

**ISO 9001  
Transition  
Guidelines**



**PREPARE FOR THE CHANGE WITH BSCIC....**

PREPARING FOR THE CHANGE  
FROM ISO 9001:2008  
TO ISO 9001:2015



BSCIC ADDING VALUE

**The adoption of a Quality Management System is a strategic decision for an Organization that can help to improve its overall performance and provide a sound basis for sustainable development initiatives.**

**Reference- ISO 9001:2015**

## AIM OF THE DOCUMENT

This aim of this Transition Guideline document is facilitating your meeting the requirements of the new international standard for Quality Management Systems (QMS) ISO 9001:2015, which replaces the previous version ISO 9001:2008.

## WHY THE CHANGE??

As per ISO, All ISO standards are reviewed every five years to establish if a revision is required to keep it current and relevant for the marketplace. TISO 9001:2015 is designed to respond to the latest trends and be compatible with other management systems.

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 organization.

2. There has been a targeted effort to simplify language used to aid in understanding & promote consistency between accreditation bodies, certification bodies, auditors & 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.

## WHY SHOULD ONE ADOPT A QUALITY MANAGEMENT SYSTEM??

A well designed and implemented Quality Management System, based on ISO 9001 has been shown to provide organizations with the following benefits: You will have consistent, repeatable processes and a common system. You will have fewer problems with failures in service or product quality.



**FIGURE 1- WHY QMS??**

## COMPARING ISO 9001:2008 WITH ISO 9001:2015

The most noticeable change to the standard is its new structure. ISO 9001:2015 now follows the same overall structure as other ISO management system standards (known as the High-Level Structure), making it easier for anyone using multiple management systems. More information can be found in Annex SL of ISO/IEC Directives Part 1 (the rules for developing ISO standards).

Another major difference is the focus on risk-based thinking. While this has always been part of the standard, the new version gives it increased prominence.

The new version of the standard brings the user a number of benefits. For example, ISO 9001:2015:

- ✚ Puts greater emphasis on leadership engagement

- ✚ Helps address organizational risks and opportunities in a structured manner
- ✚ Uses simplified language and a common structure and terms, which are particularly helpful to organizations using multiple management systems, such as those for the environment, health & safety, or business continuity.
- ✚ Addresses supply chain management more effectively.
- ✚ Is more user-friendly for service and knowledge-based organizations.
- ✚ Aligning QMS policy and objectives with the strategy of the organization

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Also there are a number of changes with respect to the terminology outlined in Table 01:

<b>MAJOR DIFFERENCES IN TERMINOLOGY BETWEEN ISO 9001:2008 &amp; ISO 9001:2015</b>	
<b>ISO 9001:2008</b>	<b>ISO 9001:2015</b>
Products	Products & Services
Exclusions	Not Used
Management Representative	Not Used
Documentation, Quality Manual, Documented Procedures, Records	Documented Information
Work Environment	Environment for the operation of processes
Monitoring & Measuring equipment	Monitoring & Measuring resources
Purchased Product	Externally provided products & Services
Supplier	External Provider

**TABLE 1- MAJOR DIFFERENCES IN TERMINOLOGY (ISO 9001:2008 vs. ISO 9001:2015)**

## STRUCTURE OF THE STANDARD

Perhaps the biggest difference between the old & the new standard is the structure. ISO 9001 2008 had five main sections (4 to 8) and ISO 9001 2015 now has seven (4 to 10). This is because the new edition uses the new *Annex SL* template. According to ISO, all future management system standards (MSSs) will use this new layout and share the same basic requirements. As a result, all new MSSs will have the same basic look and feel.

A common structure is possible because basic concepts such as management, customer, requirements, policy, procedure, planning, performance, objective, control, monitoring, measurement, auditing, decision making, corrective action, and nonconformity are common to all management system standards. While this will make it easier for organizations to implement multiple standards because they will all share the same basic requirements, it may cause some disruption in the short run as organizations get used to the new structure.

## DOCUMENTED INFORMATION

The new ISO 9001 2015 standard has also eliminated the long standing distinction *between* documents and records. Now they are both referred to as “*documented information*”.

