

# Search for Effectiveness: ISO 9001:1994 versus ISO 9001:2000

By Roderick A. Munro  
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RAM Q Universe, Inc.  
1135 Terminal Way, Suite 209  
Reno, NV 89502-2168  
Phone: 231-386-5071

## **The Issue:**

Occasionally, there is some confusion around the issue of the QMS effectiveness called out in the 1994 versus the 2000 ISO 9001 Standards. This White Paper examines at how the standards were designed and how to evaluate for effectiveness in each.

## **ISO 9001:1994**

The word effective or effectiveness shows up eleven (11) times in the 1994 standard. Note that the 1994 standard was focused primarily on the QMS, as it related to running the organization! Also, the primary responsibility was from the standpoint of the management representative who had the responsibility, but not necessarily the authority, to ensure that the system was working as it was designed to in the documented system.

## **ISO 9001:2000**

The 2000 standard uses the word effective or effectiveness six (6) times in the preamble and seventeen (17) times within the standard. In the forward to the 2000 standard, it states that the focus is “on the effectiveness of the quality management system in meeting customer requirements.” This is a very big difference from that of the 1994 standard that only focused on what the organization says that it does. Now, the organization must look to its customers for feedback and improvement suggestions to ensure an effective system.

The other big difference, in relationship to the effectiveness of the system, is that now the responsibility for the effectiveness is primarily on the shoulders of the “top management”. Yes, managers can still delegate activities within the organization, but they will be held responsible as the registration auditors question them about the various effectiveness requirements.

## **“Effectiveness” on the Process Approach:**

In the 1994 standard, “effective” looked at how well an element was working according to the written plan laid out for that element. In the process approach of 2000, the auditor is looking at customer feedback and the output measurables of various systems to view if the planned output meets the customer expectations. This is a challenge for many organizations as: many customers change their minds on a regular basis, technologies trends change the way things are done, product liability issues, and some customers expectations do not show up in engineering or other written requirements.

## **Summary:**

So when queried about the use of the word “effective” in the ISO 9001 standards, yes, the words “effective/effectiveness” do show up in both standards, however, they have very different contexts as to how the auditor (either internal or registrar) should view the use of the term(s) and what questions should be asked and of whom. Under the process approach to auditing, the auditor has the responsibility to look for areas where continual improvement is being sought by the top management to improve the overall effectiveness of the system to meet increasing levels of customer satisfaction.