



NON-APPLICABLE CLAUSES, PERMISSIBLE EXCLUSIONS, EXEMPTIONS

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

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POLLS

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 9001:2015?
- Impact of a Limited Scope
- Conclusions/Questions

Special Note



ISO 9001:2015 Focus

For purposes of today's presentation, we will examine these concepts as they are addressed in ISO 9001:2015.



Sector Specific Requirements

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



Additional Resources

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



What are Non - Applicable Clauses?

Clause 4.3 Foundation

This concept is primarily rooted in clause 4.3 of ISO 9001:2015, where it states (in part):

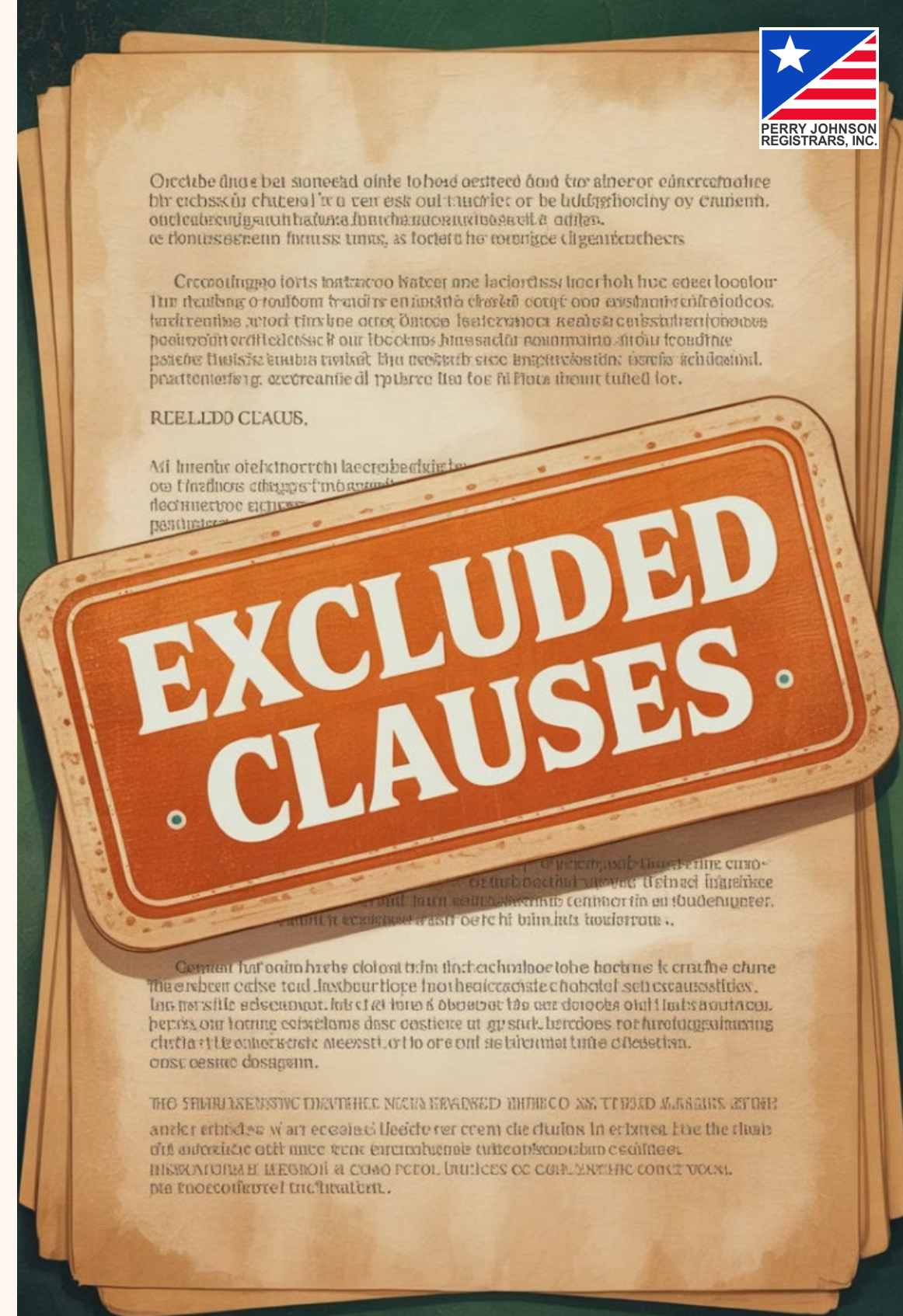
"The (organization's) scope shall state the types of products and services covered and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system."

