



What is Really Required for ISO 9000?

Executive Summary

As you begin your ISO 9001 preparations it is important to gain a good understanding of the actual requirements of the standard. If you are new to the ISO certification process you may have some misunderstandings about the requirements of the standard and what it takes to get certified.

This ISO Buyer's Guide is intended to help dispel many of the common misconceptions regarding the ISO process and to acquaint you with the major steps necessary to complete the certification. To learn more about what is required we suggest you purchase a copy of the ISO 9001 standard. You may contact the 9000World office for information about where the standard may be purchased. We also offer a number of products and services to assist you with implementing the ISO requirements and provide several additional free learning resources listed at the bottom of this Buyer's Guide.

ABOUT THIS BUYER'S GUIDE

The How to Buyer's Guides – for ISO 9000 is a series of free resources for companies seeking ISO 9001 certification for the first time. They are provided to help with the decisions involved with preparing for and achieving ISO 9001:2008 certification.

The Buyer's Guides were developed by the ISO 9000 consultants at 9000World based on hands-on experience working with hundreds of companies achieving ISO 9001 certification.

Common Misconceptions

Unfortunately, there are a number of misunderstandings regarding the ISO 9001 process and the requirements you must meet to become certified. This confusion often comes from colleagues who previously worked in an ISO certified company or experiences you may have had in the past. Below is a list of the more common misconceptions regarding ISO 9001 certification:

Top Misconceptions	The Facts
<i>ISO 9001 requires an inordinate amount of documentation; basically all of our processes have to be documented.</i>	<ul style="list-style-type: none"> • Past versions of the ISO 9001 standard required a procedure for every section (element) of the standard and work instructions for most company operations. • The current version of ISO 9001 (2008) has significantly reduced the number of "required" documents and allows the company to determine where to require procedures and work instructions. • Most smaller companies need only a few general documents to become certified.
<i>ISO certification is declining worldwide and is no longer relevant.</i>	<ul style="list-style-type: none"> • The number of certifications has increased every year since its introduction in 1987. • In many industries, ISO 9001 certification is a minimum requirement for doing business. • There are nearly 1,000,000 ISO 9001 certifications worldwide.
<i>ISO 9001 certification is very expensive to achieve and maintain and cost prohibitive for most small companies.</i>	<ul style="list-style-type: none"> • ISO 9001 costs depend upon (1) the size of your company, and (2) how much assistance you need to prepare for the certification audit.

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<p><i>It requires one or two full-time people to maintain ISO certification.</i></p>	<ul style="list-style-type: none"> • There are a few administrative responsibilities but most small companies can easily keep up with them with current resources. • It is generally not necessary to hire additional staff to keep up with ISO 9001 requirements.
<p><i>ISO 9001 certification does not lead to better quality.</i></p>	<ul style="list-style-type: none"> • Previous versions of the ISO 9001 standard did not include requirements for achieving better quality results. • The current version of the standard includes requirements for measurable continual improvement. • Companies that do not demonstrate improved results year-to-year may not be able to maintain the certification.
<p><i>Top management can delegate ISO 9001 responsibilities and not have to participate in the process.</i></p>	<ul style="list-style-type: none"> • The newer versions of the ISO standard have added specific requirements for "top management" (President, CEO, COO and his/her direct management reports) to provide planning and oversight of the ISO program. • Participation of top management is a mandatory part of an ISO certification.
<p><i>It is possible to "fail" the ISO 9001 audit.</i></p>	<ul style="list-style-type: none"> • Generally, the only way to "fail" the ISO 9001 certification is to completely neglect one or more of the main requirements of the standard. • If you have attempted to implement all of the stated requirements, you will be given a chance to correct minor non-conformances (discrepancies) following the Registrar's audit. • It is very uncommon for a company to "fail" an ISO certification if there is evidence of efforts made to comply with the requirements.
<p><i>It is not required that you must purchase a copy of the ISO 9001 standard.</i></p>	<ul style="list-style-type: none"> • The Registrar will expect that you have purchased and maintain a current copy of the ISO 9001 standard.
<p><i>The ISO 9001 requirements are lengthy and complicated.</i></p>	<ul style="list-style-type: none"> • The actual requirements in the ISO 9001:2008 standard are contained in 14 written pages. • In recent years, revisions have been made to greatly simplify both the language and requirements of the standard. • Most companies are surprised with the flexibility and simplicity of the standard.
<p><i>We must require our suppliers to be ISO certified for our company to become ISO certified.</i></p>	<ul style="list-style-type: none"> • The ISO 9001 standard states that you MAY specify specific quality system requirements for your suppliers, if necessary. • This can include specifying an ISO 9001 certification for some suppliers, or may simply mean that you ask a supplier for a copy of their quality manual or procedures. • In many cases you will not need to specify any quality system requirements for your suppliers if their performance is generally good or the products you purchase have a minor impact on your company's quality.
<p><i>Becoming ISO certified will limit our company's ability to be flexible to meet customer needs.</i></p>	<ul style="list-style-type: none"> • The ISO 9001 standard is a very flexible set of requirements that can certainly allow your company to adapt to changing customer and market expectations. • The degree of "standardization" of your company's processes can be tailored to your specific business needs.

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Summary Checklist of ISO Requirements

Below is a general description of the major requirements of ISO 9001:2008. 9000World provides a wide range of products and services to help you implement these requirements. See the related ISO Buyer's Guide entitled [Choosing an ISO 9000 Product](#) for an overview of the available assistance.

✓	Basic Requirements	Definition/Description
	Defined business processes	One or more simple diagrams showing how work flows through your company and who is responsible for each step.
	Quality policy	A short "quality slogan" issued by top management stating the company's commitment to meeting customer requirements and to continual improvement.
	Quality objectives and performance data	Measurable targets for improvement and data to show current and past performance.
	Quality manual	A general description of how your company operates and how you meet ISO 9001 requirements.
	(6) administrative procedures	The "minimum set" of company procedures that includes: <ul style="list-style-type: none"> • Document Control • Control of Records • Control of Nonconforming Product • Internal Auditing • Corrective Action • Preventive Action
	Additional documentation (if needed)	Specific procedures or work instructions determined by your company as needed to ensure company processes meet your quality objectives.
	Quality records	Historical records that demonstrate compliance with company procedures and the ISO 9001 standard.
	Training	Training for your employees that includes: <ul style="list-style-type: none"> • Management responsibilities (for your managers) • Job-specific training, as needed • ISO awareness and understanding of the quality policy • Understanding of the (6) administrative procedures • Auditing skills (for your internal auditors)
	Supplier tracking	Data that demonstrates the performance of your vendors and suppliers.
	Calibration (if applicable)	Scheduled inspection and adjustment of any equipment used for inspections and testing of your products.
	Customer feedback	Tracking of customer complaints, compliments, and overall satisfaction.
	Management representative	An assigned manager to coordinate your ISO program.
	Management review	A regular meeting of your top management team to review the progress of your ISO program and to initiate improvements as needed.
	Internal audit	A formal process by a team of employees trained to conduct an audit similar to the Registrar's audit.
	Certification audit	The audit by the Registrar that leads to your formal certification. See the related ISO Buyer's Guide entitled Choosing an ISO 9000 Registrar.

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For more information about the requirements of ISO 9001:2008 or to learn more about the products and services available from 9000World, call our office to speak with our experienced ISO 9001 consultants (866-354-0300) or send an email to isohelpdesk@9000world.com.

Disclosure

9000World and www.9000world.com are owned by Core Business Solutions, Inc., a full-service provider of products and services to assist companies in preparing for ISO 9001 certification.



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