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The Meaning of ISO

What does ISO Mean

ISO, the International Organization for Standardization, is a global, non-governmental standards publishing body. Although it's always capitalized, ISO is a word, not an acronym.

The name ISO was derived from the Greek word isos, meaning "equal."

Each member country has representatives that make up a Technical Advisory Group (TAG).

These groups' draft the standard, then members comment and vote on the standard. The document then becomes an ISO standard.

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These standards are not regulations. They are a method of getting a standard set of criteria for quality management systems. An outside agency, the registrar, will then audit to see if you have all the required elements in place. If you do, you will get ISO 9001 registration. This registration tells others all over the world that you have this quality system in place.

ISO 9001, Quality management systems – Requirements, is arguably ISO's most well-known standard, but ISO is involved in much more than management systems – there are ISO standards for everything from technological connections, railroad construction to ink color.

Also, there are many management systems standards that are not published by ISO such as AS9100, which is published by the Society of Automotive Engineering (SAE) and the International Aerospace Quality Group (IAQG). Therefore, while you may find that people use the term ISO certification to describe management systems certification, it's not a technically correct term. It can be corrected by adding the standard name: for example, ISO 9001:2015 certification.

What is an accreditation?

Accreditation is the approval of a certification body (such as a registrar, by a national accreditation or standards body such as National Accreditation Board for Certification Body (NABCB) in INDIA. In other words, it's the registrar's "certification" that deems it competent to issue certifications to your company. Therefore, as the certified organization, it is not appropriate for you to say you are accredited, because it is your registrar that holds the accreditation.

How does the audit process work?

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Typically initial certification audits are performed in two stages:

•Stage 1 Gap Assessment, your assessor's lead auditor confirms that your management system has been designed to conform with the requirements of the standard and achieve your organization's policy objectives. During this audit, our team evaluates the capability of the management system to manage compliance with statutory, regulatory, and contractual requirements. If the results of the Stage 1 audit are acceptable, your organization receives confirmation for proceeding with the Stage 2 audit. Your organization is also given a predetermined amount of time to correct any non-conformities found.

•In Stage 2, the assessor's auditor performs a full on-site audit of the management system. The objectives of the audit are to confirm that the management system conforms with all the requirements of the standard, and that your organization has effectively implemented the management system so it can achieve the organization's policy objectives. Your organization is given a predetermined amount of time to correct any non-conformities found.

After the successful completion of both stages, your organization receives a certificate that *expires after three years*.

After the initial certification, surveillance audits are performed at either 6-month or 12-month intervals (according to your organization's preference) to ensure that the management system still conforms with the standard. During a surveillance audit, the auditor only reviews a portion of the management system. At the next surveillance audit, he will audit a different portion of the management system. These samples are determined ahead of time using an audit plan.

Three years after initial certification, your organization must undergo a re-certification audit (often called a re-assessment) where the entire management system is audited again. Upon successful completion of the re-certification audit, your organization receives a new certificate valid for the next three years, and a new period of surveillance audits begins.

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This three-year cycle of surveillance and re-certification audits repeats for as long as your organization maintains its certification.

What are first-, second-, and third-party audits?

- A first-party audit occurs when an audit is performed within your organization by your own auditing resource. This is often called an internal audit.
- A second-party audit is performed by a supplier, customer, or contractor, often against their proprietary requirements.
- A third-party audit is performed by an independent body (i.e., a registrar such as assessor's) against a recognized standard (i.e., ISO 9001).

ISO 9001 Registration Process

To become registered a company must first implement the requirements of ISO 9001:

1. First evaluate your current quality system;
2. Second add systems and processes to meet the requirements;
3. Document your processes as part of your Quality Plan (manual), Procedures and Work Instructions;
4. Essentially an organization is a system of interlinked processes. The standard is geared at managing and improving those processes.
5. Identify Key Processes – those that lead to products and services- must be identified;
6. Identify the Key Process Methodology – Methods to measure and control these processes must be included;
7. Determine how you will measure and monitor quality.

