

# Standard Issues

## ISO 9001:2015 EXCLUSIONS

# Does It Apply?

**Understanding exclusions and inapplicability in ISO 9001:2015** by L.L. “Buddy” Cressionnie

**One change in ISO 9001:2015 that did not get much notice was related to how exclusions were handled.**

Previously, exclusions—clauses or requirements organizations could deem inapplicable to their quality management system (QMS) with justification—applied only to product realization requirements. The 2015 revision allowed inapplicability to be applied across all sections of the QMS standard, as long as the organization can justify that inapplicability.

What does this mean for ISO 9001 or organizations in industries such as aerospace, automotive or telecommunications?

ISO 9001:2015 clause 4.3 for determining QMS scope states:

*“The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.*

*“The scope of the organization’s quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system.*

*“Conformity to this International Standard may only be claimed 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.”*

### What are the ‘requirements of this International Standard’?

These requirements include clauses, subclauses, and even “shall” statements within the standard. Many organizations do a good job when determining entire clauses that are not applicable to the organization’s QMS and provide suitable justification. Organizations typically do not take a systematic approach to determine subclauses and “shall” statements that are not applicable.

Often, organizations are not concerned regarding compliance with these detailed requirements they determined do not apply. But if organizations do not include suitable justification for this inapplicability, their determination is not valid.

Some examples of subclause and “shall” statement inapplicability include:

- + The organization performs purchasing but does not ship from external providers to the customer, so subclause 8.4.1b requirements are not applicable.
- + The organization does not perform special processes and that clause-level

requirement was removed from ISO 9001:2015. The organization still must take inapplicability to ISO 9001:2015, clause 8.5.1f.

- + The organization does not have customer property but does receive procured parts in supplier-owned packaging that require return. The customer property requirements of subclause 8.5.3 would not apply, but external provider controls would be applicable.

Some ISO 9001:2015 requirements have words such as “shall consider” or “take into consideration.” The inapplicability of these requirements to the organization’s QMS are required to have adequate justification.

ISO 9001:2015 requires the organization to determine boundary and applicability to establish the QMS scope. It is important to understand how the requirements of clause 4 build from understanding the business environment and interested party needs into the scope and implementation of QMS processes.

The QMS scope must meet business goals by understanding external and internal issues captured in clause 4.1. The QMS scope meets the relevant interested party requirements referred to in clause 4.2 to ensure requirements can be met and appropriate applicability is determined. The QMS scope



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.<sup>1</sup>

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](http://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.<sup>2</sup>

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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Aerospace Quality System Committee (AAQSC) chair and AAQSC leader of requirements, projects, and AS9100. He is active in standards development as a liaison member to the International Organization for Standardization (ISO) Technical Committee (TC) 176, including developing future concepts, planning the next ISO 9001 revision, writing ISO 9001:2015 and ISO 9004:2018, and participating in the ISO 9001 Interpretations Committee.

TABLE 1

# Applicability of requirement examples

Case scenario	Response explanations
<p><b>1. Calibrated measurement equipment</b> 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><b>2. Build-to-print (BTP) manufacturer</b> 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><b>3. Engineering services organization</b> 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><b>4. Space launch service</b> 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><b>5. Special process outsourcing</b> 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><b>6. Manufacturer providing tooling</b> 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><b>7. Automated systems design manufacturer</b> 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>