## RISK-BASED THINKING

According to the new standard, “*risk-based thinking has always been implicit in ISO 9001*”. According to this perspective, ISO 9001 has always been about anticipating and preventing mistakes, which is what risk-based thinking is all about. So what kind of thinking is *risk-based thinking* and how is it applied?

What does the new standard expect organizations to do? The new standard expects organizations to identify and address the *risks* that could influence their ability to provide compliant products and services and to satisfy customers. It

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also expects them to identify and address the *opportunities* that could enhance their ability to provide compliant products and services and to satisfy customers.

### REQUIREMENTS AND EXCLUSIONS

Section 1.2 of ISO 9001 2008 says that organizations may exclude or ignore product realization requirements (section 7) if they cannot be applied and if doing so doesn't interfere with its ability or responsibility to meet customer and legal requirements.

The new standard takes a similar approach but, instead, seems to apply this thinking to all requirements.

Section 4.3 of ISO 9001 2015 says *“The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system”*. So once you've determined the scope of your QMS, ISO 9001 2015 says that every requirement must be applied within the boundaries defined by your statement of scope if it applies in your case.

However, while the new ISO 9001 2015 standard says that every requirement must be applied, section 4.3 and Annex A5 also says that any requirement may be excluded if it cannot be applied, if you can justify and explain why it can't be applied, and if excluding it

does not undermine your ability or responsibility to ensure that products and services are in compliance.

So, the message is clear: if a requirement can be applied you can't just ignore it. You must apply it. And if you really can't apply it, you better be able to explain why not.

### OBJECTS, OUTPUTS, PRODUCTS, AND SERVICES

The definition of the term “object” is new. The introduction of the term “object” to mean anything conceivable or perceivable and its use in various definitions (quality, design and development, innovation, review, traceability) seems to suggest that the new ISO 9001 standard can be applied to any object whatsoever. In theory at least, this greatly expands its scope.

What ISO 9000 2005 used to call a “product” the new standard now calls an “output”. The two definitions are the same. Since the term “output” was not defined in 2005, this shift in terminology suggests that the process approach is now even more central to the new standard.

And to further complicate things, the old definition of “product” has now been split into three separate definitions for the terms *output*, *product*, and *service*. “*Output*” is the general concept since both “*products*” and “*services*” are now thought of as “*outputs*”.

## OTHER CLARIFICATIONS AND MODIFICATIONS

While the previous changes could be the most important ones, the new standard has also clarified some concepts and modified others. Some of these changes are listed below.

The old standard said that a “*service*” was a type of “*product*”. Now, the phrase “products and services” is used throughout the new standard and the term “*service*” has received its own definition. This should help make it clear that ISO 9001 2015 applies not only to manufacturers but also to all types of service providers.

What used to be called “*customer property*” has been modified and greatly expanded to include products, services, and processes belonging to all types of external providers (including customers). The new standard now expects you to control externally provided products and services if they are included in your products or services or if they are provided directly to customers.

The old definition of “*continual improvement*” has changed. When ISO 9001 2008 asked you to make continual improvements it was asking you to improve your ability to fulfill requirements. Now, ISO 9001 2015 says it means enhancing performance (getting better results). This is an important shift.

According to the new standard, organizations must now identify, acquire, and share the “*knowledge*” that personnel need in order to support process operations and achieve conformity of products and services.

The old concept of “*product realization*” is gone. Most of the material in the old product realization section has been modified and moved to the new ISO 9001 2015 section on *Operations*.

The term “*management representative*” has been dropped. The management duties and responsibilities that were previously assigned to someone called a “*management representative*” may now be assigned either to one person or to many people.

“*Preventive action*” has also disappeared. It’s been replaced by “*risk-based-thinking*”, evidently because both approaches try to achieve the same thing. Both try to prevent future problems. Once you introduce risk-based thinking, you no longer need a separate clause on preventive action. It’s redundant.

While the old standard asked you to use monitoring and measuring “*equipment*”, the new standard refers to monitoring and measuring “*resources*”. This is a more flexible approach to monitoring and measuring because it recognizes the fact that these activities can often be carried out without the use of equipment.

## TRANSITION GUIDANCE

### 1. FOR EXISTING BSCIC CLIENTS:

Please note the 3 year transition period.



Please note that no certificate of QMS shall bear the expiry date later than 23rd Sept' 2018 as all the ISO 9001:2008 certificates will be invalid after this particular date i.e. 23rd Sept' 2018.

