

How to Implement ISO 9001

nqa.



Table of Contents

If you know where you're going, go ahead and [click on a chapter](#).

Introduction	1
Chapter 1: What is ISO 9001?	4
Chapter 2: The Benefits of ISO 9001	8
Chapter 3: Transitioning From ISO 9001:2008	10
Chapter 4: Preparing For ISO 9001 Implementation	14
Chapter 5: Steps to Implementing ISO 9001	18
Chapter 6: Achieving and Maintaining Certification	23
Conclusion: Working With A Professional Certification Body	25

Introduction

A Standard That Creates Trust

ISO 9001 has over

1.1 million

certified participating organizations in

178 countries.

Before a customer decides to work with you, they'll want to know they can trust you to consistently deliver quality products and services. There's no better way to show customers that you prioritize meeting their needs than becoming independently certified and complying with the internationally recognized standard for Quality Management Systems (QMS).

That standard, ISO 9001 has over [1.1 million certified participating organizations in 178 countries](#), making it the world's most prominent QMS. The standard follows eight underlying principles:

- 1.** A focus on the customer
- 2.** Leadership
- 3.** The involvement of people
- 4.** Using a process approach
- 5.** A systematic management approach
- 6.** A fact-based, decision-making process
- 7.** Mutually advantageous supplier relationships
- 8.** Continual performance improvement

As a business leader,

you understand how following these principles could benefit your company and its stakeholders. Not only will implementing ISO 9001 into your business can increase your company's profits and productivity, and improve the experiences of your customers,

employees, suppliers and all other stakeholders. You'll see customer satisfaction go up. You'll also attract new customers, and you'll reduce operating costs. Complying with ISO 9001 also ensures you're following all relevant statutory and regulatory requirements.

Before you can reap these benefits, you must, of course, know how to implement ISO 9001, and it's an attainable goal for businesses of any size. Some businesses feel that implementing a QMS, as well as maintaining compliance, will be too expensive and time-consuming and require creating a position dedicated solely to ISO 9001 implementation. Some fear they will have to change their processes entirely. This, however, is not typically the case, as your QMS should be based on the systems you currently use.

The QMS implementation process can, in reality, require relatively little funding and time. Besides, the benefits of compliance significantly outweigh the costs if the process is executed accurately and efficiently — especially since compliance typically results in increased profits.

The Resources You Need To Succeed

You need to thoroughly prepare for implementation, understand the steps to implementing ISO 9001 and determine how best to proceed with your business' needs and current situation in mind. This will help you to get the most out of your new QMS.

This guide can serve as a valuable resource and will help you understand the process of implementing ISO 9001 as it applies to your company. It will cover the basics of ISO 9001 and how it can benefit your company and its stakeholders. It will also take into account your current compliance status and guide you through the steps from preparing for the process to implementing the standard and what to do afterward.

Another way to get the most out of the process of attaining and maintaining compliance involves working with a professional certification body such as NQA. We can perform the audits you need to meet the requirements of the standard and improve your organization's performance.

Not only will we inform you of the gaps you need to fill to meet the standards, but we'll identify ways for you to improve your organization. We help you to understand

the technical requirements and steps of the certification process, so that you can implement changes correctly and efficiently. We seek to provide as much value as possible through our audits, all for a fair price.

In addition to this guide, our website contains other valuable resources. If you need more information or are interested in our services, please [contact us](#). Thank you for using this guide as you seek to improve your organization.

Chapter 1: What is ISO 9001?

The International Organization for Standardization (ISO) established the standard known as ISO 9001 to create benchmarks for quality management systems. These systems, often called QMS, are sets of procedures designed to ensure a company consistently meets the needs of customers and other stakeholders. The process, for instance, helps the business to reliably provide customers with products of a high quality.

The Purpose Of ISO 9001

Although following the standard will create changes that reverberate through all areas of a company, one can categorize the eight underlying principles mentioned earlier as creating two primary enhancements: improved efficiency and increased customer satisfaction. Implementing ISO 9001 also has many other effects. Another central tenet of the standard is continual improvement of a business' operations in the following areas:

1. Improved Efficiency

Adequate processes and systems related to these principles increase a company's efficiency and effectiveness. Though improving in these areas may indirectly increase customer satisfaction, they directly improve the company's operations:

- **Allows for better leadership:** This principle focuses on those leading an organization and encourages them to set clear objectives and expectations.
- **Keeps employees informed:** This is the principle of keeping employees informed about and involved in what the company is doing. It encourages accountability among staff and creates enhanced employee motivation and performance.
- **Improves process approach:** Using a process approach means thinking about your work as a set of activities that together help you reach a goal, rather than a string of separate tasks. This keeps you

more organized and focused on your objective.

