ISO 9001 Auditing Practices Group

Guidance on:

Scope and applicability

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INTRODUCTION

Scope of ISO 9001, scope of Quality Management System (QMS), scope of certification and audit scope refer to different things, yet they are closely linked. Auditors should be aware of the difference and interrelation between them, implications in the evaluation of the QMS and the certification scope and potential impacts in the audit process. Within the scope of the QMS, auditors should carefully analyse non-applicability of requirements. Auditors and organizations need also to be aware that, in the case of certification, the certification scope is part of the certificate that is a legal document, which, according to ISO/IEC17021-1:2015 shall identify “the scope of certification with respect to the type of activities, products and services as applicable at each site without being misleading or ambiguous.

This paper is a major revision of the earlier paper “Scope of ISO 9001, Scope of Quality Management System and Scope of Certification” and replaces it.

The current 2023 revision incorporates clarifications and new examples resulting from multiple comments and recommendations received.

DIFFERENCE BETWEEN SCOPES

ISO 9001 Scope - Clause 1 of ISO 9001 describes its scope, the subject of the standard, quality management system, and the intended results of its application by organizations.

QMS Scope - ISO 9001 Clause 4.3 states that “The organization shall determine the boundaries and applicability of the QMS to establish its scope... The scope shall state the types of products and services covered”.

Certification Scope - The scope of certification is derived from the scope of the QMS and is dependent on what the organization decides to certify within the constraints allowed by the certification scheme and any applicable statutory and regulatory requirements. This scope is used to communicate the certification status of the organization’s QMS to relevant interested parties. Sometimes the scope of certification can be smaller than the scope of the QMS and special attention needs to be given to these cases.

The term scope of certification does not have a specific definition in ISO/IEC17021-1, but the more generic definition is given in ISO/IEC17000:2020: scope of attestation - range or characteristics of objects of conformity assessment covered by attestation”.

Where the “Attestation is issue of a statement, based on a decision (7.2), that fulfilment of specified requirements has been demonstrated. Note 2 to entry: …third-party attestation are distinguished by the terms declaration, certification and accreditation…”

And the “certification is third-party attestation related to an object of conformity assessment.”

Audit Scope – “extent and boundaries of an audit (ISO 9000:2015, 3.13.5). Note 1 to entry: The audit scope generally includes a description of the physical locations, organizational units, activities and processes”. Note 1 to entry on ISO 19011:2018, 3.5 includes “virtual locations” besides “physical locations”.

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Version 3 – 01-12-2023
As integrated management system audits become more prevalent, a brief note on scope differences among them is appropriate. “When more than one management system is being audited it is important that the audit objectives, scope and criteria are consistent with the relevant audit programmes for each discipline and their respective scopes. Some disciplines can have a scope that reflects the whole organization and others can have a scope that reflects a subset of the whole organization” [ISO 19011:2018 Clause 5.5.2].

AUDITOR GUIDANCE ON QMS SCOPE

The scope is about determining applicability and limits of the QMS.

In order to establish applicability, the auditor should verify what products and services are managed within the formal QMS. The next step is to verify the processes needed to deliver the products and services, either performed or outsourced, and remaining under the responsibility of the organization.

Boundaries define the limits of the QMS. To increase understanding of the boundaries the auditor should get an insight into organizational structure and resources related to sites, physical and virtual, and infrastructure. Boundaries may be self-evident. It is advisable to review the websites of the organization and to verify the organizational claims of the selected boundaries.

For many organizations the QMS applies to all its products and services, includes all the processes performed at defined locations with established resources including people and the whole of the organization.

Both applicability and boundaries of the QMS are relevant. The first is particularly relevant to determine the scope of the certificate. Boundaries are critical to determine the audit scope.

The scope of the QMS can become more challenging to determine in circumstances where there are extensive or critical:

- number of products and services
- externally provided products, processes and services (e.g., outsourcing)
- logistics
- multiple sites
- service centres
- servicing at customer premises
- collaborative products and services
- shared facilities
- relevant legal and statutory requirements
- projects limited by time, etc.

These situations need to be carefully assessed to determine if the scope was defined correctly by the organization and stated in a clear, unambiguous, and non-misleading manner. The auditor should determine if any of these factors are present and if they affect the audit scope.
ORGANIZATIONAL BOUNDARIES

One of the more common boundaries auditors need to evaluate are the organizational boundaries determined by the organization.