Documentation Requirement

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



Justification Required

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.



Deeper Understanding

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 TC 176 committee

The people that wrote ISO 9001:2008 and ISO 9001:2015



The ISO 9001 Auditing Practices Group

Representing both the ISO and IAF



Content within the ISO 9001:2015 standard

Both auditable and guidance



The ISO/TS 9002:2016

"Quality Management Systems Guidelines for the application of ISO 9001:2015" guidance document



The TC 176 Committee Position Papers



October 2008

A short time after the ISO 9001:2008 standard was published, the TC 176 committee issued two officially binding guidance documents



First Document

Introduction and support package: Guidance on ISO 9001:2008 Sub-clause 1.2
"Application" Document: ISO/TC 176/SC 2/N 524R6



Second Document

Introduction and support package: Guidance on "Outsourced processes"
Document: ISO/TC 176/SC 2/N 630R3



Controversial Requirements

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?

Controversial Guidance

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

Parent/Sister Company Design

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.

Potential Inappropriateness

Such exemptions are **potentially** not appropriate and should not be **automatically** accepted. (clarification coming later)

Justification Options

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

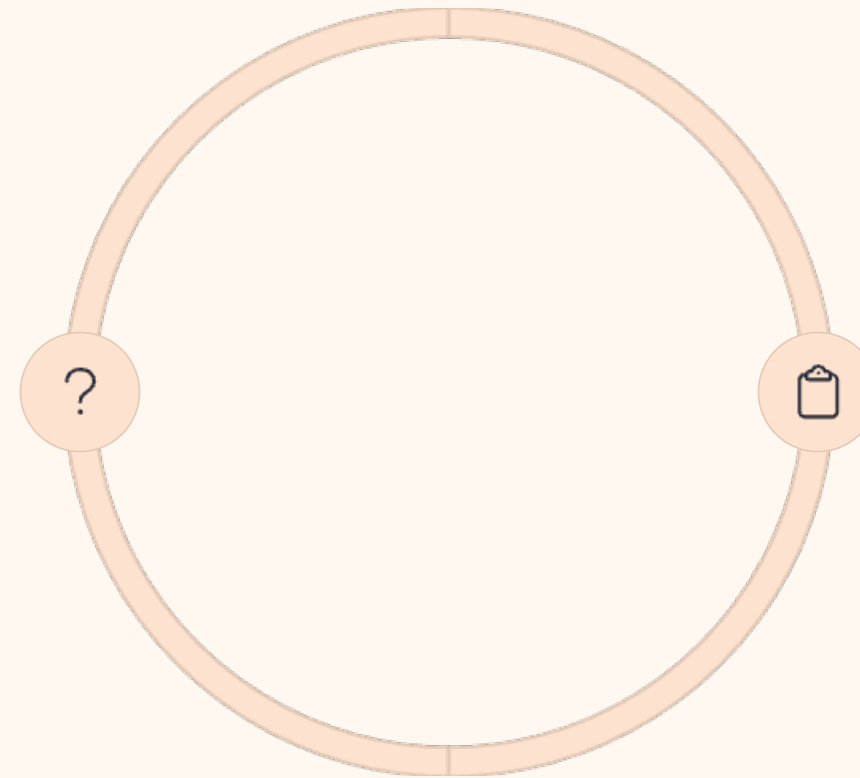
- **There is a third option that we will be exploring later.**



How Can PJR Audit Something I Don't Do?

Common Concern

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



Focus on Controls

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

What is Outsourcing?