- **Establishes a systematic approach to management:** This principle involves grouping your interrelated process together into systems to achieve more efficient management. It requires you to manage operations proactively, rather than reactively.
- **Facilitates fact-based decision-making:** ISO encourages businesses to use data and analysis to make decisions, rather than relying on opinions, immediate reactions, traditions or other means.

2. Increased Stakeholder Satisfaction

Meeting customers' needs is the primary goal of any business. These principles directly help business to meet their expectations, as well as those of other stakeholders:

- **Customer focus:** This is the first principle that ISO 9001 lists, signaling its importance. It says that businesses should focus their attention on what customers need and how to meet or surpass those expectations.
- **Mutually beneficial supplier relationships:** Businesses and their suppliers depend on each other to reach their goals. This principle encourages strong relationships with suppliers that benefit both the business and the supplier.

The eighth principle, continual improvement, deals with all aspects of a business. It asserts that always improving products, services and internal operations should be a primary business goal. You can utilize the Plan, Do, Check, Act — or PDCA — Cycle to achieve this improvement. The PDCA Cycle says you should create a plan, implement that plan, evaluate how successful it was and then improve it.



Who Is ISO 9001 For?

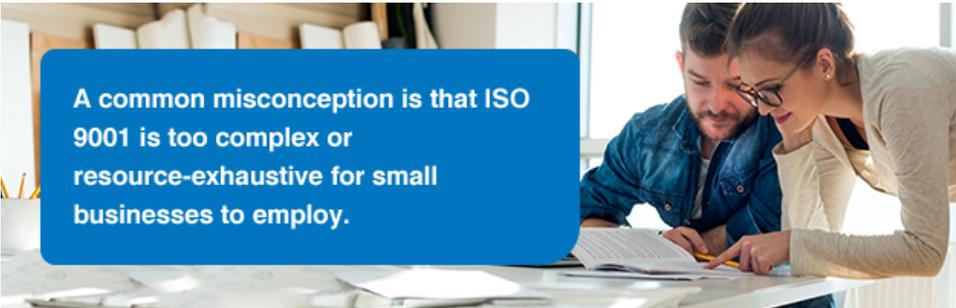
ISO designed ISO 9001 to be used by virtually any business. Organizations of all types, sizes and sectors can benefit from implementing the standard. One of the primary changes made in the most recent update of the standard seeks to make it more easily applicable to a wider variety of entities.

A common misconception is that ISO 9001 is too complex or resource-exhaustive for small businesses to employ. For example, organizations may think they need to hire a dedicated compliance employee, which could be cost-prohibitive to a small operation. While larger businesses might create such a position because it could be beneficial, doing so is not a requirement — nor is it necessary.

Other organizations might worry that

their business' systems won't fit into the standard. When you explore ISO 9001, you'll find that this is not an issue. ISO 9001 guides participants and asks them to define their own objectives. It doesn't require that all certified organizations use the same structure in their systems or their documentation clauses, and it doesn't require them to use ISO's terminology within their organization.

Some businesses seek compliance certification because a supplier, trade group or large client requires it before they will work with them. In these situations, certification is extremely beneficial and, sometimes, necessary for a company's success. It can also, however, provide advantages to organizations that do not have such requirements, as you'll discover in the next chapter.



A common misconception is that ISO 9001 is too complex or resource-exhaustive for small businesses to employ.

Versions Of ISO 9001



You can trace the history of ISO 9001 all the way back to Britain during **World War II**.

You can trace the history of ISO 9001 all the way back to Britain during World War II when the British Ministry of Defense created a standard to reduce mistakes in the manufacturing of ammunition. In 1979, after the government recommended a standard that applied to industries besides defense, the British Standards Institution created BS 5750, the first quality standard of its kind.

As this idea spread to the United States, ISO created an international version of the standard, ISO 9001:1987. ISO revised their standard in 1994 to clarify aspects of the first version. This version focused more on quality assurance than the original did.

In 2000, it underwent its first significant revision, which made process management the standard's main idea. ISO 9001:2000 also reduced the amount of documentation required and introduced the eight underlying principles.