May you still want to opt for ISO 9001:2008, transition to new standard i.e. 9001:2015 will be required in between to keep the certificate valid. However BSCIC appreciates & encourages current users of ISO 9001:2008 to implement ISO 9001:2015 at an early stage.

Please note that if your organization does not have a transition audit prior to the end of the transition period/obsolescence date of ISO 9001:2008, and 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).

However in this journey of transition, BSCIC's Assessment Scheduling Department

will work with you to ensure the timely scheduling of any transition audits that occur later in the transition period to avoid any unfortunate situation.

Based on the agreement with you, BSCIC is in a potential to conduct transition activities during a routine surveillance, recertification audit or a special audit.

Please note that the new standard was published on September 23, 2015. This means that the ISO 9001:2008 standard will become obsolete on September 23, 2018. As a result, All ISO 9001:2008 certifications issued in late 2015 and beyond will have to bear an expiry date September 23, 2018.

⚠ BSCIC will accept a client undergoing surveillance with ISO 9001:2008 version only till APRIL 1; 2016. We are sending out this communiqué 6 months in advance so that you may prepare well.

⚠ However if a client on special request puts up a request not to be able to entertain ISO 9001:2015 version in the year 2016, we may consider the client in 2017.

⚠ Please note that 1<sup>st</sup> JANUARY 2016 onwards BSCIC shall be ready to take up any client which requests its surveillance against ISO 9001:2015. Clients are welcome to state that they want the surveillance assessment to be a transition & BSCIC shall perform it

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against ISO 9001:2015. However we are not imposing the same upon the client.

⚠ If you take up your surveillance against ISO 9001:2015, we will however not raise NCRs against the new requirements. Any finding shall be raised as 'OBSERVATION'. This will continue up to SEPTEMBER 23; 2017.

⚠ From SEPTEMBER 23; 2017 to SEPTEMBER 23; 2018- Any finding which accounts to a NON CONFORMITY will be raised as a Non-Conformity however be kept as MINOR NON-CONFORMITY so that it doesn't impact the certification status of the client.

⚠ This will continue up to SEPTEMBER 23; 2018 post which the ISO 9001:2015 requirements become MANDATORY.

⚠ All clients shall be notified that they are required to close their CAPs by June 2018. BSCIC plans to transition all its clients to ISO 9001:2015 by JUNE 30; 2018.

If you have a Recertification audit in early 2016, it will be your strategic decision that to choose the version, 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 its regular recertification audit is ideal, but not in any way mandatory. You may certainly perform 2016 Recertification Audit to ISO 9001:2008, and then complete a transition audit to ISO 9001:2015 in 2017.

## 2. FOR FRESH ENQUIRIES-

If an organization is not yet certified & has been working at implementing ISO 9001:2008 for a while, BSCIC appreciates that a lot of work may have gone into preparing for certification to ISO 9001:2008. BSCIC will allow initial audits to the 2008 version of the standard HOWEVER keeping in mind that ISO 9001:2008 will be obsolete on September 23, 2018.

⚠ Since for new applicants, BSCIC needs to decide about the cutoff date beyond which old standard's application shall not be accepted, BSCIC has kept the cutoff as SEPTEMBER 23;2016.

⚠ The expiration date on any 2008 certificate issued after the publication of ISO 9001:2015 will be September 23, 2018. Thus, it may appear that you are 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.

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In any of the cases, it is important to avoid waiting until the last minute.

Please support BSCIC to ensure the following during Transition activities:

- I. All issues that require your action for compliance with the new requirements be clearly identified and raised as documented findings.
- II. Only when all identified outstanding issues have been appropriately addressed and the effectiveness of the management system demonstrated, the auditors recommend certification to the published ISO 9001:2015 standard for your organization.
- III. Your Quality Management System's Records be verified to demonstrate that all prior transition audit findings have been evaluated for corrective action and compliance before any recommendation for approval to ISO 9001:2015 be made.
- IV. BSCIC ensures that the evaluation of your conformance to the new requirements during the transition phase does not interfere with your on-going conformance to ISO 9001:2008.

May you have any queries or any issues you may want to discuss with us during the course of transition, please feel free to write in/ call on the following contact details:

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