ISO 9001 – Quality Manual Development (4.2.2)

Mark A. Randig

In order meet the documentation requirements of ISO 9001 (clause 4.2.1), the implementing organization is required to develop a quality policy and objectives, a quality manual and a minimum of six procedures (document control, control of records, control of nonconformances, internal audit, corrective and preventative action). Additional documentation is required on an as-needed basis, as necessary to ensure the effective planning, operation and control of the implementing organization's processes.

If we take a look specifically at the requirements of the ISO 9001 standard as it relates to quality manual design and development (clause 4.2.2), we find that there are actually only three requirements that a quality manual must address:

- The scope of the quality management system, including details of and justification for any exclusions,
- The documented procedures established for the quality management system, or reference to them, and
- A description of the interaction between the processes of the quality management system.

There are many sources that will tell you that re-phrasing the requirements of the standard in your quality manual is necessary - in fact, it's a requirement. If we take clause 4.2.2 at face value, this simply isn't the case.

While not compulsory, restating the requirements of the ISO 9001 standard, in the organization's own terms, has been a widely-used approach in the development of both quality manuals, as well as other related documentation. This strategy seems to be effective; it has been proven by literally thousands of implementing organizations, a correspondingly large number of which have successfully achieved ISO 9001 certification.

Paraphrasing the requirements of the standard has a degree of merit, particularly with regards to addressing how the organization complies with each clause of the standard, and where the ease at which a system can be audited is a concern (e.g., for organizations subject to frequent audits from a variety of different parties). If this approach is used, it is necessary to ensure that the existing content is modified to the extent necessary to adequately reflect and describe the specific processes used by the organization. Merely plagiarizing, and repeating verbatim, the wording of the standard is incorrect.

From a value-added standpoint however, the above method of paraphrasing is quite wasteful, as much of what gets reiterated from the standard provides little value to the user. As an alternative, we can develop a quality manual which addresses only those subjects/areas required by the ISO 9001 standard, and describe the processes used by the organization through other means (note that the ISO 9001 standard requires that the manual contains a description of the interaction between processes, not a description of the processes themselves).

This latter approach would result in a considerably smaller quality manual, but this wouldn't necessarily mean less system documentation. We may now have a 5-page quality manual, but we've then added a multitude of pages related to process descriptions. These descriptions

however, when properly developed, allow the organization to describe their processes beyond the constraints of the standard, as they do more than paraphrase. They tend to be better suited to the actual processes used by the organization, and therefore do a better job addressing the user's operational needs. They can also be effective in addressing the more complex areas within the ISO 9001 standard, such as those clauses where multiple processes exist (e.g., Design and Development, Control of Monitoring and Measurement equipment, etc.).

Which approach is the best? You're going to have to describe your processes, either within the quality manual or through additional documentation, or through a combination of both. Developing a brief manual, specific to the items required by ISO 9001, and accompanied by a series of process descriptions, is consistent with the intent of the standard; paraphrasing the standard has been the most widely-used approach and has a history of proven success. The best type of quality manual is one that suits the organization that can be used to ensure desired outcomes.

Mark Randig is the President and Founder of MAS Solutions LLC., a Houston Texas based consulting firm that specializes in helping companies achieve breakthrough performance by focusing on Quality Enhancement and Productivity Improvement. To get your FREE copy of Mark's newsletter "The Quality Specialist", go to http://www.masquality.com.