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ISO 9001 Auditing Practices Group

Guidance on:

Scope and applicability

Contents

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 QMS and certification scope and potential impacts in the audit process. Within the scope of the QMS, auditors should carefully analyse non-applicability of requirements.

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.

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 have certified. 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.

Audit Scope – "extent and boundaries of an audit (ISO 19011:2018, 3.5). Note 1 to entry: The audit scope generally includes a description of the physical and virtual locations, functions, organizational units, activities and processes, as well as the time period covered."

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 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.

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 but the first is particularly relevant to determine the scope of the certificate and boundaries are critical to determine the audit scope.

The scope of the QMS can become more challenging to determine in circumstances where there is 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;
- 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 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 and non-misleading 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 17021:2015). 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 products and services provided;
- the organization's main operational processes for its products and services, such as design, manufacture, packaging, delivery, provision, etc. (to provide understanding of the position in the value chain and the main activity),
- related sites where these activities are performed and specific scopes, if relevant;

Certification scope begins to be evaluated by the certification body during the 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 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 STD 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.
- 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 ensure 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 the 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 the QMS does not adversely affect its capability 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 shall 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 do 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 it 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 to be considered when planning the audit. The inclusion or exclusion of the processes from the scope 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, and subsequently audited, according to the requirements of ISO 9001:2015 section 8.4.

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 many other situations outsourced processes are not accessible to auditors and the audit team. The auditor will need to evaluate the type and extension of the controls that the organization has determined to apply to the outsourced processes and functions as well as the results of these controls to determine whether these are effective.

It is also important to gain an understanding of the outsourced processes to assess the scope of the QMS or the scope of the certificate. 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.
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

In this instance, although it is not in the scope of certification statement, it should be included in documented information that provides evidence of identification, control and conformance.
An alternate, acceptable scope certification statement would be “Manufacturer of galvanized racking”.
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.

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

Applicability and non-applicability of ISO 9001 requirements

Annex A.5 of ISO 9001:2015 provides clarification on the use of Application 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 this International 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);
- 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, we still need 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 validate 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 certificate

The 2015 edition replaced the concept of exclusion with applicability. In theory and by principle all requirements are applicable. This means an organization may choose to consider the entire applicability of the standard and not presenting any justification for non-applicability. The QMS covers all requirements determining the criteria for their fulfilment.

Nevertheless, the organization may not provide objective evidence that it is effectively applying all the requirements at the moment of the audit but that, in case needed it will apply them. 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 offer of product that has few changes over the years without needing to develop new products and services on a regular basis,

- 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 sections 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 frequent and apparently not directly related to the service. Those only become “active” with 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

This situation is acceptable, but it might have implications on the stated scope of the QMS and scope of the certificate, specially at the level of design and development process, that are usually stated in the scope.

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. 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.

An example is a store that starts selling online, delivering the product home. 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 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. When the project is over, and it no longer have any application of design to demonstrate, it will need to revise its scope again.

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

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