The standard saw a more minor revision in 2008. The changes primarily sought to offer clarification and increase the ability to integrate ISO 9001 with ISO's other standards. Although ISO 9001:2008 is not the most recent version of the standards, it is still in use to day, and [certifications for it remain valid until September 2018](#).

The most recent update came about in 2015 and included more extensive changes than the 2008 revision did. ISO 9001:2015 sought to make the standard applicable to more types of organizations, increased the focus on risk management and introduced Annex SL, a new structure to be used across all of ISO's standards.

Chapter 2: The Benefits of ISO 9001

ISO 9001 is so widely used across industries and countries because of the benefits it brings. It makes people more likely to work with or purchase from you, and those who do will typically be more satisfied. It achieves this by providing guidelines you can use to improve the internal processes of your company.

External Benefits

Becoming certified as an ISO 9001-compliant business can increase how likely people are to trust that you'll provide them quality product and meet their needs. They'll know you underwent independent audits that verified the processes you use against a widely accepted international standard.

Some clients, suppliers and other entities you may work with even require organizations they do business with to have this certification. This assures them that their partners will consistently provide them with quality results and won't jeopardize their progress or hamper their efforts to meet their needs.

Even those that don't require these credentials will likely still choose a certified company over a non-verified one. It shows them that you've taken the time to ensure quality and gives them a window into how your company operates.

The ISO 9001 principle of customer focus directly impacts customer satisfaction by encouraging companies to make meeting customer needs a priority and to establish processes for doing that. The principles that improve a company's internal processes will also benefit customers because they help to produce a quality product more efficiently, effectively and consistently.

The customer is not the only stakeholder that implementing ISO 9001 can benefit, either.

It impacts virtually all stakeholders including suppliers, employees and partnering businesses. The principle of mutually beneficial supplier relationships directly benefits suppliers. Working with an ISO

9001-certified business may also benefit them more indirectly, such as a reduction in the number of last-minute orders and more predictability in the needs of the business.



Internal Benefits

Along with meeting customer needs, another primary goal of any business is a healthy bottom line. Implementing ISO 9001 can help achieve this by reducing costs and increasing profits.

Well-defined and more effective internal processes mean that a business can operate more efficiently. This means it can produce more quality products in less time, increasing productivity and profitability. These consistent, high-quality results can also enable business to sell more of their products. [The adoption of ISO 9001 led to a 10 percent increase in sales in one study.](#)

A QMS helps to define the roles of individuals and departments, reducing overlap and making each employee more successful by enabling them to focus on what they need to know. In addition to

making employees more productive, ISO 9001 certification can also lead to higher pay. According to the University of California at Berkeley and Harvard Business School study, wages at ISO compliant companies were approximately 7.5 percent higher than at non-certified firms. Total payroll, which includes salary increases and new hires, grew approximately 17.7 percent more at ISO-approved companies.

These improved processes also help to reduce the occurrence of mistakes. More efficient processes mean fewer mistakes will be made, and when they are made, employees will have an effective system in place for addressing the issue. Reducing mistakes also leads to less expense and fewer wasted funds.

Chapter 3: Transitioning From ISO 9001:2008

If you have a 2008 certification, you have until September 14, 2018 to transition to the new version of ISO 9001:2015.

If your company is already certified as compliant with ISO 9001:2008, the process of implementing ISO 9001:2015 into your business will be different than if you were starting from scratch. Rather than build your QMS from the ground up, you just have to transition to the 2015 version and take note of the changes.

If you have a 2008 certification, you have until September 14, 2018 to transition to the new version of ISO 9001:2015. That date marks three years after ISO published its 2015 revisions. Keep in mind that you must remain compliant with ISO 9001:2008 until you have fully transitioned. If you achieve ISO 9001:2015 certification, it will be valid for three years — at which point you'll need to renew it.

When To Transition To ISO 9001:2015

If you need to upgrade to ISO 9001:2015, you have several options for your transition timeline. You can transition during a regular re-certification audit or surveillance audit. You may also schedule a special visit.

Perhaps the easiest route to take is to transition during your regularly scheduled re-certification audit visit. This is a convenient option because it doesn't require any extra time or money outside of your regular audits. If you pass the audit to ISO 9001:2015 standards, you will receive the 2015 certification instead of a renewal of your 2008 certificate.

NQA will automatically upgrade you to the 2015 version upon passing your re-certification audit if you are ready to do so. The process may take additional time compared to a regular re-certification visit depending on the results of the audit. If you do not wish to transition at your re-certification visit, we ask that you [contact us](#) in advance to let us know.

