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ISO 9001 Auditing Practices Group *Guidance on:*

Scope of ISO 9001, **Scope of Quality Management System (QMS)** **and Scope of Certification**

The **scope of ISO 9001** is given in clause 1 *Scope*, and defines the *scope of the standard itself*.

This should not be confused with ***Determining the scope of the QMS (clause 4.3)***, “where the organization shall determine and establish the boundaries and applicability of the QMS to establish its scope.” Scope needs to describe the types of products and services provided by the organization. Boundaries should clearly indicate processes, and related sites, departments, divisions etc. to which the organization applies a formal QMS.

The scope of the QMS in many cases is self-evident and defined by the activities taking place at a single location. The scope of the QMS will become more challenging in circumstances where there is:

- outsourcing
- logistics
- multiple sites
- service centres
- servicing at customer premises
- collaborative products and services

From a review of the nature of the organization’s operations, products and services, the extent of the QMS should be clear and not misleading. This should be expressed in the extent of processes and controls which the organisation has established.

The ***scope of the QMS*** should be based on the nature of the organization's products and services, their operational processes, issues raised in establishing the context of the organization and relevant requirements from relevant interested parties, the result of risk based thinking, commercial considerations and contractual, statutory and regulatory requirements.

Consequently, the ***scope of certification*** encompasses the **scope of the QMS** which the organization decides to be certified. As certification plays an important role in contractual and

regulatory fields, it is very important to establish the scope in a reliable and non-misleading manner.

Examples of misleading scopes:

- Scope text includes a normative standard that is not included in audit and might give the idea they are also certified to this standard
- Scope is too broad or vague and gives incorrect impression: e.g. general construction vs construction of roads only – in the case that the organization only applied for certification for construction of roads; e.g. construction vs. construction of buildings – in the case that an organization only has a license to do buildings.
- Lists of portfolio products that cannot be sustained and for which the company may not even demonstrate provision.
- Scopes with claims that cannot be substantiated, e.g.: same day home repairs.
- Scope which includes marketing or promotion statements, e.g. the cheapest and best product.

As the terms **scope of the QMS** and **scope of certification** are often used interchangeably, this can lead to confusion when a customer or end user is trying to identify what parts of an organization have been certified to ISO 9001 *versus* what product and service lines or processes are covered by the QMS.

In order to avoid such confusion and to enable identification of what has been certified, the scope of certification should clearly define:

- the scope of the QMS, types of products and services, related sites, departments, divisions etc. that are covered by it,

- the organization's main operational processes for its products and services, such as design, manufacture, packaging, delivery, etc., for the product lines that are covered,

It is essential that a scope of certification be drafted by the organization prior to applying for certification. This should then be analysed by the certification body during the Stage 1 of initial certification audit, for appropriate planning of the Stage 2 audit (see the ISO 9001 Auditing Practices Group guidance on "Two stage initial certification audit").

It is responsibility of the auditor:

- to ensure that the final statement of the scope of certification is not misleading;
- to verify, during the audit, that this scope only refers to the processes, products, services, sites, departments, or divisions etc. of the organization included in the scope of certification;
- to verify that this scope defines any non-applicable requirements from ISO 9001, and that justification for such non application is provided and is reasonable.

As an additional measure to avoid potential confusion among customers and end users, the scope of certification should be clearly defined in the organisation's documented information and make it publicly available.

Application

Annex A of ISO 9001:2015 provides clarification on the “Applicability” of its requirements. In theory and by principle all requirements are applicable. As a consequence, very few requirements will be actually subject to a “non-applicability” declaration.

Examples of where non-application can be applied:

- a service organization that has no measuring equipment to monitor or measure that needs traceability
- an organization that does not handle customer property, including information from the client
- an organization that only receives products provided by the client or by providers that are qualified by the client and so, has no responsibility to select providers

For further information on the ISO 9001 Auditing Practices Group, please refer to the paper: *Introduction to the ISO 9001 Auditing Practices Group*

Feedback from users will be used by the *ISO 9001 Auditing Practices Group* to determine whether additional guidance documents should be developed, or if these current ones should be revised.

Comments on the papers or presentations can be sent to the following email address: charles.corrie@bsigroup.com.

The other ISO 9001 Auditing Practices Group papers and presentations may be downloaded from the web sites:

www.iaf.nu
www.iso.org/tc176/ISO9001AuditingPracticesGroup

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