NON-APPLICABLE CLAUSES, PERMISSIBLE EXCLUSIONS, EXEMPTIONS

Developing a better understanding of what can and what cannot be excused in an audit assessment

Presented by Joe Krolikowski –
PJR's QMS Program Manager

Please note:

- All participants have been muted.
- Please type your questions in the “Question” section of the dashboard – we will take questions at the conclusion of this presentation.
- Please note that copies of today’s presentation will be available for download shortly.
- This webinar (and all other past PJR webinars) will also be available for re-viewing on our website under “Previously Recorded Webinars.”

Overview of Topics

- What are Non-Applicable Clauses?
- What high level requirements apply to this issue?
- What is outsourcing?
- Historical (ISO 9001:2008) aspects of these concepts
- Where is outsourcing discussed in ISO 9001:2026?
- Impact of a Limited Scope
- Conclusions/Questions

Special note

- For purposes of today's presentation, we will examine these concepts as they are addressed in ISO 9001:2026.

- These same concepts appear in many other standards, including AS9100, IATF16949, and ISO 13485, but there are applicable sector specific requirements in many cases.

- Please note that PJR offers webinars on these and many other standards. Please visit our website for further information.

What are Non-Applicable Clauses?

- This concept is primarily rooted in clause 4.3 of ISO 9001:2026, where it states (in part):

- *"The scope shall state the types of products and services covered. The scope shall include justification for any requirement of this document that the organization determines is not applicable to its quality management system."*

- Clause 4.3 also requires that the Scope (including details and justification for all non-applicable clauses) be maintained as documented information.

Exemptions

- For purposes of this presentation, we will be referring to “Non-Applicable Clauses” under the innocuous term “Exemptions.”

Exemptions in plain English

- For an exemption to truly be justified, it must be something that is not part of the organization's quality management system as defined by the scope.

- Let's dig a little deeper and get a better sense of how we are to better understand this requirement.

What high level requirements apply to this issue?

- The guidance in this area has included input from many different areas, including:
  - The TC 176 committee (the people that wrote ISO 9001:2008, ISO 9001:2015, and ISO 9001:2026);
  - The ISO 9001 Auditing Practices Group (representing both the ISO and GAC (formerly IAF));
  - Content within the ISO 9001:2026 standard (both auditable and guidance); and
  - The ISO/TS 9002: 2016 “Quality Management Systems – Guidelines for the application of ISO 9001:2015” guidance document.

The TC 176 Committee Position Papers

- In October 2008, a short time after the ISO 9001:2008 standard was published, the TC 176 committee issued two officially binding guidance documents, entitled:
  - *Introduction and support package: Guidance on ISO 9001:2008 Sub-clause 1.2 "Application" Document: ISO/TC 176/SC 2/N 524R6;* and
  - *Introduction and support package: Guidance on "Outsourced processes" Document: ISO/TC 176/SC 2/N 630R3.*
- These two papers included a requirement that many organizations, auditors, and certification bodies found rather controversial.

What did the TC 176 committee guidance say that was so controversial?

- The two guidance documents provided numerous permutations pertaining to exemptions, most of which were well understood, but one item stood out as particularly controversial.

- From guidance document 524R6:

  - *"Examples of situations where conformity to ISO 9001:2008* ***should not*** *be claimed (include) where an organization excludes a requirement on the basis that the activity has been outsourced."*

- From guidance document 630R3:

  - *"The intent of Clause 4.1 of ISO 9001:2008 is to emphasize that when an organization chooses to outsource (either permanently or temporarily) a process that affects product conformity with requirements (see ISO 9001:2008 clause 7.2.1), it can not simply ignore this process,* ***nor exclude it from the quality management system.****"*

In other words…

- Any exemption rooted in outsourcing is not an acceptable exemption and should result in a nonconformance during the audit.

- This guidance is from the committee that wrote the standard, there is no “getting around it.”

Design - the elephant in the room

- PJR has had past clients who have claimed an exemption from the design and development requirements on the basis that designs were provided by their parent or sister company.
- Such exemptions are **potentially** not appropriate and should not be **automatically** accepted. (clarification coming later)
- There are two basic justifications for an exemption of the design and development requirements:

1. The auditee receives a complete product design from their customers;

or

2. The auditee does not manufacture products based on a product design (warehouses, distributorships, service companies, etc.)

- There is a third option that we will be exploring later.

How can PJR audit something I don't do?

