

is appropriate to the organization's products and services to ensure it is appropriate to the business.

Scope and justification as documented information

The QMS scope and clause justification of inapplicability is typically documented in the organization's quality manual. Even though a quality manual no longer is required to meet ISO 9001:2015 requirements, the majority of organizations continue to maintain their quality manual. ISO 9001:2015 requires that any inapplicability with a clause, subclause or shall statement be justified with documented information.

Many organizations may find it easier to document inapplicability at the functional level. For example, procurement may have a table to indicate what external provider communication requirements from subclause 8.4.3 apply to different commodities for International Aerospace Quality Group AS9100-series standards.

Inapplicable requirements affecting product and service conformity

All ISO 9001 requirements apply to an organization's QMS unless the requirements do not affect the organization's ability or responsibility to ensure product and service conformity and enhanced customer satisfaction. So valid justification cannot be, "We just don't want to do it," or "We don't have the resources to do it." A good rule of thumb is that if the organization can apply the requirement, then it shall apply the requirement.

There are some ISO 9001:2015 requirements for which inapplicability would

be near impossible to justify because most organizations provide products or services to their customer:

- + Clause 8.1 operational planning and control required for planning, implementing, and controlling the processes for products and services.
- + Clause 8.2 for communicating, determining, and reviewing requirements for products and services to ensure customer satisfaction.
- + Clause 8.5.1 for controlling production and service provision to ensure intended results are achieved.
- + Clause 8.6 for release of products and services to the customer ensuring that all requirements have been met.
- + Clause 8.7 for controlling outputs that do not meet requirements.

When an organization makes a claim for inapplicability of this requirement, auditors need to see documented objective evidence that the following two conditions are fulfilled:

1. The requirement cannot be applied.
2. By not applying the requirement, there is no effect on the organization's ability or responsibility to ensure the conformity of its services and the enhancement of customer satisfaction.

Only if these can be proven should an auditor accept the inapplicability.

Aviation, Space and Defense Case Study examples extracted from published clarifications are provided in Online Table 1 (which can be found on this column's webpage at qualityprogress.com) to illustrate the application of requirements.

Scope is fundamental

An accurate QMS scope is fundamental to an effective QMS. All of the

requirements in clause 4 set the foundation for the QMS. An organization can review the applicability of requirements due to the size or complexity of the organization, the management model it adopts, the range of the organization's activities, and the nature of the risk and opportunities it encounters.

Often, organizations attempt to justify excluding requirements rather than looking at the control and defining effective implementation practices. **QP**

REFERENCES

1. International Organization for Standardization (ISO), ISO 9001 Auditing Practices Group Guidance on Service Organizations, Jan. 13, 2016.
2. ISO, ISO 9001:2015 quality management systems requirements, Annex A.5.

NOTE

See additional aviation, space, and defense clarifications at <https://tinyurl.com/iaqg-more-clarify>.



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TABLE 1

Applicability of requirement examples

Case scenario	Response explanations
<p>1. Calibrated measurement equipment A training service organization does not use calibrated measuring equipment so clause 7.1.5 Monitoring and Measuring Resources would be not applicable. Is this acceptable?</p>	<p>No. The organization is still required to provide resources to monitor and measure services to requirements as outlined in clause 7.1.5.1.</p>
<p>2. Build-to-print (BTP) manufacturer A BTP manufacturer creates and builds product to the customer requirements. Their design data is a “copy” of another design and the organization just makes small changes to the design. The customer makes final approval of the design. The organization states that the entire 8.3 Design and Development for Products and Services is not applicable to their quality management system (QMS). Is this acceptable?</p>	<p>No. Taking a full non-applicability to clause 8.3 is not appropriate. The organization is changing design data and therefore would be expected to ensure controls over that process are in place and effective. The same is true for reverse engineering activities not being able to claim complete non-applicability to clause 8.3.</p>
<p>3. Engineering services organization An organization provides engineering services to small organizations that do not have design capabilities. Services include developing digital product definition including blueprints, bill of materials, process specifications, and manufacturing instructions. The organization has claimed Clause 8.5.1 Control of Production and Service Provision as non-applicable. The services the organization supplies are considered under clause 8.3 Design and Development for Products and Services. Is this acceptable?</p>	<p>No. The engineering services organization is certainly performing clause 8.3 services for their customer’s QMS. The organization is required to examine their QMS as their entity. Clause 8.3 is how the organization designs and develops the services it supplies to customers. Clause 8.5.1 is how the organization controls and executes the engineering services it provides for its customers. It would be expected that the clause 8.5.1 services provided would meet requirements of clause 8.3 for their customer’s QMS. Understanding the organizational context and proper perspective is critical when determining non-applicable requirements.</p>
<p>4. Space launch service An organization is developing new space launch services for its customers. The organization took a systematic approach to researching regulatory and customer requirements, reviewing those requirements with customers, developing the service operations, and performing verification and validation activities utilizing clause 8.3 Design and Development requirements. Is this acceptable?</p>	<p>Yes. Unfortunately, many quality professionals equate design and development activity only with an engineering department designing hardware or software. Design and development of a service is appropriate when developing a new service or changing the services to customers.</p>
<p>5. Special process outsourcing A manufacturing organization outsources heat treat and plating processes. Since an external provider performs these services, the organization has taken a non-applicability to ISO 9001:2015 clause 8.5.1.f and AS9100D clause 8.5.1.2. Is this acceptable?</p>	<p>No. These special processes continue to be part of the organization’s QMS although performed by external providers. Controls to ensure compliance to requirements will be necessary through clause 8.4 requirements.</p>
<p>6. Manufacturer providing tooling A manufacturer or assembler builds and delivers parts to customer engineering requirements (build-to-print organization). The organization designs and builds tools to aid the manufacturing process. Tooling is expensive so the organization works with customers to contract tooling design and manufacturing in the production purchase order. These tools are identified as customer tools and will be provided to the customer at the end of the contract. The organization claims that tooling is not a product and therefore clauses 8.3 and 8.5 are not applicable. Is this acceptable?</p>	<p>No. After the tooling is sold to customers, it becomes part of the product associated with the standard. In this case, the organization contracts, designs, makes, and sells the tooling to the customer so most of the requirements in clause 8 would apply to the tooling product.</p> <p>If the tooling is not contracted or sold to the customer, then the development of tooling is an enabler to product build and should not be confused with the actual product being delivered to the customer. The development and making of tooling are covered under clause 8.5.1d and 8.5.1.1.</p>
<p>7. Automated systems design manufacturer A build-to-print manufacturer provides aerospace products. The organization claims that tooling is not a product and therefore clauses 8.3 and 8.5 are not applicable for tooling. Is this acceptable?</p>	<p>No. The IAQG 9100-series teams expectation is that some level of operational risk management, configuration management, product safety, and preventing counterfeit parts would occur in every ASD organization.</p> <p>It would be rare but possible to take a permissible non-applicability to clauses 8.1.X as long as the requirements in clause 4.3 have been satisfied and justified.</p>