

ISO 9000 Frequently Asked Questions

Can we include all products and services in the QMS but limit the scope of registration?

According to ISO/TC 176/SC 2/N 524, *organizations are not obliged to include all the products that it provides within the scope of its QMS, or to address the realization processes for products that are not included within the QMS. But* if you are serious about using the system to achieve and improve quality why would you want to exclude any product or service provided by your organization from the QMS? Is it because you don't want the auditors to examine the processes used to create and supply these products and services, or is it because you know these processes are not managed effectively and you don't want them to jeopardize your registration? Or is it to reduce the cost of the registration or perhaps because the customers for these products and services do not require ISO 9000 registration?

If you want all your products and services covered by the QMS but want to exclude certain ones from registration, you can do this by limiting the scope of registration. Certification/registration bodies are required to comply with the requirements of clause 3.5.3 of ISO/IEC Guide 62 ("General Requirements for bodies operating assessment and certification/registration of quality systems"). This requires them to ensure that certification/registration documents are not misleading and reflect correctly the products and product realization processes **that are within the scope of the QMS**. Therefore the products and services referred to on the certification/registration documents have to be covered by the QMS but you can have other products and services covered by the QMS that are not referred to on the certification/registration documents - but be careful ISO/TC 176/SC 2/N 524 requires *any limitation in the scope of the QMS to be defined and justified in order to avoid confusing or misleading customers and end users*.

Can we obtain certification to ISO 9001:1994 after 15 December 2000?

The simple answer is yes. However, your certificate will expire on 15 December 2003 whatever its issue date. There is therefore no advantage in pursuing certification to the 1994 version beyond 15 December 2000. If you applied for certification prior to 15 December 2000 and by July 2002 have yet to obtain a certificate, you may complete the process but beware that your certificate will expire on 15 December 2003. If you applied for certification after 15 December 2000, your certification body/registrant will have advised you that the assessment will be conducted against ISO 9001:2000.

Can we reduce the number of procedures?

The number of procedures is not the real issue here. It is the transmission of information. If you are maintaining documented procedures for activities that are not necessary for the effective operation and control of your processes, you ought to eliminate them. If you perform the activity covered by a procedure and the activity adds value why would you want to eliminate the document unless you have found a better way of transmitting the information? Maybe you could describe the activity differently or merge several procedures together if it improves usability but simply reducing numbers of documents may not improve effectiveness.

Has the intent of the standard changed?

Yes it has. Previously the intent was to achieve customer satisfaction by preventing nonconformity. Now the intent is that:

- Organizations design and manage their processes effectively to achieve corporate objectives, not that they create functional silos that compete for resources.
- Organizations choose the right things to do based on an objective analysis of the environment in which they operate, not slavishly follow procedures that serve no practical purpose.
- Management create an environment in which people will be motivated, not create bureaucratic systems of documentation that stifle initiative and creativity.

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How can we size the gap?

Find out how big the gap is between your current QMS and a fully compliant QMS by trying out our new Self Assessment Tool (*FS016*)

How do we demonstrate continual improvement?

ISO 9000:2000 defines continual improvement as a recurring activity to increase the ability to fulfil requirements. We cannot improve anything unless we know its present condition and this requires measurement and analysis to tell us whether improvement is both desirable and feasible. The first step is therefore to ensure objectives, targets or requirements exist for the performance of the product or process characteristics to be measured. The second step is to measure performance and compare it with the target. If no output meets the requirements, action taken to achieve conformity is not an improvement action. This only puts the process back to where it should have been in the first place. Eliminating special causes is not improvement but maintaining the status quo. This leaves two areas where improvement is desirable - the reduction of common cause variation and the raising of standards. Once the process is producing conforming output, action taken to reduce common cause variation or to raise standards is improvement action and can be demonstrated by charts showing performance trends over time. (Note: Special cause variation is variation that can be assigned to a specific or special condition that does not apply to other events. Common cause variation is variation that is random caused by factors that are inherent in the system).

How long have we got to implement the changes?

