Preparing for the Change – Transition to ISO 9001:2015

As everyone in the quality game is aware, there has been a lot of talk for the last two years about the changes to come with the ISO 9001 revision to be issued in 2015. ISO standards touch almost everything we do and they help to make the world a safer and more efficient place. This drives the need to evaluate the effectiveness of the standard and make changes to drive continual improvement within our own organizations and industrywide.

The task of understanding the revised standard's effect on your organization can be overwhelming. We at PJR want to ease our clients and potential clients into this new standard and have composed this simplified FAQ to address some of the most pressing questions and address what steps can be taken now to prepare for the coming change. In addition to this FAQ, PJR also offers an overview of changes to ISO 9001:2015 webinar on a monthly basis, with easy registration available at http://www.pjr.com/upcoming-webinars.

ISO 9001:2015 FAQ:

1) Why is the ISO 9001 standard changing again?

There are a number of objectives associated with this revision, but there are three that are considered most critical. 1) The International Organization for Standardization (ISO) wants to see the ISO 9001 and all of its other standards continue to grow in terms of numbers of registrations. There is a lingering perception that ISO 9001 is somehow overbearing or obtrusive to service organizations. 2) There has been a targeted effort to simplify language used to aid in understanding and promote consistency between accreditation bodies, certification bodies, auditors, and clients. 3) There has been a long standing desire to simplify and streamline the process for companies that wish to achieve multiple certifications (such as ISO 9001 and ISO 14001.) For example, many of these companies currently feel compelled to maintain multiple sets of quality and procedures manuals. This new re-write is attempting to address these and other concerns.

2) What is the expected timeline?

We are currently in the Draft International Standard (DIS) phase. The DIS standard is available for purchase, but PJR's contention is that there is actually very little value in purchasing the DIS as it will not be an auditable document. The projected publication dates for the FDIS (Final Draft International Standard) and the actual ISO 9001:2015 document are July 2015 and September 2015, respectively. It is PJR's contention that most organizations should wait until the final approved ISO 9001:2015 standard is published to make a purchase. Once the ISO 9001:2015 standard is published, a 36 month transition timeline will begin. This means that if the ISO 9001:2015 standard is published on September 15, 2015, the ISO 9001:2008 standard will be viable until September 15, 2018. All ISO 9001:2008 certifications issued in late 2015 and beyond will have to bear an expiry date that matches the cut-off for ISO 9001:2008. However, it has been emphasized that companies will be allowed to transition at their own pace, and that certification bodies will have to establish their own individual cut-off dates for ISO 9001:2008 audits. See next question.

3) My audits are normally due in late July, and the transition period ends in September. Why can't my company have its transition audit in late July 2018?

While it is true that the transition period does not end until September 2018, it is not just required that your audit is conducted by this date. If any nonconformities are discovered during the audit, they must be addressed with corrective action, and PJR's Executive Committee (decision-making body) must review and approve the audit package by the transition deadline. A late July 2018 audit does not provide enough time for this to happen. Thus, your organization could transition in July 2017 or chose to have an earlier audit in 2018, perhaps May, to allow adequate time for completion of the post-audit process. All transition audits must be completed within 120 days of the transition end date of 1 September 2018. Thus, all transition audits must be completed by 1 May 2018.

4) ***My organization is not yet certified. We have been working at implementing ISO 9001:2008 for a while. Can we still seek certification to the 2008 version of the standard and then transition later?***

PJR appreciates that a lot of work may have gone into preparing for certification to ISO 9001:2008. PJR will allow initial audits to the 2008 version of the standard until eighteen months into the transition period, or approximately 1 March 2017. Keep in mind that ISO 9001:2008 will be obsolete on or around 1 September 2018. Therefore, the expiration date on any 2008 certificate issued after the publication of ISO 9001:2015 will be 1 September 2018. Thus, it may appear that your organization is not being granted a full, three-year certificate. However, after successful transition to ISO 9001:2015, the expiry date of your certificate will be amended to reflect a full three-year certification.

5) What if we have a Recertification audit in early 2016, should we just plan on performing that audit to ISO 9001:2015?