ISO 9000:2015 Definition

Our understanding of this key concept begins with a review of the definition provided in the ISO 9000:2015 standard:

Outsource – (to) make an arrangement where an external organization performs part of an organization's function or process. - ISO 9000:2015, clause 3.4.6

Key Phrase

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.

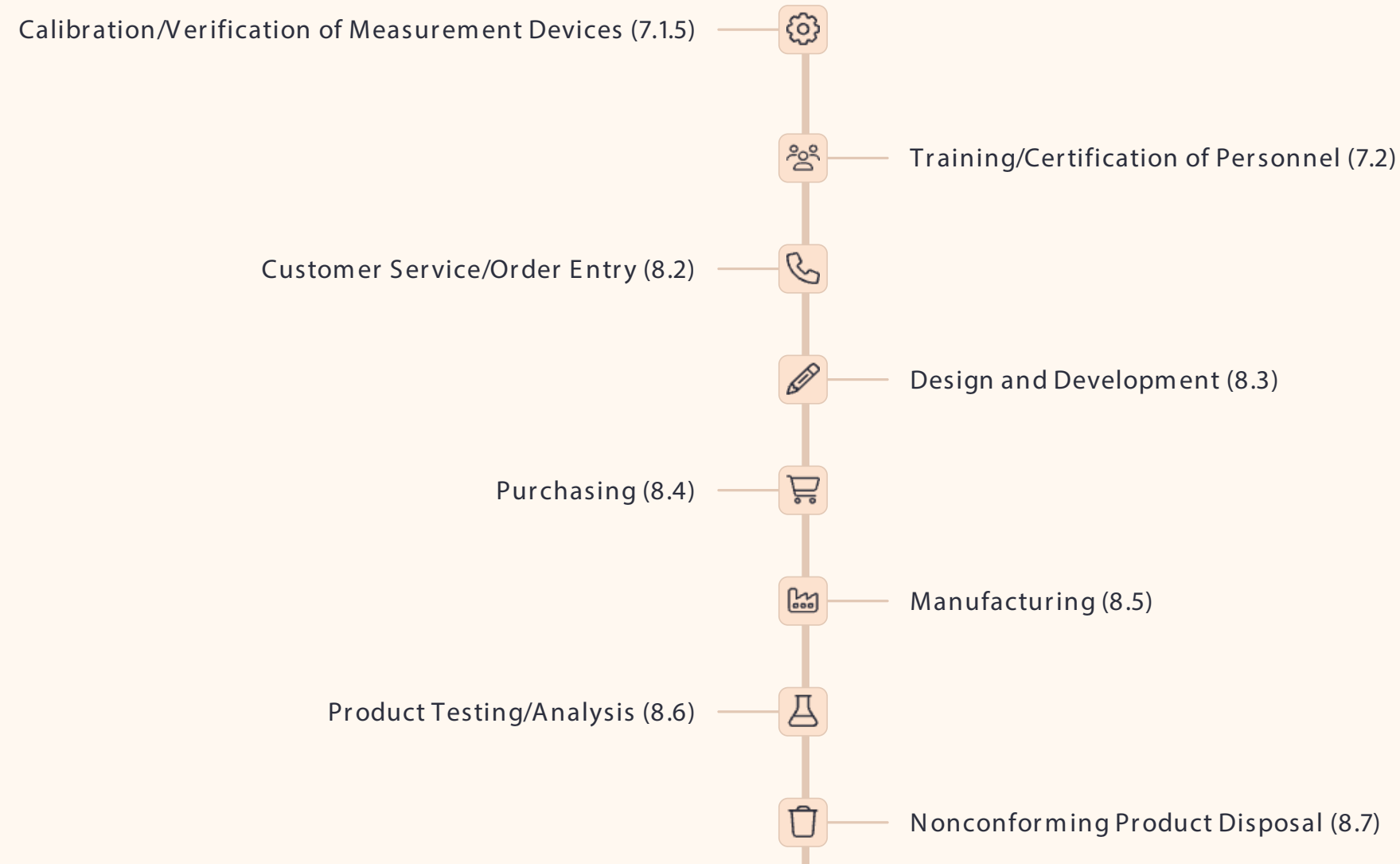
Additional Note

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 9001:2015:



Where is Outsourcing Discussed in ISO 9001:2015?