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Next Steps

1. Determine time-line for implementation;
2. Perform Gap Analysis Review how your existing quality system fits into ISO 9001:2015 format;
3. Put together an implementation plan and time-line;
4. Identify an accredited Certification Body;
5. Implement the system;
6. Run the system for 3 months to gather records, perform internal audits, have management review and make improvements;
7. Have your Registration Audit;
8. Correct any non-conformance;
9. Celebrate your registration!
10. Maintain your system with regular internal audits, management reviews and surveillance audits from your Certification Body (aka Registrar).

Benefits of Registration

Improved Operations:

- The requirements of ISO 9001 introduce good business practices for any business.
- Experts from around the world got together and identified the basic elements a business should put in place to have a good quality management system.
- By using the ISO 9001 standard to design your quality management system you are drawing on this expertise.
- You will be designing an effective quality management system that will lead to improved operations.

Improved Operating Margin:

- This improvement in operations also leads to an improvement at the bottom line, an improvement in operating margin.



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- A survey of 1000 companies showed an average improvement of 5% that managers attributed to having an ISO 9001 quality system.

External Recognition:

- ISO 9001 is recognized worldwide and when you are ISO 9001 registered other companies know that you have a "world class" quality management system in place.
- They know you have a corrective action system, a system to handle client complaints and non-conformance.
- They know that you are continually addressing problems and improving your operations and performance.

Market Expansion:

- Some marketplaces require ISO 9001 registration. You will be able to sell services or products to these markets.
- Some marketplaces do not openly require registration, but prefer to work with ISO 9001 registered suppliers.
- An unregistered company faces a definite disadvantage in these markets.

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1) Customer focus

2) Leadership

3) Engagement of people

4) Process approach

5) Improvement

6) Evidence-based decision making

7) Relationship management

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Guidance for ISO 9001:2015

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.

The potential benefits to an organization of implementing a quality management system based on this International Standard are:

- a) the ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements;
- b) facilitating opportunities to enhance customer satisfaction;
- c) addressing risks and opportunities associated with its context and objectives;
- d) the ability to demonstrate conformity to specified quality management system requirements.

The ISO 9001 International Standard can be used by internal and external parties. It is not the intent of this International Standard to imply the need for:

- uniformity in the structure of different quality management systems;
- alignment of documentation to the clause structure of this International Standard;
- the use of the specific terminology of this International Standard within the organization.

The quality management system requirements specified in this International Standard are complementary to requirements for products and services.

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This International Standard employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and *risk-based thinking*. The process approach enables an organization to plan its processes and their interactions.

The PDCA cycle enables an organization to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are determined and acted on.

Risk-based thinking enables an organization to determine the factors that could cause its processes and its quality management system to deviate from the planned results, to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise (see Clause A.4).

Consistently meeting requirements and addressing future needs and expectations poses a challenge for organizations in an increasingly dynamic and complex environment. To achieve this objective, the organization might find it necessary to adopt various forms of improvement in addition to correction and continual improvement, such as breakthrough change, innovation and re-organization.

In this International Standard, the following verbal forms are used:

- “SHALL” indicates a requirement; (135)
- “SHOULD” indicates a recommendation;
- “may” indicates a permission;
- “can” indicates a possibility or a capability.

Information marked as “NOTE” is for guidance in understanding or clarifying the associated requirement.

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1. INTRODUCTION

This Guidance has been developed to assist users in understanding the issues that need to be considered during the co-existence period between ISO 9001:2008 and ISO 9001:2015.

For new uses the Understanding of ISO 9001:2015

A wide diffusion of this implementation guidance is recommended, in particular the comparison table between ISO 9001:2008 and ISO 9001:2015 matrix showing the correlation between the clauses of these international standards can be found on the www.iso.org/tc176/sc02/publicwebsite.

The revision of ISO 9001:2015 introduces a new 10 clause structure, many new requirements and many terms. Users will need to take into consideration that changes may be necessary to their QMS.

2. BACKGROUND TO THE ISO 9001:2015 REVISION PROCESS

In order to assist organizations to have a full understanding of the new ISO 9001:2015, it may be useful to have an insight on the revision process, how this revision reflects the inputs received from users of the standard, and the consideration given to benefits and impacts during its development.

Prior to the commencement of a revision (or amendment) to a management system standard, a “Justification Study” is prepared to present a case for the

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proposed project which outlines details of the data and inputs used to support its arguments. In relation to the development of ISO9001:2015 user needs were identified from the following:

- **ISO Annex SL provides a common structure, text, terms and definitions for management**

System standards.