If your three-year renewal cycle does not work with your transition needs, you can upgrade during a routine surveillance audit visit. If you select this option, please let us know ahead of time as well. We will add additional time to the surveillance visit to allow for a full evaluation based on the revised standards.

The visit will last at least as long as a re-certification audit, but it may require additional time depending on the results of the audit. If you are successful, you will receive a 2015 certification, and your three-year cycle will reset to the date you become certified.

You can also schedule a special visit to attain your 2015 certification. You might choose to do this because of the timing of your typical annual sequence. Some companies choose this option because they want to beat their competitors to compliance with the 2015 version to show customers their dedication

to meeting quality standards. Because this is an additional visit to a company's regularly scheduled ones, it will require extra time and costs.

Changes To Focus On

If you plan to move from 2008 certification to 2015, you need to focus on what's changed between the two versions so that you meet compliance requirements and attain certification.

NQA created several tools and documents to help its clients identify changes between the two versions of the standard and compare their QMS to ISO 9001:2015. The documents include Transition Guidance, the Transition Checklist and an ISO 9001:2008- ISO 9001:2015 comparison. These documents highlight what changed in the revisions.

[NQA also created a Gap Analysis Tool](#), which enables you to compare your QMS to ISO 9001:2015 standards. It contains two tables. The first covers the new concepts that ISO introduced in its 2015 revision and explains the related clauses, processes and activities. The second section deals with requirements that ISO introduced or amended. You can use the results of your latest audit to complete the tables. We ask that you do so before your transition assessment.

The most significant change in
the 2015 standard is the introduction of
Annex SL.

The most significant change in the 2015 standard is the introduction of Annex SL. ISO now uses this document across all of its standards. This common structure, text and shared terms and definitions allow for greater interoperability and are designed to make the implementation process easier for all of ISO's standards. Annex SL organizes the standard into 10 sections:

1. Scope
2. Normative references
3. Terms and definitions
4. Context of the organization
5. Leadership
6. Planning
7. Support
8. Operation
9. Performance evaluation
10. Improvement

Another notable difference is that ISO 9001:2015 requires fewer documents than the previous version did. When preparing your documentation procedures for compliance, you may change wording to meet the new standards. You should not, however, delete procedures required by the 2008 version but not the 2015 until your transition is complete. This is because you must maintain compliance with ISO 9001:2008 until you have fully transitioned.

The Transition Process

The transition process includes four major steps:

1. Developing a transition plan
2. Pre-assessment
3. The audit
4. Certification

Businesses can use the documents and tools mentioned above to identify the new requirements in the 2015 standard and determine what they need to do to reach compliance. Using these tools, you should create an implementation plan that you will use to transition to the new standard. The plan will focus on the changes from the 2008 version.

You may opt to have an auditor evaluate your transition before your audit. You will then have an idea ahead of time of how well your revised QMS meets 2015 standards and have an opportunity to adjust your plan.

When you are ready for your audit, you can contact NQA to schedule it or prepare for it to occur during a regular visit. If you pass the audit, you will become certified to the latest version of the standard, ISO 9001:2015.

Chapter 4: Preparing For ISO 9001 Implementation

Implementing ISO 9001 can be an intimidating task, especially if you haven't sought certification before. Following an organized process and working with a professional organization like NQA can make it doable. It's a rather long process, so breaking it down into more manageable steps can help as well. That's what we'll do in the next few chapters, starting with preparing for ISO 9001 implementation.

Gap Analysis



The gap analysis, also known as a needs assessment, helps to uncover what a business must do to reach compliance.

The first step you should undertake when seeking ISO 9001 certification is completing a gap analysis. This differs from the gap analysis tool mentioned earlier, but it operates on a similar concept. The gap analysis, also known as a needs assessment, helps to uncover what a business must do to reach compliance.

This analysis goes beyond a simple checklist that compares a business' operations

to the standard. The checklist method is often not adequate for developing an effective QMS and may overlook certain requirements as well as other aspects, such as how successfully a process is executed. A gap analysis, on the other hand, offers a ["comprehensive and composite picture of all the gaps"](#) between the organization's methods of operation compared to each requirement of the ISO standard."

An organization might uncover three types of gaps through its analysis:

1. It might discover that it never implemented or planned some requirements of ISO 9001.
2. It may realize that it implements a requirement but does so informally or inconsistently, or it does not document the process as ISO 9001 requires.
3. It might come across requirements that it implements but doesn't do so effectively.