ISO 9000: 2015 defines an organization as a “person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives “

“Note 1 to entry: The concept of organization includes, but is not limited to, sole-trader, company, corporation, firm, enterprise, authority, partnership, association, charity or institution, or part or combination thereof, whether incorporated or not, public or private.

Note 2 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by modifying Note 1 to entry.”

If the organization is part of a larger entity, the auditor should check if organizational boundaries are well determined in the system. The auditor should also assess the implications to the audit scope of processes that are outside the scope of the QMS, but within the scope of the larger entity. These may have an impact on the QMS. The auditor should evaluate how these processes are handled within the audit scope.

The same exercise applies when the organization is a combination of two or more different entities.

To determine the **scope of the QMS** “the organization shall consider external and internal issues raised when establishing the context of the organization”. It is a clear expectation that these boundaries are identified as a relevant issue by the organization.

CERTIFICATION SCOPE

As certification plays an important role in contractual and regulatory fields, it is very important to establish the scope of the certificate in a reliable, non-misleading and unambiguous manner.

The terms **scope of the QMS** and **certification scope** are often used interchangeably due to the fact that in many situations they are equivalent. This can lead to confusion when an organization has chosen to limit its QMS scope to only certain processes, products or services. A customer or end user must be able to discern the scope of the ISO 9001 certification.

Certification scope is a term used to refer to the scope in the certification document. This is usually a statement that describes the “type of activities, products and services as applicable at each physical site without being misleading or ambiguous” (ISO/IEC 17021-1:2015). In the certification document the certified organization’s name and physical location (or of the headquarters, and other physical sites, if applicable) are also stated.
In order to avoid confusion and to enable identification of what has been certified, the scope of certification should define, as appropriate:

- types of activities, products and services covered.
- related sites where these activities are performed and specific scopes, if relevant.

### Examples of activities statements in QMS scopes

- “Design, manufacturing and distribution of…”
- Management of outsourced design…
- “Manufacturing and assembly of…”
- “Manufacturing, warehousing, sales and distribution”
- “Warehousing and distribution”
- “Warehousing, sales and distribution”
- “Procurement, warehousing and distribution”
- “Provision of services”
- “Provision of consulting advice services”

Certification scope begins to be evaluated by the certification body during the inquiry and application process, is reviewed throughout the certification process, and regularly at surveillance and recertification activities. The audit team has the task to assess and validate that the scope statement proposed by the organization reflects truthfully what the organization provides and what is covered by the QMS.

Auditors should not validate misleading scope statements, such as:

- Scope text includes a reference to a normative document that might give the idea they are also certified or even accredited to this standard. As ISO 9001 is a management system standard, a reference in the scope statement to product or service specifications standards can give the idea that a claim for a certified product or service is included, which would be misleading. For example, “Manufacturing of products in accordance with product standard XXXX; YYYY”.
- Scope is too broad or vague and gives incorrect impression of what the organization does: e.g. general construction vs. construction of roads only – in the case that the organization only builds roads; e.g. construction vs. construction of buildings – in the case that an organization only has capability/authorization to do buildings; manufacture of interior doors, where an organization has no capacity to provide certain types of doors such as fire protective or acoustic doors.
• Lists of portfolio products for which the organization cannot demonstrate provision, e.g., states a list of 10 products and only demonstrates to produce 3.

• Scopes with claims that cannot be substantiated, e.g., “Same day home repairs” and audit evidence demonstrates that organization infrastructure is not adequate to ensure it.

• Scope which includes marketing or promotion statements: the cheapest and best product.

• Scope that includes activities, products or services that the organization cannot demonstrate its capability to provide.

The auditor should also be aware that the scope statement can be written in a language related to its business area, that, by their nature define the activities included. This is for example the case of architecture where design and development are always included. Therefore, a scope statement such as “Architecture services” is acceptable.

It is responsibility of the auditor:

- to verify that the 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, etc. of the organization that are covered by its QMS and for which the organization can demonstrate its ability to consistently provide those products and services;
- to verify justifications for the requirements not applicable by the organization.

SCOPES OF CERTIFICATE SMALLER THAN SCOPES OF QMS

It is important to note that sometimes the organization chooses to certify only part of the products, services, processes, or sites of the organization.

