



# Heads Up

Issue: 29

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To: ANSI-RAB NAP Accredited Registrars and Accreditation Auditors

From: Randy Dougherty, Director of Registrar Accreditation

Re: ISO 9001: 2000 Permissible Exclusions

In March 2001, I presented a paper on permissible exclusions at the ASQ 9<sup>th</sup> Annual ISO 9001/ISO 14001 Conference. I have since provided this paper to a number of individuals when responding to challenges relating to exclusions. This paper has been updated based on updated guidance from ISO/TC176, and I am making it available as an ANSI-RAB NAP Heads Up.

Any decision we reach must be supported by the wording in the standard, or not be in conflict with the standard in the event a specific issue is not addressed by the standard. While the ISO/TC 176 guidance or interpretations can be used for understanding an issue, any decision for conformity or nonconformity must be supported by the wording in ISO 9001:2000.

With the issue of permissible exclusions, we will also be using document 524R4. The title of the document is ISO 9000 Introduction and Support Package module: Guidance on ISO 9001: 2000 clause 1.2 '*Application*'. The document is identified as ISO/TC176/SC2/N524R4. This is the fourth revision of this guidance (hence the R4). **Note: This latest revision was released 2004/04/29.**

A second document we will be using is document 630R2. The title of the document is ISO 9000 Introduction and Support Package: Guidance on 'Outsourced Processes'. The document is identified as ISO/TC176/SC2N630R2. It is dated 2003/11/24.

The 524R4 and 630R2 documents are available free of charge from the following websites: [www.iso.org](http://www.iso.org) and [www.bsi.org.uk/iso-tc176-sc2](http://www.bsi.org.uk/iso-tc176-sc2).

The fourth document we will also be using is IAF Guidance on the Application of ISO 9001: 2000. This is available free of charge on the IAF Web site: [www.iaf.nu](http://www.iaf.nu).

So, the four referenced sources are ISO 9001:2000, ISO/TC 176 Guidance on ISO 9001:2000 clause 1.2 '*Application*', ISO/TC 176 Guidance on "Outsourced Processes", and IAF Guidance on the Application of ISO 9001: 2000.

One of the significant changes to the ISO 9000 standards with the year 2000 revision was that ISO 9001:2000 replaced ISO 9001:1994, ISO 9002:1994, and ISO 9003:1994.

This decision to replace the three standards with one standard also meant that all requirements of this single standard may not be applicable to all organizations. This is subject addressed by clause 1.2.

Let us review clause 1.2. The first paragraph states: "All requirements of this International Standard [ISO 9001:2000] are generic and are intended to be applicable to all organizations, regardless of the type, size and product provided." From the definitions in clause 3, we know that the term "product" also means "service." And from the note to clause 1, we know that "product" applies to a product or service intended for a customer of the organization. The first paragraph does not allow for any exclusion. In fact, it clearly states the intent for all requirements to be applicable to all organizations.

The second paragraph states: "Where any requirement [or requirements] of this International Standard cannot be applied due the nature of an organization and its product, this can be considered for exclusion." This is the stated recognition that a requirement may not be applicable. This second paragraph creates the "permissible exclusions." For it to be considered, one must determine that the requirement cannot be applied, due to the nature of the organization and the product. The word "cannot" is very significant.

The third paragraph states: "Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements." The second paragraph established one significant criterium for considering an exclusion (that the requirement cannot be applied). The third paragraph establishes additional criteria: limited to clause 7, and not affect the organization's capability, or responsibility, to provide product that meets customer requirements. Clause 7 is "Product realization." The limitation means all other requirements must be met by any and every organization that is registered to, or claims conformance to, ISO 9001:2000. This limitation to clause 7 also reinforces the wording of the second paragraph "due to the nature of the organization and the product." If a requirement is not related to a specific product, it cannot be excluded. Requirements that apply to the organization alone cannot be excluded. If a requirement is necessary for the product to meet customer requirements, it cannot be excluded. And we know from clause 7.2.1 that it does not matter if these requirements are explicitly specified by the customer, or are required by regulations or otherwise necessary for the product for its intended use, the requirements cannot be excluded.

This puts a lot of constraints and limits on what can be excluded.