Some gaps will be obvious, but others will be harder to spot. Those that are less concrete, such as the last two types, will also be harder to identify due to their more qualitative nature. To get the most out of a gap analysis, someone who is familiar with your industry and is a competent quality systems auditor should conduct it.

Creating A Plan

Once you've completed your gap analysis, you can use what you learned through the report to formulate your plan for implementing ISO 9001. Creating your plan will involve defining the actions you need to take to close the gaps you've identified.

The more detailed your plan is, the easier it will be to implement, and the more successful it will be. The plan should include the actions to be taken, who is responsible for what tasks, how long each action will take and the order in which staff should complete them. The plan should also identify key milestones and the intended objectives of each action, so all employees can measure progress.

When preparing for ISO 9001 implementation, it can be helpful to keep the big picture in mind so that you can plan for what's ahead of you. A business might use the five-phase approach for how to implement ISO 9001:

1. Planning
2. System design
3. System implementation
4. Audits, review and improvement
5. Certification

During the planning phase, you should primarily focus on planning. However, it's helpful to know what's ahead so that you can incorporate that into your plan. When you create your plan, make it so that it can accommodate audits and improvements, for example.

Five-phase approach for how to implement ISO 9001:

1



PLANNING

2



SYSTEM
DESIGN

3



SYSTEM
IMPLEMENTATION

4



AUDITS, REVIEW
& IMPROVEMENT

5



CERTIFICATION

Just as the overall implementation process breaks down into steps, break down each activity into steps as well. This creates a clearer path forward and establishes reasonable expectations.

As a part of your ISO 9001 implementation plan, you also need to create a communication plan. Seeking ISO 9001 certification will impact virtually all of your company's employees, as well as other stakeholders. Everyone affected should be informed about the changes that may occur.

The communication plan should include what you need to communicate, what medium you will use, when you will get the message out and who will communicate it. You may want to explain why you're seeking certification, how it will benefit employees, the changes employees will need to make and how to prepare for audits. You could communicate these things via a newsletter, emails or an in-person meeting.

Designing Documentation

In previous versions of ISO 9001, especially the very earliest, documentation was a central requirement. ISO explicitly laid out what to document and how to do it, and it became second nature for many complying companies to record every procedure they implemented. As time went on, ISO gradually decreased the requirements for documentation. The 2015 revision saw the most significant departure from mandated documentation yet.

In ISO 9001:2015, the standards organization replaced the requirement for documented procedures with one for documented information. [ISO has emphasized recently](#) that ISO 9001 requires "a documented quality management system" rather than a "system of documents."

ISO has emphasized recently that ISO 9001 requires **“a documented quality management system”** rather than a **“system of documents.”**

This change comes with benefits, but also challenges. Businesses implementing the standard now have more flexibility in what they choose to document. This enables the standard to apply more readily to a wider range of organizations and lets the organization choose what documentation procedures it feels are best for its operations. It also presents a challenge, though, as businesses must now put more effort into determining what to document and what documentation procedures to use.

How should a business decide what to document? It might be helpful to review the purposes of documentation. [According to ISO](#), these purposes include:

- Communicating information
- Providing evidence of a completed activity
- Sharing knowledge
- Preserving or dispersing an organization's experiences

Your organization might also use documentation for other reasons.

When deciding what to document, review your current documentation and determine whether it adequately meets your needs and whether it serves a suitable purpose. Based on this evaluation, you might choose to continue your documentation processes as they are, add new procedures, discontinue certain practices or revise the processes you currently use.

For any changes in documentation procedures, you should create a detailed plan in a manner similar to how you created the implementation and communication plans. The plan should:

- Describe the changes to be made
- Establish a timeline for completion
- Assign responsibilities
- Define benchmarks for measuring progress
- Create a strategy for evaluating effectiveness

Chapter 5: Steps to Implementing ISO 9001

Once you've adequately prepared for ISO 9001, you can begin implementing it into your business. One of the first things you should do is assess the scope of the changes you need to make to reach compliance. Whether you need to make a few small changes or many wide-reaching ones will impact how you move forward.

When Few Changes Are Needed

If a business was already operating in a manner consistent with a majority of ISO 9001 requirements, implementation of the standard will likely involve relatively few changes. In fact, most businesses find that they were already complying [with around 80 percent of ISO 9001 requirements](#) before seeking certification.



If this is case, the implementation will be less demanding and may move more quickly. It serves more as validation that their processes are effective and that they were producing quality products than an as agent for change. In these cases, added formalities

may be the most significant adjustment. You may need more documentation, people's responsibility may become more clearly defined or operations may be held to a stricter schedule.