In September 1999 a joint meeting was held between the International Accreditation Forum (IAF), ISO/TC176 and ISO/CASCO (ISO Committee for conformity assessment), to establish common and consistent messages to ensure a smooth transition to the new standards. This agreement can be summarized as follows:-

- Organizations are encouraged to make the transition to ISO 9000:2000 as soon as possible
- Organizations may seek certification for their quality management systems against the 2000 version from 15 December 2000
- Organizations may continue to seek certification for their quality management systems against the 1994 version up to 14 December 2003.
- Organizations that reach the end of their three year assessment period after 15 December 2000 will be re-assessed against the 2000 version

How many requirements are there in ISO 9001:2000 compared to ISO 9001:1994?

Those that use ISO 9001 often make use of the fact that there are 20 elements, so many shall statements, so many procedures. All these parameters have changed with ISO 9001:2000.

Parameter	ISO 9001:1994	ISO 9001:2000
Elements	20	5
Clauses	59	51
Shalls	138	136
Procedures	18	6
Records	20	21

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How will the changes affect us?

In the past some organizations assumed that compliance to ISO 9000 would bring significant improvement in customer satisfaction levels. They also assumed that by merely meeting the requirements of ISO 9000 they would be designing a quality management system that would achieve higher levels of customer satisfaction. Both these assumptions may not have been valid in cases where a focus on certification masked the real benefits. However, ISO 9000:2000 will change these perceptions as it not only requires customer expectations to be identified and understood but also requires processes to be designed to produce outputs that satisfy these expectations. If your QMS does not enable the organization to accomplish its objectives it will need to be redesigned.

Is our ISO 9000 certificate against the 1994 version valid for three years?

All certificates issued against the 1994 version of ISO 9001, ISO 9002 or ISO 9003 have a maximum validity of 3 years from 15 December 2000 - the date of publications of ISO 9001:2000. Therefore whenever your ISO 9000 certificate was issued it expires on 15 December 2003, even if it is issued on 14 December 2003. Different rules apply to sector schemes. You therefore have to make the transition to ISO 9001:2000 prior to 15 December 2003 if you wish to retain ISO 9000 certification.

What are the mandatory procedures?

There are 6 mandatory procedures.

1. Document control
2. Control of records
3. Control of nonconformity
4. Internal audit
5. Corrective action
6. Preventive action

However, the standard requires the organization to provide the documentation needed to ensure the effective control and operation of its processes and this may therefore result in many more documented procedures being necessary than the six identified.

What are the new requirements?

There may be fewer shall statements in ISO 9001:2000 but that does not mean there are fewer requirements. Every shall statement may contain several requirements. Every 'comma' or 'and' adds another requirement. Transition Support has analysed these requirements and identified 250 individual requirements which is fewer than the 320 in ISO 9001:1994. However, what is surprising is the number that are new and not equivalent to any requirement in the 1994 version. For more detail purchase a copy of our guide Transition to ISO 9001:2000 ~ Analysis of the differences and implications.

New requirements	119
No change in intent	107
No change in requirements	17
Less onerous requirements	7
Total	250

What use are the 8 quality management principles?

The standard has been based on eight quality management principles. This means that each of the requirements applies one or more of the principles. By linking a requirement to a principle you get a reason for the requirement. By linking a detected nonconformity with a principle you

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get a very persuasive reason for management to take action. By using the principles to validate your processes you will not only know that they are compliant with the requirements but also effectively managed. By using the principles to size the gap you focus the attention of management on the things that matter! See [FS020](#)

What's the difference between Procedure Auditing and Process Auditing?

Procedure auditing is characterised by the auditor firstly verifying that a documented procedure is in place that addresses the relevant requirements of ISO 9000 and secondly that the procedure is being followed. Deviation from the requirements in either the design of the procedure or its implementation resulted in a nonconformity. Process auditing is completely different. This is characterised by the auditor establishing firstly that the objectives of the process are aligned to the objectives of the organization and that these are derived from the needs of all the interested parties. Secondly, the auditor establishes whether the results meet the process objectives, whether they are being achieved under controlled conditions and in the best way and whether they are relevant to the goals of the organization. So the transition from procedure auditing to process auditing is a transition from auditing for conformity to auditing for performance.

What's the difference between Accreditation and certification?

Accreditation is a process by which organizations such as Certification Bodies and Registrars are authorized to conduct certification of conformity to prescribed standards such as ISO 9000. Accreditation is therefore the product of the accreditation process therefore Certification Bodies are accredited not certified. Certification is a process by which Certification Bodies and Registrars verify that organizations (the producers of product or service) have demonstrated conformity with prescribed standards. Certification is a product of the certification process therefore organizations are certified not accredited to ISO 9000.