Let us re-review the second paragraph. "Where any requirement [or requirements] of this International Standard cannot be applied due the nature of an organization and its product, this can be considered for exclusion." I think it is significant that the wording in the standard states that a requirement "can be considered" for exclusion. To me, this leaves flexibility that a requirement does not **have** to be excluded. This is reinforced by the last paragraph of clause 4.1, which states "Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such processes shall be identified within the quality management system." So an organization does not have to exclude a requirement just because it does not have the capability to do it; it can include it even if it outsources it, and as long as it controls it.

Further, if an organization has responsibility for an activity that affects the ability for a product to meet customer requirements, an exclusion is not permissible even if the organization does not do the activity. In such an instance, clause 4.1 is not an option for the organization, it is a requirement. Another authority for this conclusion is ISO guidance 630R2. Clause 2.2 of this guidance states: "The intent of Clause 4.1 is to emphasize that when an organization chooses to outsource...a process that affects product conformity...it can not simply ignore this process, or exclude it from the quality management system. The organization has to demonstrate that it exercises sufficient control to ensure that this process is performed according to the relevant requirements of ISO 9001:2000..."

So we have another limitation and constraint on what can be excluded.

One last point. Let us re-look at clause 4.1. It states: "Control of such outsourced processes shall be identified within the quality management system." And let us re-look at clause 4.2.2, that states: "The organization shall establish and maintain a quality manual that includes a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2)..."

The challenge is how to apply all of this. This is a formidable challenge for any individual practitioner, be it an individual applying this within his or her organization, a consultant, or an auditor. This challenge is much more formidable when we consider applying this uniformly and consistently among all organizations, registrars and accreditation bodies. There was, and continues to be, joint sessions involving ISO/TC 176 (the writers of the standard) with ISO/CASCO (committee on conformity assessment) and IAF (the International Accreditation Forum, which is an association of national accreditation bodies) resulting in the IAF guidance.

I refer to the guidance from ISO and the IAF.

We begin to apply this with very careful consideration of the scope of the quality management system. The IAF Guidance states: "Certification/Registration Bodies will need to take particular care in defining the scope of the certificates issued to ISO 9001: 2000, and the permissible exclusions to the requirements of that standard."

IAF guidance 3 states: "Certificates issued to ISO 9001: 2000 shall clearly state in words the scope of the quality management system (QMS) in a way that will not mislead customers, and shall ensure that the information is available to the user to determine which categories of product and product realization processes are included within the scope of the certification/registration. In particular, scope statements shall be explicit in stating the responsibility for product design and development and other principle realization processes such as manufacturing, sales, and service."

Further, IAF guidance 3 states that the registrar shall review the validity of any exclusion during certification and surveillance audits.

So the challenge is clear. The appropriate bodies have recognized the challenge, and have provided guidance. And registrars have been given the specific assignment, and responsibility, to determine the validity of exclusions.

In its guidance 524R4, ISO/TC176 includes Annex A with several case studies and examples. I thought it would be wonderful if there were a decision tree, or algorithm, by which anyone could

reach a consistent conclusion or decision about a proposed exclusion by answering a series of questions which could be answered as a clear yes or a clear no. At the risk of being proven wrong, I offer such a tool: a decision tree or algorithm.

Use of the tool first requires a careful definition of the organization. Second, that there be a clearly statement of the product (or service) included in the scope of a QMS. Then one asks the following questions to determine if the product realization process (PRP) may be excluded.

1. Is the PRP within clause 7?  
If no, the exclusion is not acceptable. Stop. (ISO 9001:2000, 1.2)  
If yes, go to question 2.
2. Is the PRP necessary to meet customer requirements for the product?  
If no, the exclusion is acceptable. Stop. (ISO 9001:2000, 1.2)  
If yes, go to question 3.
3. Does the organization do the PRP?  
If yes, the exclusion is not acceptable. Stop. (ISO 9001:2000, 1.2)  
If no, go to question 4.
4. Is the organization responsible for the PRP?  
If yes, the exclusion is not acceptable. Stop. (ISO 9001:2000, 1.2)  
If no, the exclusion is acceptable. Stop. (ISO 9001:2000, 1.2)

I applied this tool to the examples in guidance 524R4 and reached the same conclusions.

One very common challenge has about excluding 7.3 (design and development) for an organization that provides a service instead of a product. As stated in the ISO 9001:2000, section 3 terms and definitions, "...wherever the term "product" occurs, it can also mean "service." Therefore, this exclusion, as with all exclusions, must be justified in the organization's quality manual (ISO 9001:2000, clause 4.2.2.a.). Also see Example 6 of 524R4.