Outsourcing requirements discussed in ISO 9001:2015 appear as follows:

Clause 8.4.1

"The organization shall ensure that externally provided processes, products, and services conform to requirements" – ISO 9001:2015 clause 8.4.1

Clause A.8

"All forms of externally provided processes, products, and services are addressed in 8.4, whether through an arrangement with an associate company, or outsourcing processes to an external provider" – ISO 9001:2015 Clause A.8



Outsourcing Discussed in Other Relevant Publications

ISO/TS 9002:2016

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."*

ISO 9001 Auditing Practices Group

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!










Focus on Controls

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
-  Work Instructions
-  Requiring the External Provider to maintain a management system certification

Example

Outsourced Calibration

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

Auditor Review

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

Focus on Controls

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

In this scenario, none of the applicable clauses from ISO 9001:2015 that pertain to calibration/verification (7.1.5) would be claimed as an exemption.



Website Review

Part of Audit Process

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.

Key Assessment Points

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.

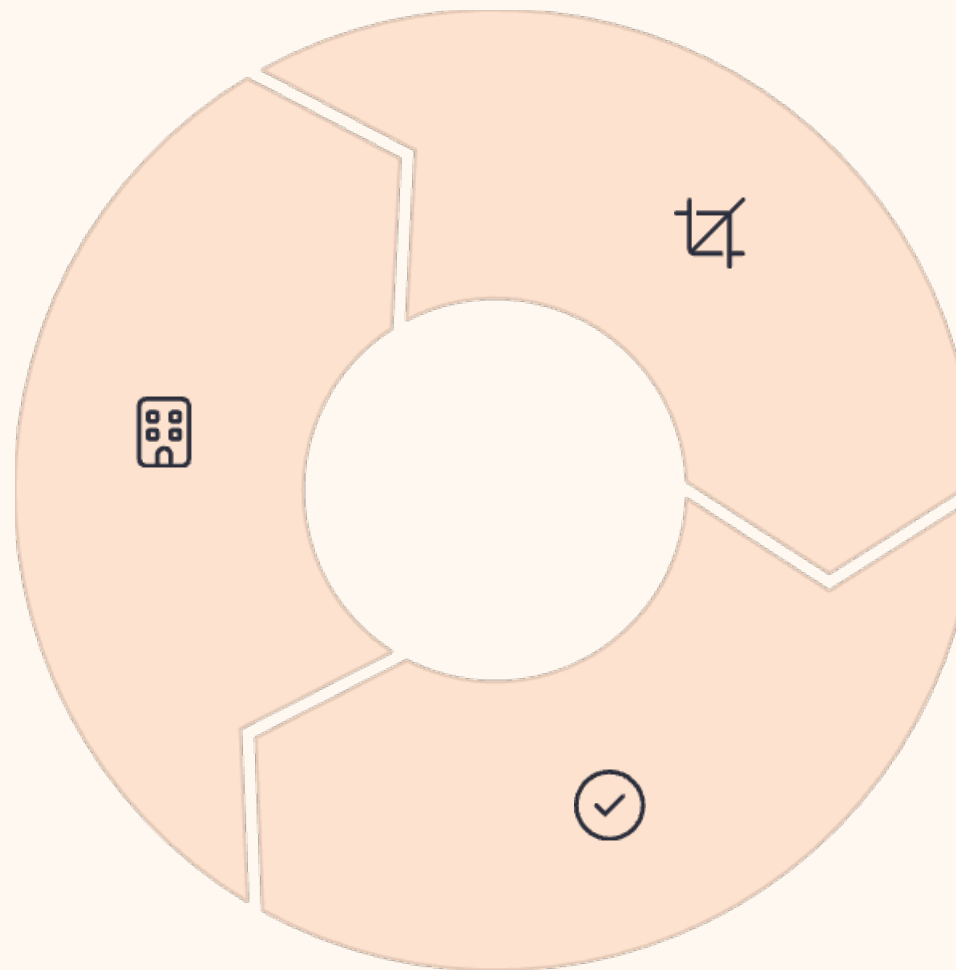
"We did design our products, but all products were designed 30 -40 years ago."

