

“Output matters!”

Introduction

The ISO 9000 Advisory Group (comprising representatives from ISO/TC 176, ISO/CASCO, ISO/COPOLCO, IPC and the IAF) has recently made a number of recommendations to address increasing concerns that certified organisations are not delivering consistent, conforming product complying with customer requirements (ref. ISO 9001:2000 clause 1.1.)

The following paper by Jack West, first published in the July 2006 issue of Quality Digest magazine, addresses this topic and emphasises the theme that “Output matters!”

Conformity to individual requirements of ISO 9001:2000 such as document control, control of records, personnel competence and calibration of measuring equipment are important, but should not be the central focus of a quality management system. They should be seen as a means of achieving the desired output, which is consistent, conforming product

Jack West's Paper

It's often said that an organization can have a good quality management system (QMS) that conforms to ISO 9001 and yet still produce "junk." This observation derives from the perfectly valid distinction between third-party registration of a QMS and product certification. Certifying a QMS is no absolute guarantee that the product produced by the certified organization will be in conformance with requirements. Nonetheless, ISO 9001 contains many requirements that, taken together, should provide reasonable assurance that a system's output will meet customer requirements.

ISO 9001 requires that an organization's quality policy include commitments to meeting requirements and continually improving its QMS. The standard requires that product designs be validated to ensure they will meet requirements for given applications. ISO 9001 also requires that a product be verified to ensure it meets requirements. Identifying and meeting customer requirements is a consistent theme throughout ISO 9001. For example, one of the expected outputs of a management review is a decision regarding product that doesn't meet customer requirements.

ISO 9001 Clauses Demonstrating That Output Matters

1.1 "Scope"

"This International Standard specifies requirements for a quality management system where an organization

- a) needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and
- b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements."

5.2 "Customer focus"	"Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1)."
5.3 "Quality policy"	"Top management shall ensure that the quality policy ... b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system ..."
5.6.3 "Review output"	"The output from the management review shall include any decisions and actions related to b) improvement of product related to customer requirements ..."
6.1 "Provision of resources"	"The organization shall determine and provide the resources needed b) to enhance customer satisfaction by meeting customer requirements."
7.2.1 "Determination of requirements related to the product"	"The organization shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements related to the product, and d) any additional requirements determined by the organization."
7.3.2 "Design and Development inputs"	"Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include a) functional and performance requirements ..."
7.3.6 "Design and development validation"	"Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. ..."

8.2.1 "Customer satisfaction"	"As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. ..."
8.2.4 "Monitoring and measurement of product"	"The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. ..."
<i>Material quoted from ISO 9001:2000, used by permission of ISO</i>	

We need to stop perpetuating the myth that organizations can truly be in conformance with ISO 9001 and still produce product that doesn't meet customer requirements. ISO 9001-registered organizations and auditors alike tend to focus on conforming to the details of ISO 9001 and often lose sight of the basic requirements. Never lose sight of the product! A claim that an organization conforms to ISO 9001 should mean to the organization's customers that it can consistently provide product that meets customer requirements.

We must make certain our systems deliver conforming product to our customers. The standard requires it, and the credibility of ISO 9001 registration demands it. It's the output of our QMS that matters to our customers.

Note: This article summarizes several important concepts related to ISO 9001:2000 that are explained in more detail in ISO 9001:2000 Explained, Second Edition by Charles A. Cianfrani, Joseph J. Tsiakals and John E. (Jack) West (ASQ Quality Press,2001).

About the author

John E. (Jack) West is a consultant, business advisor and author with more than 30 years of experience in a wide variety of industries.

This article is an edited version of 'Guidance on cultural aspects of auditing' 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 go to:

<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.

DECEMBER 2006