This scope is acceptable if the types of products and services stated in the certification scope are also stated in the QMS scope, including the processes to deliver them. The auditor needs to assess that the organization demonstrates that what is outside the scope of certificate does not adversely affect the capability of the QMS within the scope of certificate to fulfil the requirements of the standard and deliver the expected outcomes.

The auditor should also verify that the certificate scope statement accurately communicates what is included.

Examples:

• Catering company that provides meals in canteens that are property of the client and only includes in the certification scope the provision of catering services at specified client’s sites, although its QMS applies globally to all catering services – a non-misleading statement would be something like: “provision of catering services (...) applied at the locations listed (...).

• Local government that only requires certification for the processes related to some specified services, e.g.: building licenses issuing, provision of water, managing electoral processes, versus all the services it provides. The certification document could further differentiate by
e.g.: “local government designation + department designation followed by the scope statement.

- Hospital that only applies the QMS to specific specialities (e.g. emergency room, etc.); - The entity would be identified as Hospital J – Emergency service + statement of the service.

- A manufacturing enterprise that only chooses to certify one product line from various; - the scope statement would only specify the product included.

- A big organization that chooses to gradually apply the QMS to certain products and services or sites and gradually enlarges the scope.

AUDIT SCOPE

Understanding the scope of the QMS and scope of the certificate is critical to define the audit scope. The audit scope should be consistent with the audit program and audit objectives, meaning that the audit scope will not always cover all the QMS scope. The audit scope includes factors such as locations, functions, activities, and processes to be audited, as well as the time period covered by the audit.

The boundaries of the QMS will affect the audit plan in terms of access to relevant information.

Understanding of the scope enables determination of what to audit, the location of the processes and any constraints on access, as well as logistical issues.

It is also important for an auditor to take into consideration the use of electronic and communication technologies by the auditee organization when defining the Audit Scope. Particularly, virtual locations of the organization should be considered.

ISO 19011:2018 Clause 3.5 Note 2 to entry – “A virtual location is where an organization performs work or provides a service using an on-line environment allowing individuals irrespective of physical locations to execute processes”. Auditors should be aware that in many cases sales are done electronically, work is done outside the physical location of the organization (e.g., home office, collaboration, virtual teams, etc.)

Where these virtual locations are part of the QMS scope they should also be included in the audit scope and audit time should be allocated. Appropriate audit techniques such as remote auditing, may be the most appropriate to audit virtual locations. In any case they may not replace the need for face-to-face interviews with people involved, even when using long distance meeting facilitators.
INFLUENCE OF OUTSOURCED PROCESSES ON QMS, CERTIFICATION AND AUDIT SCOPES

As stated earlier, the definition of the QMS scope becomes more complex when one or more processes or part of them are outsourced by the organization. Although an organization chooses to outsource a process or part of it, the responsibility for the products and services provided remains within the organization.

The outsourced processes should be considered when planning the audit. The inclusion or exclusion of the outsourced processes from the scope of the QMS and the certification scope statement needs to be evaluated.

A wide range of situations can be observed, from total outsourcing of production, parts of the product or service provision being outsourced, outsourcing that only occurs in work peak situations, etc.

An outsourced process is an externally provided product, process or service, that should be handled, according to the requirements of ISO 9001:2015 clause 8.4, as well as any other applicable requirements to the outsourced process itself (e.g. qualification of personnel, infrastructure, controls, etc.).

The auditor should consider applying a risk-based approach to determine the risk of the outsourced processes in the achievement of the intended outcomes of the QMS. This may affect the audit scope and the time needed to assess the outsourced processes.

In many cases outsourcing occurs within the facilities of the organization, as it is often the case of maintenance at industrial sites or large buildings. In these cases, the relation between the control of the outsourced process by the organization and the outsourced processes itself is very strong and maybe even difficult to differentiate. It is usually easy and feasible to audit the outsourced processes performed in the organization facilities. This is often the case when auditing construction sites, where many contractors operate, and the auditor can audit the process and the control of the process by the auditee.

In other situations, outsourced processes are not accessible to auditors and the audit team. Taking into consideration risk-based approach to auditing, the auditor will need to evaluate the type and extent of controls that the organization has determined to apply to the outsourced processes, the results of these controls and whether they are effective.