This is admittedly rare but has come up on a few occasions.

Exemptions Rooted in a Limited Scope

Full Operation Certification

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



Limited Scope Cases

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

Potential Exemptions

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

Manufacturing Scenario

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.)

Warranty Provisions

Recall that ISO 9001:2015 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.

Limited Scope Exemption

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?



Nonconformance

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.



Dispute or Appeal

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 Calculation

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



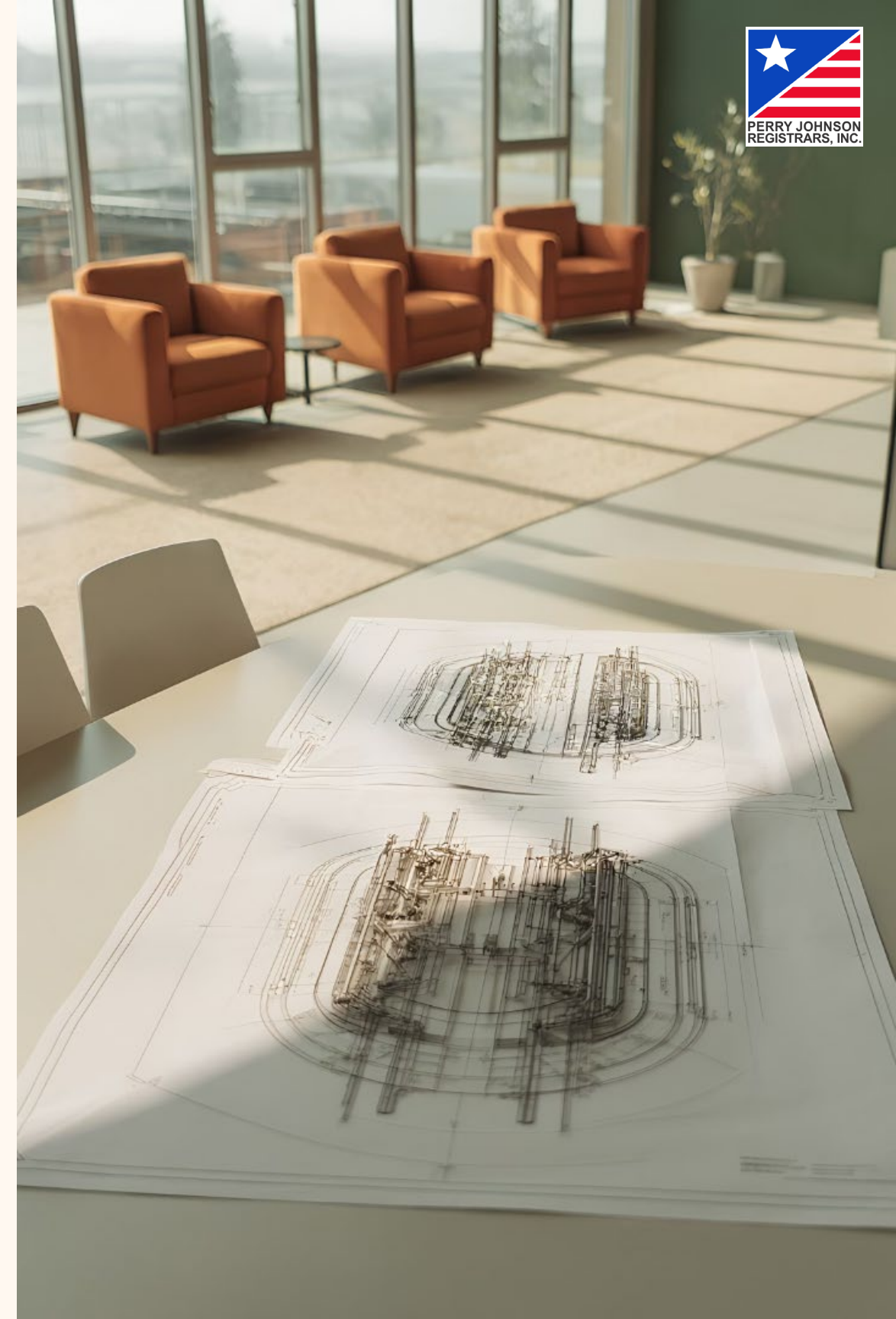
No Exemptions

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.



Certificate Indication

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.

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ANAB Response

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 Position

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."

PJR Approach