Although in these situations, the organization's processes are adequate, they sometimes fall behind on implementing their QMS. This is because formalities seem to be less important than more concrete changes, making employees less likely to follow through on them. Management can remedy this by using the communication plan to explain the value of the formalities, their role in ISO 9001 compliance and the benefits of certification.

When More Extensive Changes Are Needed

In other cases, organizations find that they need to change more about their operations to achieve compliance. These situations will require more extensive use of resources, greater effort and a longer amount of time, but the company will also see a more pronounced improvement once it becomes compliant.

Those businesses that already complied with 80 percent of ISO requirements may also find that the other 20 percent requires

significant overhaul. Even companies with relatively few or minor changes may need to apply the following strategies for how to implement ISO 9001.

Every business will need to make its own unique revisions to its processes, but you may run into one of these typical kinds of changes. You may find that you need to:

- Improve design control requirements to encourage more consistent results
- Update internal audits and system performance review procedures
- Take corrective actions to stop a problem from re-occurring
- Take preventative actions to stop a potential problem from beginning

Making these alterations is not simply a matter of writing down a goal or outlining a new process, nor is it sufficient to focus purely on directly changing the action. You also need to concentrate on supporting processes and related considerations. Business leaders need to take a more big-picture view of the issue.

A photograph of a man in a grey suit standing and presenting to a group of people seated around a table in a meeting room. He is holding a whiteboard marker and pointing at a whiteboard. The whiteboard has some text on it, including 'QMS' and 'ISO 9001'. The people are looking towards the presenter.

Many businesses turn to coaches or consultants to help them implement the ISO 9001 standard.

Many businesses turn to coaches or consultants to help them implement the ISO 9001 standard. While tasking someone within the organization with implementing the changes may be a less expensive strategy up front, it could cause the implementation to take longer and become more expensive in the long run. If the employee doesn't have the necessary expertise, for example, they might make mistakes along the way, delaying certification.

A consultant or coach can also offer actionable advice for improving processes, which can serve as valuable evidence of compliance. A consultant can provide verification that employees successfully completed process improvements. While NQA does not offer consulting services, we do have [a referral program for consultants](#) to help you find a qualified professional that can meet your company's needs.

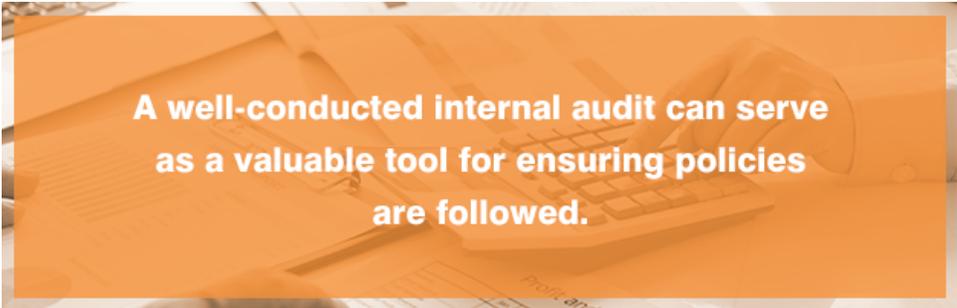
Internal Audits

Internal audits offer a way for organizations

to verify whether their QMS meets requirements and expectations. An auditor can check the implementation of the QMS against the requirements of the ISO 9001 standard and company policies as well as determine whether it meets customer and employee needs.

A well-conducted internal audit can serve as a valuable tool for ensuring policies are followed, improving processes and preparing for external audits. Based on the evidence collected during an audit, the auditor will typically suggest actions to be taken. If the auditor finds that a process is meeting objectives, they might suggest a process improvement in line with the principle of continual improvement. If they determine that it's not meeting goals, they will suggest a corrective action be taken.

The fact that internal auditors are independent makes them a valuable resource. Being independent means that, although they are a part of the organization, they are set apart from the activities they audit. Organizations achieve



A well-conducted internal audit can serve as a valuable tool for ensuring policies are followed.

this independence through status and objectivity. Internal auditors should remain separate from the activities they audit. For example, they should not take part in writing policies. This separate status allows them to be objective because the results of the audit do not reflect on them. Maintaining independence and objectivity are critical to successful internal auditing.

