

## **ISO 9001**

The ISO 9001 document establishes the requirements of the quality management system. According to the Introduction to ISO 9001:2000,

"This International Standard may be used by internal and external parties including certification bodies to assess the organization's ability to meet customer, regulatory, and the organization's own requirements."

In other words, this is the requirements document for a company wanting to Register or Certify to ISO 9001.

Notice that the only standard discussed here is ISO 9001. That is because the 2000 revision replaced ISO 9002 and ISO 9003 with ISO 9001. Organizations that are currently registered to ISO 9002 or 9003 may take exception to the non-applicable clauses of ISO 9001 in accordance with section 1.2 of the standard.

For an organization to claim an exception to a clause or element in ISO, the element must truly be not applicable based on the nature of the organization and its product. The exclusions are limited to paragraphs within clause 7 and must not

"affect the organization's ability or responsibility, to provide product that meets the customer and applicable regulatory requirements".

Basically, this means that if you have activities that are necessary in any way to provide your product or service to the customer, these activities must be included in your system. If you outsource any activity that affects product conformity, you are also responsible for ensuring control of these outsourced processes and the controls identified in your quality system.

For instance, a company that was registered to ISO 9002 thereby excluding the Design organization from the scope of its quality management system would no longer be able to exclude design under the 2000 revision. Any exclusions an organization takes must be documented in the Quality Manual.