

## Scope of ISO 9001, scope of the quality management system (QMS) and the scope of certification

The scope of ISO 9001 is given in clause one scope, and defines the scope of the standard itself. This should not be confused with the scope of the QMS, which is a term commonly used to describe the organization's processes, products (and/or services), and related sites, departments, divisions etc to which the organization applies a formal QMS. Note: this does not necessarily include all the processes, products, sites, departments, or divisions etc of the organization. The scope of the QMS should be based on the nature of the organization's products and their realization processes, the result of risk assessment, commercial considerations, and contractual, statutory and regulatory requirements.

While ISO 9001 is generic and is applicable to all organizations (regardless of their type, size or product category), under certain circumstances, an organization may exclude complying with some specific ISO 9001 requirements (from clause seven), while being permitted to claim conformity to the standard. This is because it has been recognized that not all the requirements in this clause of the standard are relevant to all organizations. ISO 9001 itself makes allowance for such situations, through clause 1.2 application. Consequently, the scope of registration/certification encompasses the scope of the QMS, as well as describing any excluded ISO 9001 requirements.

As the terms are often used interchangeably, this can lead to confusion when a customer or end user is trying to identify what parts of an organization have been registered/certified to ISO 9001, what product lines or processes are covered by the QMS, or what ISO 9001 requirements have been excluded. In order to dissipate such confusion and to enable identification of what has been registered/certified, the scope of registration/certification should clearly define:

- the scope of the QMS (including details of the product lines and related sites, departments, divisions etc that are covered by it)
- the organization's main processes for its product realization or service delivery activities (such as design, manufacture and delivery), for the product lines that are covered
- any ISO 9001 requirement that has been excluded

It should be noted that the scope of registration/certification is not the same as the certificate that is awarded to the organization after successful demonstration of conformity to ISO 9001. The certificate will usually include a synthesized description of the scope of registration/certification, but not the details of the ISO 9001 requirements that have been excluded; however, it may include a note to refer to the fact that the exclusions are detailed in the organization's quality manual.

It is essential that a scope of registration/certification be drafted by the organization prior to applying for registration/certification. This should then be analyzed by the certification body during the stage one audit, for appropriate planning of the stage two audit (see the guidance on the need for a two-stage approach to auditing).

It is the responsibility of the auditor:

- to ensure that the final statement of the scope of registration/certification is not misleading
- to verify that this scope only refers to the processes, products, sites, departments, or divisions etc of the organization that were assessed during the registration/ certification audit
- to verify that this scope defines any excluded requirements from ISO 9001, and that justification for such exclusions is provided and is reasonable

As an additional measure to combat potential confusion among customers and end users, the scope of registration/certification should be clearly defined in the organization's quality manual and any publicly available documents (this includes, for example, promotional and marketing material). However, promotional statements should never be included in the scope of registration/ certification itself.

ISO/TC 176/SC 2 has developed document N524, the ISO 9000 introduction and support package: guidance on ISO 9001, sub-clause 1.2 'application' to provide users with information regarding the intent of ISO 9001 clause 1.2 'application', including some typical examples of its use in practical situations. (N524 is available for free download from [www.iso.org/tc176/sc2](http://www.iso.org/tc176/sc2)). Additionally, the International Accreditation Forum has published its guidance on the application of ISO 9001, issue two, which should also be referenced.

This article is an edited version of 'Scope of ISO 9001:2000, Scope of Quality Management System and Defining Scope of Certification' from the website of the ISO 9001 Auditing Practices Group, and is reproduced courtesy of ISO and the IAF. These papers were developed on current best practice and therefore have not been formally endorsed as International Accreditation Forum (IAF) guidance or ISO TC176 interpretations. For further information about the Auditing Practices Group

<http://isotc.iso.org/livelink/livelink/fetch/2000/2122/138402/138403/%203541460/customview.html?func=ll&objId=3541460&objAction=browse&sort=name>.

The ISO 9001 Auditing Practices Group is an informal group of QMS experts, auditors and practitioners drawn from the ISO Technical Committee 176 Quality Management and Quality Assurance (ISO/TC 176) and the IAF. It has developed a number of guidance papers and presentations that contain explanations about the auditing of QMSs. These reflect the process-based approach that is essential for auditing the requirements of ISO 9001.

**JANUARY 2005**