To get the benefits of an internal audit, it's crucial to make sure the individual conducting the audits has the proper qualifications. A quick research or training session will not be enough to prepare someone to audit for the first time, as an effective audit must consider a host of related factors — rather than just determining whether employees are following a standard or procedure. It's also important to consider when audits will be performed and to identify the criteria that the auditor should assess.

Management Review

The results of internal audits serve as one of several valuable tools that can be used during the management review process. The management review needs to take into account evidence, such as what's provided by internal audits, to evaluate whether the QMS is still adequate. Typically, management will also meet with people responsible for process implementation to review progress as well as the effectiveness of the policies themselves.

The review should also consider changes in regulations, customer demands, updated company goals and other new developments. Based on these considerations, management must decide whether processes are sufficient as they are or whether they might need to be updated, either because they are inadequate or

because of changes in conditions.

Corrective action can take place if you use tools to build a reliability program. Some [trusted tools to systematically build that system](#) include:

- Shainin System
- FRACAS (Failure Reporting And Corrective Action System)
- 5 Whys
- Kepner/Tregoe Process
- 7 or 8 steps

Management reviews help to ensure that a company's QMS remains effective, that progress toward objectives continues and that processes are improved. It's typical that, based on the results of these reviews, adjustments need to be made to processes

throughout their use to fulfill the continual improvement principle of ISO 9001.

Improvement

Improvement is a critical aspect of implementing ISO 9001 for organizations that want to get the full benefits. While achieving certification produces some advantages on its own, the companies that really work to use it to improve their processes on a regular basis will get the most out of it. This is an aspect that NQA focuses on when conducting audits.

One common point of discussion surrounding improvements deals with a subtle difference — the difference between continuous and continual improvement. Continuous brings to mind a more constant stream of improvements, which may be accomplished through small changes to daily actions. Continual improvements may be less pervasive and take place on a larger scale over a longer period of time.

Whichever method an organization uses, improvement is a central tenet of ISO 9001

that any organization implementing the standard must consider. Most likely, some of both forms of improvement will appear in an organization. Management should seek to improve all aspects of their business and should identify improvement actions related to refining the QMS, meeting resource needs and improving the product to better meet customer needs.

However enhancement is accomplished, management has the responsibility to direct the process of achieving it. Management should create a detailed plan for every improvement to be made and provide the necessary time and resources to those responsible for executing that plan. The improvement strategy should always include a way to measure progress and create tangible results.

Chapter 6: Achieving and Maintaining Certification

Don't begin the certification process until you've completed all the stages of the

PLAN, DO, CHECK, ACT CYCLE.

Don't begin the certification process until you've completed all the stages of the Plan, Do, Check, Act Cycle.

1. To apply, simply fill out [a quote request form on our website](#) or call us to discuss your certification requirements and process. Our quick quote form provides us with basic information about your company and request, allowing us to determine the scope of the required assessment. Fill out the form with your information, and a member of our team will contact you within 24 to 48 hours. Alternatively, you can call us at (800) 649-5289 or (978) 635-9256 to discuss your needs.

2. The next step in the process is the initial certification audit. This consists of two mandatory visits conducted by NQA. During this step, we will assess your QMS against the requirements of ISO 9001. Note that before this stage can begin, you must demonstrate that your QMS has been active for at least three months and that you have conducted a full cycle of internal audits of your system.

Stage 1: The first stage of the initial certification audit is a preliminary visit to verify that the organization is prepared for a full evaluation. During this stage, the auditor will confirm that the QMS

meets ISO 9001 requirements and complies with legislative requirements. They will also check that the QMS has been adequately implemented. At the end of the preliminary visit, the assessor will formulate a report that notes any non-compliance or areas for improvement as well as an assessment. They will also set a date with management for the next stage of the assessment.

Stage 2: The next state of the initial certification audit is the full assessment of the QMS. During this visit, the auditor will perform sample audits of all of the processes and activities required for ISO 9001 certification and document objective evidence of how QMS implementation conforms to the standard. As with the preliminary visit, the auditor will produce a report on any non-compliance or potential improvements. If any major gaps are discovered during the final assessment, the auditor will not issue certification at that time. Before they can issue certification, they must verify that the organization corrected the issue. If the organization does not fix the problem within six months, NQA must conduct another stage two assessment before granting certification.

3. If the organization passes the audit, it will receive certification to the standard. The auditor will then set up a schedule for regular visits. The auditor will conduct a surveillance visit once a year and a recertification audit every three years. The surveillance audits serve to ensure compliance is still being met during the three-year recertification cycle. At the end of three years, if the company passes the recertification audit, its certification will be renewed.

