

Quality Matters:

What's new in the ISO 9000 family?

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This article is one of several being prepared for this section of Tappi Journal by members of the Process and Product Quality Division.

The world has become a much smaller place in recent years; it is a rare company that has no foreign competitors. Global competition must be met with global marketing strategies. Quality is an important part of such strategies worldwide. An important part of many quality strategies is using the ISO 9000 family of standards and guides. The ISO 9000 family is written and revised by the International Organization for Standardization's Technical Committee 176 (ISO TC 176). The 1987 version of the ISO 9000 family is under revision now and is expected to be reissued by late 1993 or early 1994. Planned changes are being made in two phases.

General Phase 1 changes

There is no intention to stiffen requirements or to change the applications of the standards.

Clause numbers will be identical for all parts of 9001, 9002, and where applicable 9003. Numbering of 9004 will not be done in this revision.

Terminology has been reviewed to make sure it is consistent with ISO 8402: current edition.

Emphasis on manufacturing language has shifted somewhat toward the generic.

"Notes" in the requirements standards continue to be guidance information to be followed at the discretion of the user. Normative references found at the beginning of the standard are considered to be extensions of the standard and, as such, are requirements.

An emphasis on preventive action is seen throughout the standards.

Specific Phase 1 changes

ISO guide 9000:1987 will be replaced with "ISO 9000-1:1994". This revised guidance document contains many of the quality management principles that will be developed in the Phase 2 revisions.

ISO 9001 has several changes that will affect users:

- The use of a quality manual to describe the quality management system is now required.
- A requirement for providing trained personnel for management and performance of work has been added to the requirement for trained verification personnel.
- Design control now covers both design verification and design validation.
- Increasing emphasis on the "Quality Plan" is seen. The document now asks for "quality plans or other appropriate documents."
- The "Process Control" clause has been expanded. Human qualifications as well as those for machines are mentioned.
- The "Corrective Action" clause has been modified to include preventive action. For example, the document directs the user to "use appropriate sources of information to analyze potential causes of nonconformance," instead of just dealing with nonconformances when they occur.
- The "Statistical Techniques" clause is now a requirement.

ISO 9002 will be even closer to 9001 than before. Comments for ISO 9001 above apply. A clause on "Servicing" has been added as well.

ISO 9003 has the same clause changes as 9001, but is expected to continue phasing out over time. According to recent data*, the number of registrations in the United States is near 1500, with 61% of the sites registered to ISO 9002, 36% to ISO 9001, and only 2% to ISO 9003.

ISO Guide 9004 will be renumbered as ISO 9004-1. ISO 9004-1 gives information on how to apply new guidance documents and standards that have been added to the ISO 9000 family since 1987. At this point, standards are intended to be used in contractual situations, and guidance

*"ISO 9000 registrations take quantum jump in US," *Quality Systems Update* 3(7): 1993.

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documents are intended to support these standards. It is not possible to "register" to a guidance document (e.g., ISO Guide 9004:1987), though it might contain information useful to registration to a standard (e.g., ISO 9001:1987).

ISO 9004:1987 is of interest as it not only clarifies ISO 9001, ISO 9002, and ISO 9003, but mentions "requirements of society: requirements including laws, statutes, rules and regulations, codes, environmental considerations, health and safety factors, and conservation of energy and materials" (ISO 9004:1987 3.3). It also covers product safety and reliability.

On the U.S. national scene, expect the American Society for Quality Control (ASQC) to renumber the newly issued revisions to be consistent with international practice: Q90 will be Q9000-1, etc.

Phase 2 Changes

The next scheduled "5 year" revision of the ISO 9000 family is under way now. Phase 2 revisions will be major and will be completed during the next review cycle. This cycle, expected to be complete by the late 1990s, will move the ISO 9000 family much closer to Total Quality Management. Phase 2 proposed criteria include the following:

- Review infrastructure and numbering, as well as relations with other TC 176 standards
- Examine the need for multipart numbers to ISO 9000 and ISO 9004
- Review the need for multilevel ISO standards such as ISO 9001, ISO 9002, and ISO 9003
- Continue to keep terminology current with ISO 8402
- Review impact of ISO 9001, ISO 9002, and ISO 9003 and other series items on each other
- Remember that the standards need to be applied to external audits and need to meet the needs of companies of various sizes (small, medium, large).

Other items of interest

An ISO resolution is currently pending opposing proliferation of quality management standards. According to the U.S. Technical Advisory Group (TAG) to TC 176 Chairman Donald Marquardt, "proliferation of standards" is an international problem. Many industries and trade organizations are being tempted to take bits and pieces of the ISO 9000 family and make "their own standard." Reginald Shaughnessy (chairman of International TC 176) recently urged the various national TAGs to TC 176 to help solve the problem by writing with a goal of producing "truly generic standards in principle and practice." It is possible that by the year 2000 a single Total Quality Management Standard could be in place to be used for both internal and contractual situations. Details for specific applications would be supplied in guidance documents; for example, ISO 9003 "Guidelines for the Application of ISO 9001 to the Development, Supply and Maintenance of Software."

While ISO 9004:1987 makes brief mention of the environment, don't expect to see an expansion of this topic in the ISO 9000 quality management family. The ISO Central Secretariat has authorized formation of a separate technical committee (TC 207) for production of environmental management standards.

The U.S. TAG to TC 176 is in the process of expanding its membership to more fully reflect the needs of U.S. manufacturers, educators, and service providers. TAPPI has applied for membership and expects to have a representative on the U.S. TAG before the end of the year.

For a more detailed look at the proposed revisions, copies of the Draft International Standards 9000-1, 9001, 9002, 9003, and 9004-1 are available from ASQC (800-248-1946) or ANSI (212-642-4900). **T**

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