



ISO/TC 176/SC 2

GUIDANCE FOR HANDLING REQUESTS FOR INTERPRETATION OF THE REQUIREMENTS OF ISO 9001

1. INTRODUCTION

This document provides guidance to ISO Member Bodies for handling requests for interpretation of the requirements of the ISO 9001 standard.

The elements described in this document cover:

- The communication between the requester and a Member Body;
- The communication between a Member Body and ISO/TC 176/SC 2.

The ISO/TC 176/SC 2 Secretary will only accept requests for interpretation from Member Bodies and only on ISO 9001.

2. HANDLING OF REQUESTS FOR INTERPRETATION BY A MEMBER BODY

Each Member Body is encouraged to set up a process for handling requests for interpretation, to try to provide a response to an enquiry.

The requester should be advised to consult the ISO 9000 series of standards and other published support documents, as well as the listing of ISO/TC 176/SC 2 approved Interpretations (see: <https://committee.iso.org/home/tc176sc2>) before submitting a request.

If the Member Body is able to provide a satisfactory response, this should be sent to the enquirer and also be copied to the ISO/TC 176/SC2 Secretariat for future reference.

If the Member Body is not able to provide a response then it should submit a request to ISO/TC 176/SC 2 using the "Request for Interpretation" form.

3. PREPARING A REQUEST FOR INTERPRETATION TO ISO/TC176/SC2

The Member Body should prepare a request in the following manner.

The question should be a request for interpretation, not for information. It should seek to clarify what is required in the standard, and not how the requirement(s) could or should be fulfilled. Therefore, the overall strategic intent is to provide interpretations

related to **What** is required and not **How** to implement a requirement and to confirm the original intent of the standard.

The question should:

- be formulated in a way that it can be answered with a **Yes** or **No**. If possible, the question should read: “Does clause xyz require that”;
- **not** be **conditional** (the use of leading words like when, if, etc. should be avoided);
- be limited to **a single issue**; multiple issues on the same subject should be submitted as separate requests;
- make a **clear** and **correct reference** to the clause of the ISO 9001 standard;
- be **generic**, i.e. regardless of product, type and size of organization, country or situation;
- be accompanied, if necessary, by background scenario describing the situation that gave rise to the question, in order to make the request **clear**; and
- be communicated in the manner and format specified by the Member Body.

4. EXAMPLES ON FORMULATING INTERPRETATION REQUESTS

The examples below are shown to clarify which types of request have been presented in a format that can or cannot be responded to by the ISO/TC 176/SC 2.

EXAMPLES OF QUESTIONS THAT CAN BE ANSWERED BY ISO/TC 176/SC 2

Question: Does sub-clause 7.3.1 b) allow the organization to decide on the need, appropriateness and extent of the review, verification and validation to be carried out at each design and development stage?

Question: Does sub-clause 4.2.3 a) require that documents required for the QMS be reviewed as well as approved prior to issue?

EXAMPLES OF QUESTIONS TO BE SENT BACK TO THE REQUESTER WITHOUT INTERPRETATION

Question: Should the design of the packaging necessary to preserve the conformity of product up to destination be part of the output activities (7.3.3)?

Unacceptable because: It is not possible to provide a generic interpretation in response to this request. It is an implementation question (How to do).

Question: In the last line of the second paragraph of clause 4.2.4, we consider that the term “disposition” needs to be clarified. In which context should this term be used?

Unacceptable because: This is a terminology and implementation issue. It is not a question on a requirement of the standard.

5. WHERE REQUESTS FOR INTERPRETATION SHOULD BE SENT

ISO Member Bodies should send requests for interpretation on the Interpretation Request Form, duly completed in accordance with the preceding instructions, by e-mail to:

Mr. Charles Corrie

Secretary ISO/TC 176/SC 2

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