What's the difference between an Audit and an Assessment

An audit is an examination of results to verify their accuracy by someone other than the person responsible for producing them. An assessment is a judgement made about the results. Assessment goes further than an audit as it involves the determination of actions necessary to make the assessed entity compliant. Therefore, in assessing opportunities for improvement, you would not only identify such opportunities but also make some judgement on the benefits to be gained and the actions to be taken to realize the improvements.

What's the difference between Corrective action and Preventive Action?

Correction is an action taken to restore an entity to operational condition - fix, rework, repair are all corrections. Corrective action is action planned or taken to stop something from recurring. It could be a one-off event, a recurring event or an inherent condition. Corrective action can, therefore, be considered to be an instrument of both process control and process improvement. A problem has to exist for you to take corrective action. When actual problems do not exist but there is a possibility of a problem occurring, the action of preventing the occurrence of the problem is a preventive action. One cannot therefore take both corrective and preventive action following an incident or nonconformity. Preventive action takes many forms. Both planning and training are preventive actions. Risk assessment, failure mode and effects analysis (FMEA), hazard and critical control point analysis (HACCP) are all techniques that serve to prevent failure or nonconformity. This explanation may not align with common usage of the terms but is the interpretation given in ISO 9000:2000 and hence is what the terms are meant to mean in ISO 9001.

What's the difference between Manual Owners and Process Owners?

The implementation of ISO 9000:1994 tended to result in lots of documents that were compiled into departmental manuals and consequently each manual had an owner, probably a

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departmental manager. Their task was to keep the manuals up to date. Providing the manuals reflected what people in the department did, they passed the audit. ISO 9000:2000 on the other hand is not about manuals or documentation, it is about processes. These are dynamic, not static. Processes deliver results and to do so consistently, they need to be managed. This is the task of the Process Owner. So the transition from Manual Owner to Process Owner is a transition from maintaining documents to managing processes - a much more difficult job and one requiring attention to all eight quality management principles (*FS020*)

What's the difference between Processes descriptions and flowcharts

Flow charts are simply a graphical method of showing the sequence and interaction of activities. There are not full process descriptions primarily because they invariably do not contain all the information necessary to operate the process. A process description on the other hand would identify: the process objectives, the process inputs and outputs, the process flow, the key activities and methods and information used, the human and physical resources to operate the process, key performance measures, measurement methods and location of the results.

What's the difference between Training and Competence

Training is an environment in which people practice techniques to acquire skills. A seminar in which the participants do nothing except listen to a presenter may be education but it is not training. There has to be acquisition of skill not simply knowledge. However, a trained person is not necessarily a competent person. Competence is the ability to demonstrate use of education, skills and behaviours to achieve the results required for a job. A person may have acquired the necessary skill under classroom conditions, but in the environment where that skill needs to be applied, the person might be ill equipped due to other factors that affect his/her ability to do the job. When the qualified person is able to produce the results required of a job can that person be said to be competent. The transition from training to competence is a transition in which acquired skills and knowledge are transformed into capability. Competence is concerned with outcomes rather than attributed abilities.

What's the difference between Verification and Validation?

Verification is the act of establishing the truth or correctness of a fact, theory, statement or condition. 'Is it what it claims to be?' 'Does it meet the specification for which it has been produced?' Validation is a process for establishing whether an entity will fulfil the purpose for which it has been selected or designed. 'Will it perform the function for which it is required regardless of it meeting some pre-defined requirements? Validation has to do with the subject in question being the right subject, whereas verification has to do with the subject being right. One would validate a design once and verify that all product of that design conforms with that design.

What's the principal differences between ISO 9000:1994 and 2000?

ISO 9000-2000 is a complete rewrite of ISO 9000 and ISO8402

- ISO 9002, ISO 9003 and ISO 8402 together with many parts of ISO 9000 and ISO 9004 have been withdrawn
- There is one Quality System Requirements standard (ISO 9001) and one Quality Management Standard (ISO 9004)
- Out go the 20 elements of ISO 9001 - replaced by an 8 section structure:
 - 1 Scope
 - 2 Normative Reference
 - 3 Terms and Definitions
 - 4 Quality Management System Requirements
 - 5 Management Responsibility

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- 6 Resource Management
- 7 Process Management
- 8 Measurement Analysis and Improvement

No longer will ISO 9001 focus only on quality assurance. The focus is on customer satisfaction. All requirements now serve to provide organizations with the capability to satisfy their customers

What's the process approach?

