

ISO 9000:2000 Exclusions Fact Sheet

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Exclusion from the system or exclusion from registration?

The idea that requirements are included or excluded appears to treat the standard as a design tool when in fact it is a measurement tool. As a design tool, it suggests that a system is designed to meet the standard, when in reality, the system is designed to meet business needs. As a measurement tool, if characteristics were missing from the system, they would not be measured and the requirements deemed not applicable. There is a belief that the system is only that which is addressed by the standard when in reality the system is the means by which the organization's objectives are achieved and therefore the question of exclusions does not arise. Exclusion is therefore an issue only in connection with certification not with system design.

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 product 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.

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.*

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