- **The results of a formal “Systematic Review” on ISO 9001:2008 that was performed by the members of ISO/TC 176/SC2**

- **Feedback from the ISO/TC 176/SC2 Working Group on Interpretations**

- **an extensive worldwide “User Feedback Survey” on ISO 9001 was performed by ISO/TC**

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The Justification Study identified the need for a revision to:

- ☐ **adapt to a changing world**
- ☐ **enhance an organization's ability to satisfy its customers**
- ☐ **provide a consistent foundation for the future**
- ☐ **reflect the increasingly complex environments in which organizations operate**
- ☐ **ensure the new standard reflects the needs of all relevant interested parties**
- ☐ **align with other management systems**

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The key focuses of the ISO 9001:2015 revision were to enhance clarity and compatibility with other management system standards.

The benefits identified for the ISO 9001:2015 edition:

- **Provides clarity**
- **Enhanced leadership involvement in the management system**
- **Risk-based thinking**
- **Simplified language, common structure and terms**
- **Aligning QMS policy and objectives with the strategy of the organization**

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3. USER GROUPS

3.1 Individual organizations using ISO 9001 (including industry associations)

a) Current Users of ISO 9001:2008

This user group is defined as having completed or being in the process of implementing ISO 9001:2008, regardless of whether they are certified or not, or whether they intend to be certified or not.

b) New Users

A New User is defined as an organization that is either beginning to use ISO 9001:2008 or ISO9001:2015 for the first time or is a potential user of the standard in the future.

c) Users of Industry Sector Schemes based on ISO 9001:2015

These user groups are defined as those using quality management system programs based on ISO 9001:2015 that include additional requirements, that either can be certified or accredited under the guidance of a particular Industry Sector Scheme (e.g. ISO/TS 16949 *Quality systems –Automotive suppliers*).

3.2 Other user groups

These are defined as being:

- a) National Standards Bodies (NSBs)**
- b) Accreditation Bodies (ABs)**
- c) Certification/Registration Bodies (CB/RBs)**
- d) Trainers and Consultants**

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4. IMPLEMENTATION GUIDANCE

4.1 Generic guidance

All users groups are strongly advised to note the IAF's Informative Document ID 9:2015 (see:

<http://www.iaf.nu/upFiles/IAFID9Transition9001PublicationVersion.pdf>) for

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implementation of accredited certification to ISO 9001:2015, which details the agreed implementation plan for accredited certification as follows:

Accredited certification to ISO 9001:2015 shall not be granted until the publication of ISO 9001:2015 as an International Standard.

Certification of conformity to ISO 9001:2015 and/or national equivalents shall only be issued after official publication of ISO 9001:2015 (which should take place before the end of 2015) and after a routine surveillance or re-certification audit against ISO 9001:2015.

Validity of certifications to ISO 9001:2008

ISO 9001:2008 certifications will not be valid after three years from publication of ISO 9001:2015.

The expiry date of certifications to ISO 9001:2008 issued during the transition period needs to correspond to the end of the three year transition period.

Figure 1 - Implementation timetable for ISO 9001:2015, for all user groups IMPLEMENTATION GUIDANCE FOR ISO 9001:2015

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To benefit from the changes introduced into ISO 9001:2015, users (from all user groups) should note the recommendations given in the table below. Recommendations for specific user groups are given in section 4.2 further down.

To get acquainted with the new edition of the standard use the following resources:

- ☐ **Annex A (informative) – New structure, concepts and terminology**

Support material found at

www.iso.org/tc176/sc02/public:

- **ISO 9001:2015 Change Summary**
- **Correlation matrices between ISO 9001:2008 and ISO**
-

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9001:2015, which provides a before and after view of the clauses

- **Risk Based Thinking**
- **Process Approach**

Determine the impact of the changes of the new version on your current use of ISO 9001 and plan any necessary remedial actions.

Use the Plan-Do-Check-Act methodology to manage the implementation.

Note that the actions may need to vary according to your user group (see 4.2 below).

4.2 Guidance for specific user groups

These recommendations complement the generic guidance to all user groups given in section 3.0 above.