This will be a strategic decision that each company makes on its own, but there are a few key points to bear in mind. If you have had a chance to examine your quality system against the revised requirements and feel that you are ready, you can certainly request that a transition audit to ISO 9001:2015 be performed. Timing the transition to your regular recertification audit is ideal, but not in any way mandatory. You could certainly perform your 2016 Recertification Audit to ISO 9001:2008, and then complete a transition audit to ISO 9001:2015 in 2017.

6) Is it better to transition earlier?

As described in the question above, it is important to avoid waiting until the last minute. However, there is no difference if you transition in April 2016, April 2017 or April 2018, for example. An ISO 9001:2008 certificate is still valid until the end of the transition period. In no way should an ISO 9001:2015 certificate be perceived as better than an ISO 9001:2008 certificate until the obsolescence date of that standard.

7) What happens if my organization doesn't transition on time?

If your organization does not have a transition audit prior to the end of the transition period/obsolescence date of ISO 9001:2008, then you will no longer be certified as of the end of the transition period. In order to become certified to ISO 9001:2015, you will need to start over with an initial audit (Stage 1 and Stage 2).
If your organization does have its transition audit but the audit package is not closed prior to the end of the transition period/obsolescence date of ISO 9001:2008, then an ISO 9001:2015 certificate will be issued as soon as the package can be closed. This means that there will be a lapse in your certification status. Our Scheduling Department will work with you to ensure the timely scheduling of any transition audits that occur later in the transition period to avoid this unfortunate situation.

8) What are the critical changes?

PJR has prepared a separate report showing a clause by clause analysis on the changes within the ISO 9001 standard, but there are two important standouts. 1) **ISO 9001:2015 has eliminated the terms "Documents," "Procedures," and "Records."** All of these terms have been replaced with the ubiquitous "Documented Information." The rationale of this change is that it opens the door to a greater understanding and acceptance of alternative methods of controlling a quality management system. ISO is not interested in outdated, dogmatic views of how a process can be controlled or shown to be effective. Consequently, these outdated terms have been eliminated. 2) **The introduction of Risk Management**. Risk Management has been talked about a great deal over the past year. There are already two ISO standards (ISO 14971 and ISO 31000) and numerous other published materials on methods that can be used to achieve Risk Management. Our analysis has concluded that at least two existing processes within ISO 9001:2008 can be applied to an effective Risk Management program. These are 7.1 Planning of Product Realization and 8.5.3 Preventive Action. Risk Management is being viewed

as a system wide component of the quality management system (in much the same way Continual Improvement was when ISO 9001:2000 was published), but it has been emphasized many times over that a formal Risk Management process will not be expected.

9) What is Annex SL, and what does it have to do with ISO 9001?

Annex SL is a portion of the "ISO/IEC Directives Part 1 – Consolidated ISO Supplement – Procedures Specific to ISO" document. This standard regulates and controls the process of developing, updating, and issuing ISO published standard. The full text of Directives Part 1, including the Annex SL text can be found here: http://www.iso.org/sites/directives/directives.html#toc_marker-76. Annex SL can be thought of as a ten section blueprint to be used for all ISO standards. It promotes (among other things) common terms and core definitions for many of the terms used in the ISO family of standards. It is through the mandatory structure of Annex SL that organizations will be better enabled to achieve multiple certifications such as ISO 9001, ISO 14001, and OHSAS 18001, because each of these standards will have the same 10 sections and the same core terms and definitions.

10) We've already been certified for a long time and our procedures are well implemented, do we have to change them?

PJR's analysis has concluded that for the average ISO 9001:2008 certified company, the impact of the revised standard will be minimal and quite manageable. It is important to bear in mind that the ISO is seeking greater inclusion for the ISO 9001 standard. They want to see it continue to grow into new sectors and be even more user friendly than it is now. Requiring a company to aggressively overhaul their current ISO 9001:2008 system is not consistent with this objective.

11) What are some examples of things we're already doing that would be viewed favorably under the Risk Management requirement?

