



**GABRIEL
REGISTRAR**

Transition Planning & Guidance

ISO 9001:2015, Quality Management Systems



Preparing for the Change – Transition to ISO 9001:2015

As everyone to be in the world of eminence is aware, the world now has a new version of ISO 9001. 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 industry wide.

The Change

All ISO management system standards are subject to a regular review under the rules by which they are written. Following a substantial user survey, the committee decided that a review was appropriate and created the following objectives to maintain its relevance in today's market place and in the future:

- Integrate with other management systems.
- Provide an integrated approach to organizational management.
- Reflect the increasingly complex systems in which organizations operate.
- Enhance an organization's ability to address their Quality, environmental impacts to the society.

The task of understanding the revised standard's effect on your organization can be overwhelming. We at GR want to ease our clients and potential clients into these new standards 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.

Transition Milestones

This is currently the most frequently asked questions from our clients. We have developed this to bring you a simplified overview. Before detailing our recommendations, let's review the facts: The management of GR is conditionally committed on the following dates:

	ISO 9001:2015
Publication of the official standard	15 September 2015
Transition period start date	15 September 2015
Transition period end date	14 September 2018
Certifications on earlier version (ISO 9001:2008) become no longer valid from	14 September 2018
Cut-off date for the Initial Certification activities on earlier version (ISO 9001:2008)	31 July 2018
Cut-off date for the all certification activities on earlier version (ISO 9001:2008)	31 July 2018
Cut-off date for transfer of certificate to 2015 version (from ISO 9001:2008)	31 July 2018

Training Requirements

- Training of all process owners in ISO 9001:2015 standards including documentation.
- Internal auditors need to be trained for conducting internal audits in the newer version of the standards.



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?

The new standard was published on September 15, 2015. This means that the ISO 9001:2008 standard will become obsolete on September 14, 2018. As a result, all certifications of these two standards issued in late 2015 and beyond will have to bear an expiry date September 14, 2018. 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. GR has established cut-off plan for ISO 9001:2008 in two tiers. This is explained as a response to the next two questions.

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

While it is true that the transition period does not end until September 14, 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 GR's technical review committee (decision-making body) must review and approve the audits 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 September 14, 2018. Thus, all transition audits must be completed by 31 July 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 earlier versions of the standard and then transition later?

GR appreciates that a lot of work may have gone into preparing for certification to ISO 9001:2008. Keep in mind that ISO 9001:2008 will be obsolete on September 14, 2018. Therefore, the expiration date on any 2008 certificate issued after the publication of ISO 9001:2015 will be September 14, 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 the earlier version of the standards?

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 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 earlier versions, 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 certificates be perceived as better than an ISO 9001:2008 certificates 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 audits are 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 audits can be closed. This means that there will be a lapse in your certification status. Our admin 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 to ISO 9001?

GR 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_Consolidated.xhtml#x---Annex-SL--normative---Proposals-for-management-system-standards 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?



GR'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 favourably 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?

Yes. You will be expected to provide some form of transition training to your staff. At a minimum, GR 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 this has always been the case, the competency of your internal auditors will be judged by the overall effectiveness of your internal audit process.

14) What steps can we take right now?

The International Accreditation Forum (IAF) has published an Informative Document (ID 9) which recommends the following steps be taken in the transition to ISO 9001:2015 respectively.

- 1 A full review of the standards 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 and or environmental 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.
- 5 A full system internal audit followed by a Management Review should be complete.
- 6 Corrective Actions for all internal audit findings should be in process or complete.
- 7 Coordinate with GR for planning of transition arrangements.

15) 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.”

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

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

The requirements will be the same whether you are a currently certified GR client or a transfer candidate. GR will transfer an ISO 9001:2008 certificate until 31 July 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.gabrielregistrar.com. Should you have further questions or require assistance please contact our office.