

# ISO 9000:2000 In Plain English

## Introduction

There are those who want to believe that the standard has not changed very much (if at all) and do not believe it has changed in its intent and as a consequence do not have to change their approach. The sad thing is that if the standard is perceived as not having significantly changed, it will continue to wreak havoc by being interpreted and used in the same inappropriate way that it has been for the last 14 yrs. But there is another way. By looking at ISO 9000 as a framework upon which can be built a successful organization (rather than as a narrow set of minimum requirements) significant benefits can be gained. There are real benefits from managing organizations as a set of interconnected processes focused on achieving objectives that have been derived from an understanding of the needs of customers and other interested parties. ISO 9000 merely brings together concepts that have been applied in organizations for many years – not some unique concepts of management that only exist to put a 'badge on the wall', but it appears that the use of international standards to consolidate and communicate these concepts has not been as effective as we believed it would be.

One of the great problems in our age is to impart understanding in the minds of those who have the ability and opportunity to make decisions that affect our lives. There is no shortage of information – in fact there is too much now we can search a world of information from the comfort of our armchair. There are those whose only need is a set of principles from which they are able to determine the right things to do. There are countless others who need a set of rules derived from principles that they can apply to what they do and indeed others who need a detailed prescription derived from the rules for a particular task. ISO 9000 has been used as a **prescription** when in fact it was intended to be a set of **principles**. ISO 9000:2000 is a series of three International Standards for Quality Management Systems. They specify requirements and recommendations for the design, assessment and improvement of management systems.

ISO 9000 contains the definition for the terms used in the family of standards and must be used for the requirements in ISO 9001 and the guidance in ISO 9004 to be understood.

ISO 9001 is a measurement tool. It is not a design standard. The management system should be designed to enable the organization to achieve its goals. ISO 9001 can then be used to determine whether the system contains all the necessary provisions. Designing a management system to meet ISO 9001 is like learning to answer questions in a particular examination – the exam does not cover everything you need to know to live a successful life. Likewise, ISO 9001 does not cover everything you need to do to become a successful organization – you have to do more.

ISO 9004 contains guidance on management system development and improvement. It is not an explanation of the requirements in ISO 9001 or a guide to their implementation.

ISO 9001 contains 8 sections.

1. Scope
2. Normative terms
3. Terms and definitions
4. Quality management system
5. Management responsibility
6. Resource management
7. Product realization
8. Measurement, analysis and improvement

**The requirements are contained in sections 4 to 8 and are not mutually exclusive - hence there is a lot of overlap and duplication**

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## Quality management system

These requirements are the basic requirements for establishing a management system and emphasize the principle actions necessary to develop, implement, maintain and improve such a system. The focus has moved away from documentation towards processes and therefore these general requirements capture some of the key activities that are required to develop an effective system of interconnected processes. Although the clauses in section 4 are not intended as a sequence there is a relationship that can be represented as a cycle, but first we have to lift some clauses from section 5 to commence the cycle. The words in bold indicate the topics covered by the clauses within sections 4 of the standard.

The cycle commences with the Organization's purpose (clause 5.3) from which are developed objectives (clause 5.4.1). In planning to meet these objectives the **processes are identified** (clause 4.1a) and their **sequence and interaction** determined (clause 4.1b). Once the relationship between processes is known, the **criteria and methods** (clause 4.1c) for effective operation and control can be developed and **documented** (clause 4.2.1). The processes are described in terms that enable their effective communication and a suitable way of doing this would be compile the process descriptions into a **quality manual** (clause 4.2.2) that not only references the associated **procedures** (clause 4.2.1) and **records** (clause 4.2.4) but also shows how the processes interact. Before implementation the processes need to be **resourced** (clause 4.1d & 6.1) and the **information** (clause 4.1d) necessary to operate and control them deployed and brought under **document control** (clause 4.2.3). Once operational the processes need to be **monitored** (clause 4.1e & 8.2) to ensure they are functioning as planned. **Measurements** (clause 4.1e & 8.2) need to be taken to verify that the processes are delivering the required output and actions taken to **achieve the planned results** (4.1f & 8.2.3). The data obtained from monitoring and measurement that is captured on **controlled records** (clause 4.2.4) needs to be **analysed** (4.1e & 8.4) and opportunities for **continual improvement** (clause 4.1f & 8.5) identified and the agreed actions **implemented** (clause 4.1f & 8.5).

## Management responsibility

These requirements are amongst the most important in the standard. There is a clear linkage between customer's needs, policy, objectives and processes. One leads to the other in a continuous cycle. The cycle commences with a **Vision** (clause 5.3a)- a statement of what we want to be or do, and then a **Focus on customers** (clause 5.2) for it is the customer that will decide whether or not the organization survives. It is only when you know what your market is, who your customers will be and where they will be that you can define the **Purpose** or **Mission** (clause 5.3a) of the organization (where you want to get to - what you want to become) and from the mission come the **Policies or Values** (clause 5.1b & 5.3) that will guide you on your journey. These policies help frame the **Objectives**, (clause 5.4.1) the milestones en route towards your destination. The policies won't work unless there is **Commitment** (clause 5.1) so that everyone pulls in the same direction. **Plans** (clause 5.4.2) have to be made to achieve the objectives and these plans need to identify and layout the **Processes** (clause 4.1 & 5.4.2a) that will be employed to deliver the results - for all work is a process and without work nothing will be achieved. The plans also need to identify the **Responsibilities and Authority** (clause 5.5.1) of those who will be engaged in the endeavour. As a consequence it is essential that effective channels of **Internal Communication** (clause 5.5.3) be established to ensure that everyone understands what they are required to achieve and how they are performing. No journey should be undertaken without a means of knowing where you are, how far you have to go, what obstacles are likely to lie in the path ahead or what forces will influence your success. It is therefore necessary to collate the facts on current performance and predictions of what lies ahead so that a **Management Review** (clause 5.6) can take place to determine what action is required to keep the organization on course or whether any changes are necessary to the course or the capability of the organization in order to fulfil its purpose and mission.