Conclusion: Working With A Professional Certification Body

The benefits of implementing ISO 9001 are substantial and far-reaching. It produces internal benefits, such as improved processes and increased profits, as well as external ones, such as increased customer trust and higher satisfaction among stakeholders.

To really get the most out of ISO 9001 implementation, it helps to work with a professional certification body such as NQA. We provide a complete range of certification services and focus on opportunities for improving your organization during our audits as well as meeting the requirements of standards. We help you to understand technical requirements and offer actionable advice, so you can enjoy the benefits of a successful QMS.

We seek to provide as much value to our clients as we can through our certification services, so they can do the same for their customers through their various business operations.

Contact Us

If you'd like more information or have questions or comments, [contact us by filling out this online form](#), emailing us at usainfo@nqa.com or calling us at (800) 649-5289, (978) 635-9256 or (219) 363-6151. If you'd like a free quote, [complete our online quick quote form](#), and a member of our team will contact you via email or phone within 24 to 48 hours.

Sources

Introduction

<https://www.nqa.com/en-us/certification/standards/iso-9001>

<http://www.nqa.com/en-us/contact-us>

Chapter 1

<https://www.iso.org/iso-9001-quality-management.html> (PPT linked to on this page)

<https://www.british-assessment.co.uk/guides/the-8-principles-of-quality-management/>

<http://www.iso9001consultant.com.au/FAQ-quality-basics.html>

<https://www.iso.org/obp/ui/#iso:std:iso:9001:ed-5:v1:en>

<https://medium.com/@cabem/the-history-of-the-iso-9000-series-3e7b4e87c43>

<https://www.nqa.com/en-us/certification/standards/iso-9001>

https://www.nqa.com/Nqa.com/media/PDF-Download-Documents/USA%20Documents/ISO-9001_TransitionGuidance.pdf

Chapter 2

<https://www.nqa.com/en-us/certification/standards/iso-9001>

<https://www.bsigroup.com/LocalFiles/en-GB/small-business/UK-SB-BSI-ISO-9001-Whitepaper-UK-EN.pdf>

http://www.dir.ca.gov/chswc/reports/iso_9001_2008_august.pdf

Chapter 3

<https://www.nqa.com/en-us/clients/transitions/9001-2015/iso-9001-2015-faqs>

<https://www.nqa.com/en-us/clients/transitions/9001-2015>

<http://www.nqa.com/en-us/contact-us>

https://www.nqa.com/Nqa.com/media/PDF-Download-Documents/USA%20Documents/ISO-9001_TransitionGuidance.pdf

<https://www.nqa.com/Nqa.com/media/PDF-Download-Documents/USA%20Documents/NQA-ISO-9001-2015-Transition-Checklist-01-12-2016.pdf>

Chapter 4

<https://www.nqa.com/en-us/resources/blog/september-2014/key-steps-in-implementing-iso-9001-step-1-gap-analysis>

<https://www.nqa.com/en-us/resources/blog/october-2014/key-steps-in-implementing-iso-9001-step-2-planning>

<https://www.nqa.com/en-us/resources/blog/october-2014/preparing-for-iso-9001-2015-using-your-2008-quality-management-system-part-3>

https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/documented_information.pdf

Chapter 5

<https://www.nqa.com/en-us/resources/blog/december-2014/key-steps-in-implementing-iso-9001-step-4-implementation-part-i>

<https://www.nqa.com/en-us/resources/blog/december-2014/key-steps-in-implementing-iso-9001-step-4-implementation-part-ii>

<http://www.imsworld.org/blog/difference-between-corrective-and-preventive-actions/>

<https://www.nqa.com/en-us/consultants>

<https://www.nqa.com/en-us/resources/blog/january-2015/key-steps-in-implementing-iso-9001-step-5-internal-audits>

<https://www.compliancealliance.com/our-services/audit-independence>

<https://www.nqa.com/en-us/resources/blog/february-2015/key-steps-in-implementing-iso-9001-step-6-management-review>

<https://www.iso9001help.co.uk/561.html>

<https://www.nqa.com/en-us/resources/blog/march-2015/key-steps-in-implementing-iso-9001-step-7-improvement>

Chapter 6

<https://www.nqa.com/en-us/certification/our-process>

<http://www.nqa.com/en-us/quick-quote>

Conclusion

<http://www.nqa.com/en-us/contact-us>

<http://www.nqa.com/en-us/quick-quote>