There are a number of activities that are required under ISO 9001:2008 standard that are likely going to help you demonstrate compliance to Risk Management. These include 5.6 Management Review (an assessment of your overall quality system leading to targeted improvement efforts), 7.2.2 Review of Requirements related to the Product (an assessment of customer expectations against your current capabilities with steps taken to resolve discrepancies), 8.5.3 Preventive Action (an assessment of potential problems with actions taken to avoid those issues in the first place), and 6.2.2 Training (an assessment of competency needs with steps taken to ensure that personnel are fully qualified and competent.)

12) Will our staff have to complete transition training?

It will depend on the extent of revisions that you make to your quality management system, but generally – yes you will be expected to provide some form of transition training to your staff. At a minimum, PJR would expect that awareness training of the new standard would be provided, as well as an assessment of the new standard's impact on the various processes and personnel. However, it is entirely conceivable that the majority of your staff will feel no effect from your company's transition to ISO 9001:2015.

13) What about our internal auditors, will they have to complete transitional training?

Internal auditing is viewed in the same light as any other required competency within a quality management system. Namely, the organization is responsible for determining what competencies are required for its internal auditors, as well as the methods to be used to achieve those competencies. To put it more plainly, each organization will have to decide on its own the extent to which transition training will be needed. It is conceivable that a seasoned team of internal auditors could complete a period of self-study and successfully transition to auditing ISO 9001:2015. As has always been the case, the competency of your internal auditors will be judged by the overall effectiveness of your internal audit process.

14) Will the other standards (AS9100, TS16949, etc.) be updated also?

All of the major sector specific standards, including TS 16949, AS9100, and TL9000 have indicated their intentions to transition and continue their alignment with ISO 9001. The timelines for these other standard updates are not fully known at this time, but a 2016 publication date seems likely for all three. At present the only major standard that is not planning to continue its alignment to ISO 9001 is ISO 13485, which is in the midst of its own update with a targeted publication of early 2016.

15) What steps can we take right now?

Your preparation process can include a review of the currently available DIS, or the soon to be available FDIS. As mentioned earlier PJR does not recommend purchase of either of these documents, but they can provide early planning assistance if needed. Additional resources for planning at this phase will be coming online over the course of 2015. Expect to see an official transition guide from the ISO itself, and likely additional written materials from other bodies such as ANAB and RABQSA. PJR will also be providing additional materials, particularly after the FDIS is published. The International Accreditation Forum (IAF) has published an Informative Document (ID 9) which recommends the following steps be taken in a the transition to ISO 9001:2015. 1) A full review of the ISO 9001:2015 standard should be performed by Top Management to identify the gaps that need to be addressed. 2) A plan of implementation should be developed with assigned responsibilities. 3) All quality management system documents (including the quality and procedures manual (if applicable)) should be updated to reflect any new or revised processes. 4) All necessary awareness and transition training should be completed. 4) A full system internal audit followed by a Management Review should be complete. 5) Corrective Actions for all internal audit findings should be in process or complete. 6) Coordinate with PJR for planning of transition arrangements.

16) Will extra audit time be needed for my transition audit?

Yes, if you plan on transitioning on a normal surveillance or recertification audit, extra time will be added to your audit. Guidance published by the International Accreditation Forum clearly states the following: "Where transition audits are carried out in conjunction with scheduled surveillance or recertification (i.e. progressive or staged approach), additional time is likely to be required to ensure that all activities are covered for the existing and new standards."

PJR has completed an analysis of the new requirements and our technical experts have analyzed the time it would take to effectively audit these requirements in different companies.

17) Our organization is considering transferring our accredited ISO 9001:2008 certification to PJR. How does the transition timeline impact our plans to transfer?

The requirements will be the same whether you are a currently certified PJR client or a transfer candidate. PJR will transfer an ISO 9001:2008 certificate until 1 May 2018. Subsequent to this date, we cannot guarantee that all transition activities will be completed prior to the transition deadline.

These helpful FAQ's will also be available via download on www.pjr.com. Should you have further questions or require assistance please contact our office for a Project Manager in your area.