

How the new ISO 9001:2000 interpretation process works

BY EDUARDO GERMANO WOHLGEMUTH



Eduardo Germano Wohlgemuth, is Convenor of the ISO/TC 176 Working Group on Interpretations.

Gerente do Departamento de Engenharia da Qualidade, WEG Industrias Ltda - Divisão Corporativa, Brazil.

Tel. + 47 372 4950.
Fax + 47 371 3952.
E-mail eduardow@weg.com.br

A Working Group on Interpretations was formed by ISO technical committee ISO/TC 176 in 2000 with the key objectives of preventing ambiguous and vague interpretations of ISO 9001:2000, developing a database of interpretations, ensuring the credibility of the interpretations provided, and setting up an interpretations process. (see "Interpretations of the ISO 9000 family of standards", *IMS* March-April 2002).

A pilot project was implemented in June 2000 and over 40 interpretations were dealt with from May 2001 to the end of the trial run in June 2003. Consultants submitted 41 % of the pilot project requests for inter-

pretation, followed by standardization and certification bodies (27 %), manufacturers (13 %) and public utilities (10 %), with the construction sector and “others” representing the remaining 9 %.

Geographically, Canada provided 27,5 % of the requests, Italy 20 %, Brazil 15 % and Israel 7,5 %. The remaining 30 % of requests were accounted for by Argentina, Australia, China, Colombia, Mexico, Russia, Singapore, South Africa and the United Kingdom.

Some 50 % of all pilot project requests concerned interpretations of ISO 9001:2000 Clause 7 *Product realization*, followed by Clause 4 *Quality management system* (25 %), and Clause 8 *Measurement, analysis and improvement* (approximately 12 %) – see **Figure 1**.

The interpretations process is now fully operational and is available to all ISO 9000 users worldwide, via the national standards institutes that make up ISO (listed with contact details on ISO's Web site: www.iso.org) and international organizations having liaison status with ISO/TC 176 (these organizations are listed on the ISO/TC 176 section on the ISO Web site).

What not how

The overall strategic intent of the process is to provide interpretation related to *what to do* and *not how to do it*, without changing any requirement of the ISO 9001:2000 standard, or its original intent. Requests for interpretation must be submitted on the official Interpretation Request Form (available from ISO national member institutes and ISO/TC 176 liaison organizations), and in a format that allows a Yes/No answer to be given.

Any organization or individual can submit a request for interpretation of an ISO 9001:2000 clause, but must do so via an ISO member or liaison organization. These should then ensure that the request is clear and in the appropriate format, and that



Figure 1 – Pilot requests for interpretation by ISO 9001:2000 clause

Clause 4 – Quality management system

Clause 5 – Management responsibility

Clause 6 – Resource management

Clause 7 – Product realization

Clause 8 – Measurement, analysis and improvement

the ISO/TC 176, *Interpretations Database*, has been checked to determine whether the question has previously been addressed. If not, the request is forwarded to the WG on Interpretations Secretariat¹⁾.

When a proposed interpretation has been commented upon, balloted and approved by ISO/TC 176, it is designated as an “official interpretation” and is added to the ISO/TC 176, *Interpretations Database*, and the original requester informed.

Formulating requests

Your question should be a request for interpretation, not for information, and seek clarification of what is required in the standard, and not how the requirement(s) should be fulfilled. Again, the objective is to provide interpretations related to *what to do* and *not how to implement a requirement*.

Your question should:

- be formulated so that it can be answered Yes or No, e.g.: “Does Clause 4.2.3 require that”;

1) ISO member bodies and ISO/TC 176 liaison organizations should send requests for interpretation on an Interpretation Request Form by e-mail to:

Naoum D.L. (Numpy) Tsitsimitse, Secretary, ISO/TC 176/WG on Interpretations, ABNT/CB-25 Brazilian Committee for Quality, Avenida Treze de Maio 13, sala 1214, 20003-900 – Rio de Janeiro – RJ, Brazil.

Tel. + 55 21 2532 5272.

Tel. + 55 21 2240 8743.

Fax + 55 21 2220 6376.

E-mail interpretacao@abntcb25.com.br

Consultants submitted 41 % of the pilot project requests for interpretation

- not be conditional, i.e. the use of when, if, etc. should be avoided;
- be limited to a single issue. If you require interpretation of multiple issues on the same subject, they should be submitted as separate requests;
- make a clear and correct reference to the specific ISO 9001:2000 clause;
- be generic, i.e. regardless of product, size or type of organization, country or situation;
- be accompanied, if necessary, by background information to the question in order to make the request clear;
- be submitted on the official Interpretation Request Form via your ISO member body for your country, or an ISO/TC 176 liaison organization only.

The overall strategic
intent of the process
is to provide
interpretation related to
what to do
and *not*
how to do it

Here are some examples of questions that ISO/TC 176 will *not* answer:

- Should the design of the packaging necessary to preserve the conformity of product up to its destination be part of the output activities defined in 7.3.3 *Design and development outputs*?"

Reason for rejection: It is not possible to provide a generic interpretation in response to this request. It is an implementation question – *how to do it*.

- “Does point a) of clause 7.6 *Control of monitoring and measuring devices* require calibration and verification as alternative activities, or as supplementary activities?"

Reason for rejection: It is not a question which can be answered by Yes or No.

Acceptable and unacceptable

Here are examples of questions that ISO/TC 176 *will* answer:

- “Do the requirements of Clause 7.5.2 *Validation of processes for production and service provision* include the validation of the equipment, locations and people involved?"
- “Does the requirement that ‘documents ... shall be controlled’ in Clause 4.2.3 *Control of documents* – a) *to approve documents for adequacy prior to issue* mean that the documents required for the QMS have to be reviewed and approved?"

Guidelines

Guidelines giving user-friendly information on how the process works and how to use it are currently being prepared by the ISO/TC 176 Working Group on Interpretations, and will be issued to the ISO national member institutes. At press time of this issue of *IMS*, the launching of the ISO/TC 176 Interpretations Database was expected on 1 December 2003