- This is the most common response we get from auditors and clients expressing frustration over this requirement.

- Remember, we're not auditing the actual activity itself, but rather the outsourcing controls applied.

What is Outsourcing?

- Our understanding of this key concept begins with a review of the definition provided in the ISO 9000:2026 standard:

- ***Outsource*** – *(to) make an arrangement where an external organization performs part of an organization's function or process.* - ISO 9000:2026, clause 3.3.12

- It is important to note the phrase "*an organization's function or process.*"

  - This means that the organization still has ownership of the function or process, even if they don't perform it in their facility.

- This point is further emphasized in the Note that appears right after the definition:

- "*An external organization is outside the scope of the management system, although the outsourced function or process is within the scope.*"

Examples of outsourced processes

- The following are examples of outsourced processes that organizations may choose to outsource. Each has been paired with the respective clause from ISO 9001:2026:

- Calibration/Verification of Measurement Devices (7.1.5);
- Training/Certification of Personnel (7.2);
- Customer Service/Order Entry (8.2);
- Design and Development (8.3);
- Purchasing (8.4);
- Manufacturing (8.5);
- Product Testing/Analysis (8.6); and
- Nonconforming Product Disposal (8.7.)

Where is outsourcing discussed in ISO 9001:2026?

- Outsourcing requirements discussed in ISO 9001:2026 appear as follows:

  - "*The organization shall ensure that externally provided processes, products, and services conform to requirements*" – ISO 9001:2026 clause 8.4.1

  - "*Externally provided processes, products and services refer to activities or outputs supplied by a provider that is not included within the scope of the organization's quality management system. This includes purchased products or services, arrangements with an associate organization, or processes performed at the interface between the provider and the organization or customer.* ***Accountability for conformity remains with the organization, even when provision is outsourced***." – ISO 9001:2026 clause A.8.4

Outsourcing discussed in other relevant publications.

- ISO/TS 9002:2016 discusses this requirement, and indicates (clause 8.4.1) that "*External providers could include the organization's corporate headquarters, associate companies, suppliers, or someone to whom the organization has outsourced a process.*"

- The ISO 9001 Auditing Practices Group also weighed in on this issue in their guidance document written for "Scope of ISO 9001." This document indicates that "Outsourcing" is to be considered an input to the development of an organization's scope.

Remember!

- When we audit an outsourced activity, we're not auditing the actual activity itself, but rather confirming that appropriate controls have been established.

What kinds of controls do they mean?

- In general, any methodology of control should be acceptable. A short list of acceptable methods includes the following:
  - Contracts;
  - Purchase Orders;
  - Email communication;
  - Website Terms and Conditions;
  - External Provider Audits;
  - Requiring the External Provider to maintain a management system certification; and
  - Work Instructions.

Example

- Consider the case of a company that chooses to outsource 100% of their calibration/verification activity to a calibration laboratory.

- What will the auditor likely review?

  - Contract issued to the calibration laboratory;
  - Calibration records issued by the calibration laboratory;
  - Gage labeling applied by the calibration laboratory.

- None of these equivocates to a review of the actual calibration/verification activity.

- In this scenario, none of the applicable clauses from ISO 9001:2026 that pertain to calibration/verification (7.1.5) would be claimed as an exemption.

Website Review

- PJR's auditors and the members of our Executive Committee has been instructed to review the client's website as a regular part of the audit process. Remember that an organization's website is admissible as audit evidence.

- We're looking for a few key things during this assessment:

  - Does the website appropriately reflect the organization's scope?

  - Does the website reference design activity (and the organization is classified as "No Design")?

Design activity noted on the website

- When we note design on an organization's website, and they are classified as “No Design”, the explanation usually falls into one of a few categories:
  - “*Corporate provides the designs.*”
    - We have now learned that this isn’t acceptable.
  - *“Well, we don’t really provide design services, we just want to attract potential customers by saying we do.*”
    - While PJR certainly understands the desire to grow a business, we cannot accept this either. The organization’s website and design classification must be aligned with each other.
  - *“We did design our products, but all products were designed 30-40 years ago.”*
    - This is admittedly rare, but has come up on a few occasions.

Exemptions rooted in a limited scope

- Most of PJR's clients intend for their entire operation to be included in their ISO 9001 certification.

- There are a small number of cases where the client wishes to have a limited scope, whether for financial or other reasons.

- Where this is the case, it is possible that a portion of the ISO 9001 standard may be considered for exemption that would not have been possible in a "full scope" situation.