It is also important to gain an understanding of the outsourced processes to assess the scope of the QMS, to determine the audit scope activities and the need to audit the outsourced processes as well as to evaluate the scope statement.

In relation to the scope statement of the certificate, the auditor should be able to determine:

a) the cases in which the outsourced processes need to be stated, as being a critical responsibility of the organization,
b) the cases where they need to be stated as outsourced to ensure the statement is not misleading,
c) the cases where it is not relevant to state outsourced processes in the scope statement.
Due to the complexity of arrangements and situations encountered it is impractical to attempt to define rules that apply to all cases and situations. The following cases provide some examples:

**Case 1**

Company X used to manufacture their product. They ceased to manufacture it and now purchase the product according to their specified requirements.

The following certificate scope statements reflect what the organization does:

“Provision of products X and Y (generic description of the products)”

The certificate scope statement “manufacture of products Y and X” would no longer be correct.

**Case 2**

Manufacturer of racking. The organization outsources plating of the product.

It would be inappropriate to have a certification scope that says it is a provider of plating processes.

However, the manufacturer must include plating within the scope of its quality management system and demonstrate how it is integrated and controlled. An acceptable scope certification statement would be “Manufacturer of galvanized racking”.

An alternate method should be to include in documented information evidence of identification, control and conformance.

Methods of control might include:

- Supplier on-site audit verifying:
  - Current industry specific technical specifications
  - Process specifications
  - Qualified staff
  - Appropriate infrastructure
  - Measurement/test methods and equipment
    - Thickness gauges
    - Titration process
  - Process validation and re-validation
  - Verification of appropriate special process certification
  - Purchase order with specifications,
  - Process for handling product in and out
  - Acceptance criteria for verification or further test
  - First article inspection
The auditor is responsible for assessing the level of control of the outsourced process.

Case 3

An organization designs and sells fashion collections. They are fully responsible for the design. They have marketing and sales processes to sell their collections to several customers. Once they have demands they order the production to outsourced factories that they control within their QMS.

The following certificate scope statement reflects what the organization does:

Design and commercialization of fashion clothes collection.

The certification scope statement: Design, manufacturing and commercialization of fashion clothes collection would be considered misleading as the organization is not manufacturing the clothes.

Case 4

An organization outsources warehousing services and 10% of final packaging volume that needs to be done manually to meet customer-specific requirements that cannot be performed on the production lines. Both outsourced processes are quality critical, and the organization performed a risk assessment prior to outsourcing.

The organization defined the outsourced process in detail, determining the monitoring and controls needed that include to oversee its execution according to the specified requirements with its own personnel.

The scope “production, … of … as well as outsourced warehousing and co-manufacturing packaging processes …” is a scope statement that reflects adequately the scope of the QMS and enables the organization to communicate it to its customers.

In some sectors the description of the certification scope defines the nature of the activities performed by the organization: manufacturer, assembler, distributor.

APPLICABILITY AND NON-APPLICABILITY OF ISO 9001 REQUIREMENTS

Annex A.5 of ISO 9001:2015 provides clarification on the use of Applicability and auditors need to be familiar with it and use the Annex to clarify audit judgments when needed.

ISO 9001 requires (see 4.3) an organization to determine and document its scope, including the types of products and services covered. Further, it requires the organization to provide justification for any requirement of the standard that the organization determines is not applicable to the scope of its quality management system. The organization may only claim conformity to ISO 9001 if the requirements determined as not being applicable do not affect the organization’s ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.
Examples of common non-applicability of requirements:

- A barbershop that has no measuring equipment to monitor or measure that would require traceability (ISO 9001:2015, section 7.1.5.2).
- An organization that does not handle customer or supplier property, including customer information (ISO 9001:2015, section 8.5.3).
- A police department which does not apply the requirement of determination of criteria for selection of suppliers because it is the responsibility of other authority in accordance with Federal Law #XXXX (ISO 9001:2015, section 8.4.1 in part “…The organization shall determine … criteria for the selection … of external suppliers”).
- An organization that does not specify requirements for the products and services it delivers, having no design nor development activities, as they are provided by another parent organization or by its customers with no further development (ISO 9001:2015, section 8.3).