4.2.1 Organizations using ISO 9001:2008

a) Current users

Organisations that are already certified to ISO 9001:2008 should contact their certification/registration bodies (CB/RB) to agree a program for analysing the clarifications in ISO 9001:2015 in relation to their individual quality management systems and for upgrading their certificates.

Certified organizations should bear in mind that ISO 9001:2008 certificates have the same status

as new ISO 9001:2015 certificates during the co-existence period.

Organizations in the process of certification to ISO 9001:2008 should change to using ISO

9001:2015 and apply for certification to it.

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b) New users

New users should start by using ISO 9001:2015.

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c) Industry Sector Schemes

Users of specific sector schemes are recommended to refer to the organization that is responsible that sector scheme', e.g. for:

- ☐ **ISO/TS 16 949 refer to the IATF (www.iatfglobaloversight.org)**
- ☐ **TL 9000 refer to the QuEST Forum (www.questforum.org)**
- ☐ **AS9100/EN9100 refer to IAQG (www.iaqg.org)**

4.2.2 National Standards Bodies

Information regarding the 2015 edition of ISO 9001 should be communicated to standard users, in a timely manner, by the national standards bodies (NSBs). It is recommended that NSB actions be synchronized with the information flows from ISO and ISO/TC 176/SC2.

NSBs are responsible, at a national level, for communicating the issues regarding the changes from ISO 9001:2008 to ISO 9001:2015 to all interested parties and for providing translations of the new edition of the standard in their national languages. It is recommended that they coordinate their communications regarding these issues with other local interested parties (for example: ABs, CB/RBs, professional quality associations, etc.).

Translation Issues - If a requirement for translation of the new standards exists, the translation process should be started as early as possible, in order to provide the equivalent national edition as soon as possible.

An NSB should analyse if there are interpretation problems in the national ISO 9001:2008 version due to former translation problems. In affirmative cases the NSB should carry out an extensive translation of the standard. If interpretation divergences still remain, the NSB is recommended to apply for clarification to the ISO/TC 176/SC2 Interpretations Working Group using the established "Interpretations" process (see: www.iso.org/tc176/sc02/public).

4.2.4 Accreditation Bodies

ABs should refer to the IAF's Informative Document ID 9:2015for the implementation of accredited certification to ISO 9001:2015 (see 4.1 above).

4.2.5 Certification Bodies

CBs should refer to the IAF's Informative Document ID 9:2015for the implementation of

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Accredited certification to ISO 9001:2015 (see 4.1 above).

CBs should remember that certificates of conformity to ISO 9001:2015 and/or its national equivalent adoptions can only be issued after the official publication of the amended standard.

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It is important that accredited certification bodies ensure that their auditors are aware of the clarifications introduced in ISO 9001:2015, and their implications, prior to conducting audits to that standard.

4.2.6 Training Bodies and Consultants

All trainers and consultants should be aware of the clarifications in ISO 9001:2015. All training bodies and consultants are recommended to determine the need for updating training programs and documentation, or any other changes necessary, to the services they provide.

5.0 FREQUENTLY ASKED QUESTIONS

While this Implementation Guidance provides recommendations on a number of issues facing the different user groups during the co-existence period, it does not address more general questions about the ISO 9000 standards. Instead ISO/TC 176/SC 2 has prepared a set of

frequently asked questions (FAQs) to provide such advice.

It is expected that the FAQs will be updated on a more regular basis than this Implementation

Guidance. For the latest version of the FAQs, reference should be made to the open access web site at www.iso.org/tc176/sc02/public .

6.0 AUTHENTICITY OF INFORMATION REGARDING ISO 9001:2015

The first point of contact for information regarding the requirements of ISO 9001:2015 should be your National Standards Body (for a listing of ISO's member National Standards Bodies, see www.iso.org/iso/about/iso_members.htm).

Other recommended sources of information are:



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- **ISO's web site www.iso.org provides general information regarding the ISO 9001:2015 revision programme (as well as details of its member National Standards Bodies).**
- **The ISO/TC176/SC2 web site, www.iso.org/tc176/sc02/public provides detailed information on the ISO 9001 revision program and is updated on a regular basis.**