Example

- An organization manufactures clothing for industrial and commercial markets. For purposes of this example we will presume that there are two primary product lines:
  - Leather goods (industrial applications); and
  - Polyester goods (commercial applications.)

- Recall that ISO 9001:2026 includes warranty provisions in clause 8.5.5.

- Assume that the organization offers warranty returns on their Polyester (commercial) products, but not on their Leather (industrial) products.

- If such a company chooses to only pursue ISO 9001 certification for their Leather (industrial) product line, they may be able to claim a full or partial exemption from clause 8.5.5.

What happens if an inappropriate item is being claimed as an exemption?

- The most appropriate result of an incorrectly claimed exemption is a nonconformance. We explored what the probable clause numbers to cite are earlier in this presentation.

- PJR clients are afforded the right to issue a dispute or appeal of an auditor's decision. This process is discussed in PJR procedure PRO-10 (available anytime on our website.)

Full Design – Outsourced

- In mid-2017, PJR rolled out a new certification option for clients who receive some or all of their product designs from a parent/affiliate company. This option is referred to as “Full Design – Outsourced.”

- The following specific things will happen to any client classified in this way:

  - Audit time is **potentially** calculated in the same manner currently used for clients classified as “No Design.” (clarification coming in the next few slides)

  - Any organization that is classified as “Full Design-Outsourced” must not claim any part of the relevant design sections of their standard as an exemption.

  - The certificate issued to such a client must indicate “Design” as part of their scope.

Outsourced process controls must be assessed

- When PJR rolled out our new “Full Design-Outsourced” classification option, we reached out to the ANSI National Accreditation Board (ANAB) to ensure that we had their “blessing” on this process.

- ANAB generally indicated that they felt our new process was appropriate, but emphasized (as is stated in the ISO 9001 standard itself) that controls must be applied to outsourced processes, and that those controls must be included in the audit process.

  - “*The complexity, activities, and risks that are present due to an outsourced provider of processes, products or services need to be controlled / confirmed as detailed in ISO 9001: 2015 section 8.4.*”

  - “*Section 8.4 of ISO 9001: 2015 has many requirements that apply to the organization - (and must be confirmed / evaluated by the CB when certifying an organization with outsourced products, processes, or services.)*”

Audit time reductions are not automatic

- ANAB also indicated that they strongly object to any "automatic" time reductions regarding product design status.
  - "*In all cases - the CB is required to clearly, effectively, and realistically justify & document justifications for any adjustment (either increase or decrease in audit time) from the established (IAF MD 5) audit day tables.*"
- In other words, PJR cannot be expected to initially reduce audit time for a classification of "Full Design-Outsourced" unless an onsite auditor has provided assurance that the controls applied to outsourced processes are mature, highly effective, and can be assessed with no added audit time.

Four options for design

- PJR now has four classification options pertaining to an organization's design status.
- Let’s review these options over the next several slides.

Full Design

- An organization that is responsible for the design of at least one of the products they manufacture.
  - All sections of clause 8.3 are applicable for companies classified in this manner.

No Design

- An organization that receives all designs from their customers or otherwise does not interact with product designs (warehouses, staffing companies, etc.)
  - All sections of clause 8.3 are claimed as “not applicable” for companies classified in this manner;
  - Special Note: If an organization receives product designs from parent/affiliate companies but does not have any responsibility for product design, and **does not advertise or otherwise represent that they are responsible for any product design activity** – they may also qualify for classification as “No Design.”

Partial Design

- An organization that provides technical input, review, verification, or other design services to their clients but does not typically have responsibility for final design approval (note that PJR has few clients classified in this manner at this time.)
  - Portions (but not all) of clause 8.3 are claimed as “not applicable” for companies classified in this manner.

Full Design-Outsourced

- An organization that receives all or some of its product designs from parent/affiliate companies or subcontractors and advertises or otherwise represents that they are responsible for product design activity.
  - All sections of clause 8.3 are applicable for companies classified in this manner.

Conclusion

- Perry Johnson Registrars wants to ensure that our audit process is value added for our clients while addressing all applicable requirements.

- Ensuring that all Exemptions are justified is an important part of this process.

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- *"Understanding PJR's PRO-3 and related bylaws governing proper promotion of your management system certification"*
  - This webinar offers helpful information on how to promote your certification and stay within the various bylaws that dictate such practices.
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