A set of requirements or an entire clause cannot be considered non-applicable in the scope of the QMS (and the scope of the audit plan) only on the reason they are outsourced.

In an ISO 9001 audit, if an organization outsources a process that has defined requirements within the standard, the auditor still needs to consider those requirements in the audit scope, besides the obvious need to audit the control of externally provided products and services. This occurs with some frequency with design and development, that may be totally or partially outsourced or made in collaboration with other organizations. The organization should ensure adequate and competent control over the outsourced activities or process and the auditor should not accept non-applicability of ISO 9001 clause 8.3 requirements in this circumstance. Attention is drawn to the fact that not all requirements within 8.3 may be applicable. For more details read APG paper on design and development.

**APPLICABILITY OF DESIGN AND DEVELOPMENT, SCOPE OF THE QMS AND OF THE CERTIFICATE**

The 2015 edition replaced the concept of exclusion with applicability. The starting point is that all requirements are applicable. This means an organization may choose to consider all requirements of the standard to be applicable and not present any justification for non-applicability. In this case, the QMS covers all requirements, and the organization should determine the criteria for their fulfilment.

Nevertheless, the organization may not be able to provide objective evidence that it is effectively applying all the requirements at the moment of the audit but that, if a situation arises where it needs to apply them it can do so. This situation is common by several reasons:

- the organization used to exclude 7.3 in ISO 9001:2008 and is now becoming aware that application of design and development process improves the effectiveness of the QMS,
- the organization has a stable product that has undergone few changes over the years and does not develop new products and services on a regular basis. (Note: in case changes occur, it is expected that the organization applies at least 8.3.6 Design and development changes)

- design and development are not required in daily provision of services, as changes in customer needs are properly dealt with through requirements in ISO 9001:2015 subclauses 8.2 and 8.5. Nevertheless, requirements for the services may imply requirements for the infrastructure and resources to provide them. In these cases, design is not conducted on a frequent basis and is not directly related to the service. The design and development process is only activated by changes in technology, legal requirements, or the need to change the infrastructure and resources that support the service,

- usually, the organization does not provide any design and development, but changing circumstances require the need to consider it,

Such situations are acceptable but might have implications on the stated scope of the QMS and scope of the certificate, especially if the design and development process is to be mentioned. In some other cases, e.g., for tendering purposes, the (i) reference to design in the scope statement is very important, such as “management of outsourced designed” and this may be acceptable, providing the evidence for the activity is provided.

If the organization has responsibility for design and outsources the design and development process, the scope statement for certification shall include the words "Design of ..." or “Development of ...” or “Design and Development of ...” or “Design management of ...” or “Provision of design and development services” or “Development of training courses, new technologies” (not preparation of course materials). The use of the word “design” may not always be appropriate to the context of the organization and may be replaced by alternative wording,

Under what circumstances can an organization include design and development in the certificate scope? The auditor should assess the capability of the organization to conduct design and development according to an established process, through verifiable evidence of its application. Note the previous consideration on the possibility of parts of the design and development process being outsourced, in which case evidence is required on the capacity and any required qualifications of the outsourced process and on the control of the process (8.3) If this is not demonstrated, design and development should not be stated in the certification scope, although the organization still might consider potential applicability.

**SCOPE AND CHANGES**

It is important to remember that scope changes with time and circumstances and needs to be revised and updated, and consequently, audited regularly. What the organization does today, may be different within a year.

Even if products and services provided are apparently the same, changes in processes, infrastructure, location may have implications in the products and services themselves and in scope definition. Organizations may also wish to introduce changes in scope, either extending or reducing scope to new products, services or locations, either providing clarifications in the scope statement.

An example is a store that starts selling online and delivering the product to the consumer. In this situation a new service is created that might have implications on scope statements and definitely on audit scope.
Another example is a construction company that only builds, but one day has a contract or needs to answer a tender where it becomes responsible for the design. It may need to outsource the process or make other arrangements and include it in the QMS scope. If the tender is lost, or when the project is over, and it no longer have any application of design to demonstrate, it will need to revise its scope again to exclude this activity.

In case of third part certification, it is up to the certification body to determine the activities needed to collect the information to evaluate the change in scope. This may vary in function of the changes to be introduced, ranging from a simple rewording to an extraordinary audit to extend the scope.

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