will be seeking stakeholder inputs on potential enhancements to the ISO/TS 16949 standard. Additionally, customer requirements are being analyzed for potential inclusion in the future standard. Completion of the revised quality management system standard is targeted for Q4 2016. Posted on 16 Feb 2015"

Q11. When is the deadline to upgrade to 2015?

Please refer to slide 57. Current certificates will have to be upgraded within three years of issuance of the revised Standard.

Q12. You showed several examples of "not a process map" and one bad process map. Could you explain what a good process map looks like, requires, etc.?

ISO9001:2015 requires all processes to be identified. Furthermore, clause 4.4b requires the "sequence and interaction of the process" be defined. A process map is not required, but is a good way of showing compliance to these three requirements. A good process map should identify the processes, show their sequence and interaction. Slides 34-35 comply with these requirements. Additional information on this subject will be provided on March 25th as part of the review of section 4 requirements.

Q13. So we will have to re-do our internal auditor certifications that we currently have?

Not necessarily. Please see FAQ questions B1, B2 and B3.

Q14. Why change to ISO 9001:2015, just stay at ISO 9001:2008

ISO committee is made up of 163 member countries, each with a single vote. All ISO standards are normally reviewed every five years to assure that they are still relevant and adequate in an ever changing world.

In the case of ISO 9001, the increasing diversity of ISO 9001 users had to be considered, including the increased interest in the service industries as well. It was also necessary to verify the impact of the new developments in knowledge and technologies which have changed significantly during the last few years, broader user interests and changes in industries.

In 2010 and 2011, ISO conducted an extensive web-based user survey, asking about the need for a revision and the future needs and interests of the standard users.

The answers were evaluated and the majority asked for changes to be made to consider the above factors and for ease of applying the standard to all types or organizations and industries.

In 2011 the responsible ISO committee, the Technical Committee 176, started the systematic review of the standard and decided in March of 2012 to have it revised.

The changes are intended to better assist organizations in meeting customer requirements and enhancing customer satisfaction. Also, the new requirements are meant to be easier to implement. All current certificates to ISO9001:2008 will be required to be upgraded to ISO9001:2015 within three years of issuance of the new standard.

Q15. Will TS 16949 Auditor training likely be required? Or, will ISO 9001 training be adequate?

TS16949 training requirements are governed by IATF. Any training requirement will be announced by them.

Q16. When will you be offering the internal auditor training?

Additional information concerning the Internal Auditor Training Program will be made available during the March 25th Webinar. All future webinars will continue to be provided free of charge.

Q17. How do we register for the internal auditor training?

The link is http://ul-dqsusa.com/iso-90012015-training.

Q18. Do you accept other training certificate from other organization, e.g. the XXX Group. Is formal internal auditor training required?

Please refer to FAQ questions D1, D3 and D4.

Q19. Will there be any webinars in the coming months that deal with any changes to the TS-16949 standard?

Yes, part of our commitment to assisting our clients, future changes will be communicated as well. It is a bit early now for those webinars to be scheduled as the changes are currently being worked on.

Q20. What is the ballpark cost for the internal auditor certification?

Additional information concerning the Internal Auditor Training Program will be made available during the March 25th Webinar

Q21. Is it a requirement to recertify client internal auditor? Are you saying internal auditors need to be certified for ISO 9001:2015?

No. However, all auditors must be deemed “competent“ to conduct these audits in line with the Process approach requirements. Please refer to FAQ questions D1, D2 and D4.

Q22. Is it required to attend the internal audit training at UL's selected place of training Will the on-line training module AND the 2 day training session both be required

Internal Auditor Training program is an optional new service that we will be offering to ensure our clients know what our auditors know. We will be using the same Auditor Training process that our auditors will have to complete prior to conducting any audits to ISO9001:2015. To obtain auditor certification, completion of the on line module and attendance of the two day training session will be mandatory. Although completion of this extensive training may be optional for our clients, all UL DQS auditors will be required to complete this training prior to conducting any audits to ISO9001:2015.

Q23 For family owned companies, involvement of management is very rare and the real actions are really limited to the doers in the company. I am afraid that to be able to implement the new requirements

On the contrary, the new requirements have been defined so as to make them easier to implement in smaller organizations. With reduced need for documentation, the ISO9001:2015 is less prescriptive. Please attend our upcoming webinars where we will discuss in detail each of the requirements and show ways of complying with those requirements. The focus may be different now, but ways to comply with the new requirements are practically endless.