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

Design Responsibility

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

Customer-Provided Designs

An organization that receives all designs from their customers or otherwise does not interact with product designs (warehouses, staffing companies, etc.)

Clause Exemption

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

Technical Input

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

Uncommon Classification

Note that PJR has few clients classified in this manner at this time

Clause Applicability

Portions (but not all) of clause 8.3 are claimed as "not applicable" for companies classified in this manner

Full Design - Outsourced

Parent/Affiliate Designs

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.

Clause Applicability

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.



"Your ongoing relationship with PJR."

This webinar explores what is expected of PJR's client when changes occur at your business while also providing a detailed explanation of the disputes process.



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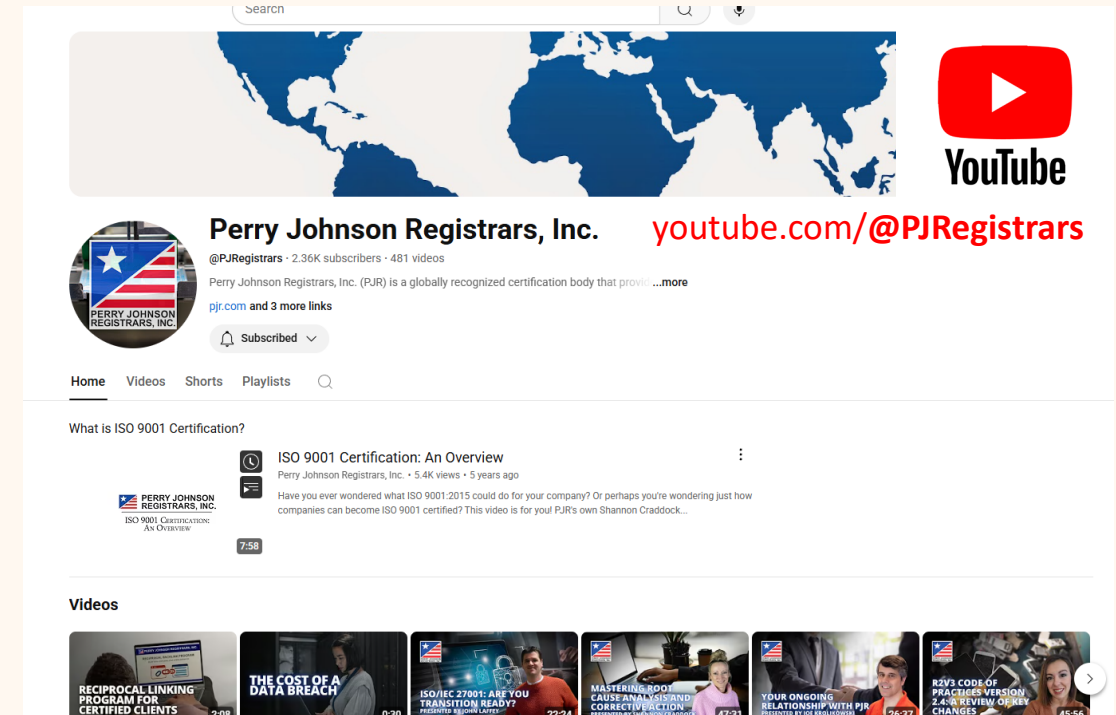
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