The process approach to management is one in which activities are designed to achieve objectives. Where activities convert inputs into outputs of added value. Where the sequence of activities utilize resources to produce results regardless of the function that performs them and whether the resources are internal or external to the organization. It is an approach in which there is a focus on results and outcomes. Where the factors affecting these results and outcomes are identified and the process designed to prevent failure and secure success. This contrasts with the procedural approach where the focus is on tasks and following rules, where who does what is important, where one follows procedures regardless of whether the results add value for the organization. See [FS020](#)

What's the systems approach?

The systems approach to management is one in which all the processes within the organization are designed to work together to achieve the organization's goals. It is where the processes are linked together to form a chain that converts stakeholder needs into satisfied stakeholders. It is an approach where the interfaces and interaction between processes is managed in order to balance the needs of all interested parties. This contrasts with the functional approach to management where the focus is on achieving departmental objectives, where managers compete for resources, where work is accomplished through departmental procedures and where there is intense internal competition and rivalry. See [FS020](#)

When will the next revision ISO 9000 series be carried out ?

ISO have declared that the ISO 9000 family of international standards will not be revised before 15 December 2005 so as to give sufficient time for the changes to take effect.

Why should we do more than necessary to get the certificate?

Unfortunately, ISO 9000, is just a badge on the wall for more than 90% of registered organizations - obtained to win business rather than to keep it. It does not have to be! If ISO 9000 is embraced as a tool for improvement and not a prescription for certification it can bring business benefits.

- Did you base your system on "Say what you do - do what you say?"
- Is your quality manual structured around the 20 elements of the standard?
- Does your system only deliver contented auditors?
- Is your system bolted onto the organization ?
- Do you believe your system is a set of documents that has to be maintained?
- Do you believe you need separate systems to meet environmental, health and safety objectives?

If you answered 'yes' to any of these questions your system is not adding value and your management team has not yet realized that ISO 9000 is about business improvement - not certification.

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If your management system does not improve the bottom line, you should seriously consider replacing it with one that does. ISO 9004 is recommended for those organizations that wish to move beyond the requirements of ISO 9001 in pursuit of continual improvement of performance. It follows therefore that settling on ISO 9001 will send out signals to your competitors that you don't wish to move beyond the basic requirements - that you are only interested in the badge on the wall. Why would any organization not want to improve? No organization would surely want to be classed as mediocre!

Will the auditors use a different approach?

The external auditors should use the process approach to auditing. (see <http://www.iqnet-certification.com>) They should provide added value. However, many will continue to establish that you do what you say you will do rather than verify your system enables the organization to achieve its objectives.

Will we need to extend the scope of registration?

ISO 9001 contains requirements that apply to several business processes including marketing, sales, product and service design, production, purchasing, installation, servicing, maintenance, distribution, service delivery and customer support. Claims of conformity to ISO 9001 are not acceptable unless exclusions are limited to requirements within clause 7 and such exclusions do not affect the organization's ability, or responsibility, to provide product that fulfils customer and applicable regulatory requirements. Therefore you can only exclude processes for which you are not responsible (whether in-house processes or subcontracted processes).

Organizations that design the products they supply but are currently registered to ISO 9002 will need to revise their QMS to bring design and development within the scope of registration. Organizations that have only registered the maintenance or distribution side of their business will have to bring in all the other parts of the organization into the QMS. Organizations that have registered only specific product line or services will need to bring all product lines and services into the QMS.

Will we need to rewrite all our procedures?

If your procedures define how the tasks identified in your process descriptions are performed they may not need to be rewritten. But you will firstly have to determine the processes and sub-processes required to deliver the organization's objectives and identify the essential tasks that need to be performed. If any of your procedures do not tell you how to proceed when performing a task you should consider regrading them.

Will we need to rewrite our quality manual?

Unless your quality manual is written around your business processes rather than the 20 elements of the standard, you will have to rewrite it. [See FS014](#)

Transition Support Ltd
Building 7/4
Vantage Point Business Village
Mitcheldean
Gloucestershire GL17 0DD
United Kingdom

Tel: 00 44 (0)1594 546151
Fax: 00 44 (0)1594 546153

www.transition-support.com