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## Resource management

A management system is not simply a set of documents but a dynamic entity that delivers results. In order to make things happen, the objectives and plans for their achievement that were established by implementing sections 4 and 5 of ISO 9001, need to be resourced. Whatever the resource, they firstly have to be planned, then acquired, deployed, maintained and eventually disposed of. The detail of each process will differ depending on the type of resource being managed. Human resources are not 'disposed off' but their employment or contract terminated and although the standard does not address disposal of any resources resource disposal impacts the environment and other interested parties. Without the full support of all interested parties the organization will not survive. The standard does not address financial resources specifically but clearly they are required to implement and maintain the management system.

If we link the clauses of the standard to form a cycle centred on resource management the cycle would commence with the **determination of resources** (clause 6.1) particularly the determination of the skills and **competences** (clause 6.2.2a) needed to achieve the organization's objectives. This also includes financial resources, **human resources** (clause 6.2) and physical resources in the form of materials and **infrastructure** (clause 6.3) such as buildings, facilities, equipment and communications. Once the resources have been determined they need to be acquired through such processes as personnel recruitment and **purchasing** (clause 7.4). Before deployment of resources an appropriate **work environment** (clause 6.4) will need to be created to prevent deterioration of product and the physical resources, to provide conditions in which the human resources are motivated to achieve their objectives and provide any necessary **awareness** and **training** (clause 6.2.2). Purchased materials and equipment will be subject to **verification** (clause 7.4.3) and measuring devices subject to **calibration** (clause 7.6). During operations the **infrastructure** and **work environment** will need to be **maintained** (clause 6.3 & 6.4) including **calibration of measuring devices** (clause 7.6) and the **effectiveness of training evaluated** (clause 6.2.2c). As the needs of the interested parties change the resources may no longer be capable of sustaining the organization's performance and so **continual improvement** (clause 8.5.1) will need to be initiated to enable the organization to meet its objectives.

## Product realization

Product realization brings together all the processes required conceive and supply products and services that meet customer needs and expectations. The requirements of section 7 however, do not cover all aspects of these processes as the monitoring, measurement, analysis and improvement elements have been collected together to form section 8.

If we link the requirements of section 7 and 8 together in a cycle, the cycle commences by scanning the environment to gain an understanding of customer needs and expectations. In doing so we need to **communicate with customers** (clause 7.2.3) and **determine the requirements** (clause 7.2.1) of customers, of regulators and of the organization relative to the product or service to be supplied. This will undoubtedly involve more **customer communication** (clause 7.2.3) and once requirements have been determined we need to **review the requirements** (clause 7.2.2) to ensure they are understood and confirm we have the capability to achieve them. If we have identified a need for new products and services, we would then need to **plan product realization** (clause 7.1) and in doing so use **preventive action** (clause 8.5.3) methods to ensure the success of the project and take care of any **customer property** (clause 7.5.4) on loan to us. We would undertake product **design and development** (clause 7.3) and in doing so we would probably need to **identify product** (clause 7.5.3), **purchase materials** (clause 7.4), components and services, build prototypes using the process of **production provision** (clause 7.5) and **validate new processes** (clause 7.5.2). After **design validation** (clause 7.3.6) we would release product information into the market to attract customers and undertake more **customer-communication** (clause 7.2.3). As customers enquire about our offerings we would once more **determine the requirements** (clause 7.2.1) in order to match customer needs with product offerings and our ability to supply. Now faced with real customers demanding our products, we would **review the requirements** (clause 7.2.2) and confirm we had the capability to supply a product that matched their needs before entering into a commitment to

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supply. We would then proceed to **plan product realization** (clause 7.1) once again and undertake **production or service provision** (clause 7.5). During production or service delivery we would maintain **traceability** (clause 7.5.3) of the product if applicable, perform **measurement and monitoring** (clause 8.2) and **control the measuring and monitoring devices** (clause 7.6). We would **monitor and measure processes** (clause 8.2.3) and **monitor and measure products** (clause 8.2.4) at each stage of the process. If we found variations we would undertake the **control of nonconforming product** (clause 8.3) and **analyse data** (clause 8.4) to facilitate **corrective action** (clause 8.5.2). Throughout production or service delivery we would seek the **preservation of product** (clause 7.5.5) and take care of **customer property** (clause 7.5.4). Once we had undertaken all the **product verification** (clause 8.2.4) and **preserved** (clause 7.5.5) the product for delivery, we would ship the product to the customer or complete the service transaction. To complete the cycle **customer communication** (clause 7.2.3) would be initiated once more to obtain feedback on our performance.

## Measurement, analysis and improvement

Measurement, analysis and improvement processes are vital to the achievement of quality. Until we measure using devices of known integrity, we know little about a process or its outcomes. . With the results of valid measurement we can make a judgement on the basis of facts. The facts will tell us whether we have met the target. Analysis of the facts will tell us whether the target can be met using the same methods or better methods or whether the target is the right target to aim for. Measurement, analysis and improvement elements cannot be represented as a cycle as they are strictly sub-processes within each business process as explained above.

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