ISO 9001:2015 – Anticipating Auditor Expectations in Key Areas

Presented by:
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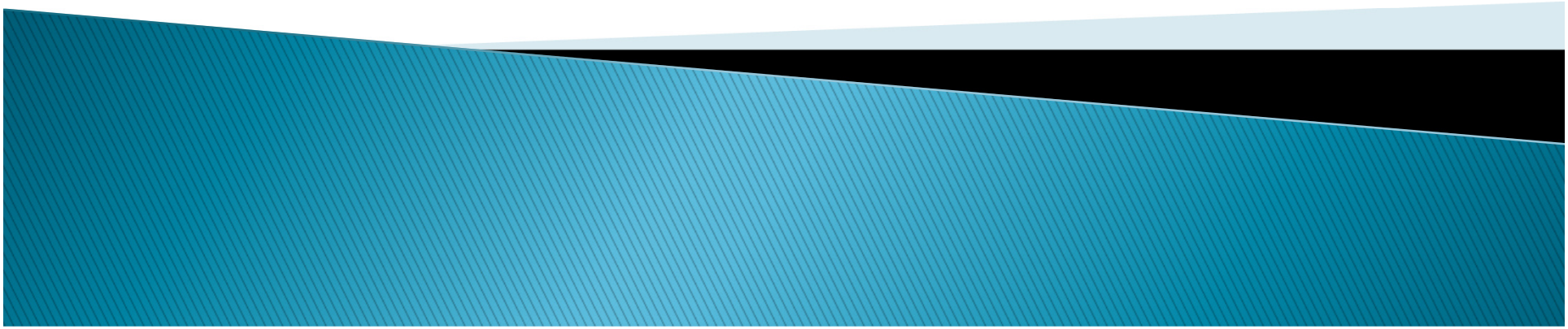
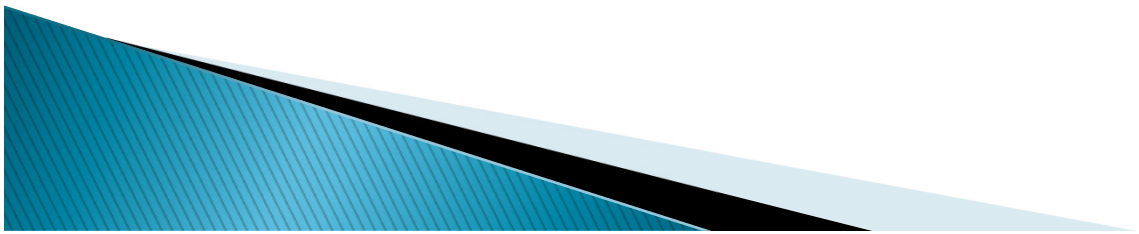


Please note:

- All participants have been muted.
- Please type your questions in the “Question” section of the dashboard – we will answer all 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

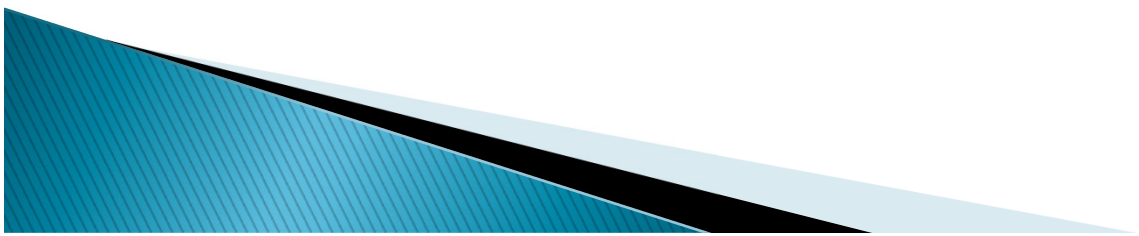
- Opening Comments (ISO 9001 – an interpretive document, nonconformances that don't change)
- Data Sampling Disclaimer/Methodology
- Examination of key areas
  - Management Review
  - Internal Audit
  - Quality Objectives
  - Monitoring and Measuring resources
  - External provider approvals
- Two additional key areas
  - Risk
  - Interested Parties
- Leadership's role – the Leadership interview
- Concluding remarks/Questions



Recognition that ISO 9001:2015 is in an interpretive document.

- When ISO 9001:2015 was published, it was the first version of ISO 9001 to include an explanatory Appendix (Appendix A.)

- It has since become one of the only ISO published standards to have a separate supplemental standard (information coming on the next slide) for explanatory purposes.

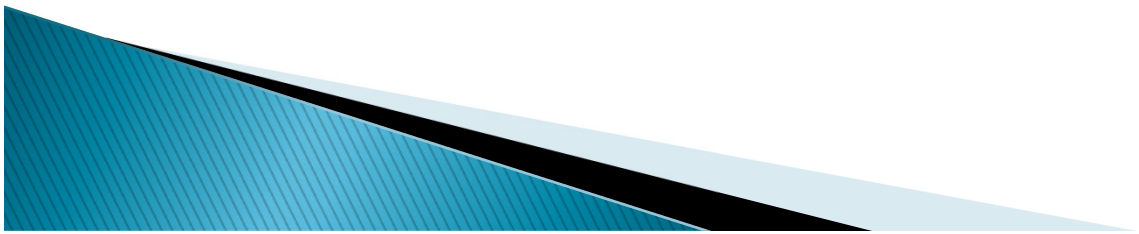


ISO/TS 9002:2016

- ISO/TS 9002:2016 was published on November 1, 2016 (hereafter this document will be referred to as ISO 9002.)
- ISO 9002's full title is "Quality Management Systems – Guidelines for the application of ISO 9001:2015."
- It is an officially sanctioned guidance document that provides clause-by-clause ideas on fulfilling the requirements.
- It is similar in style and content to the older (2000) version of ISO 9004.

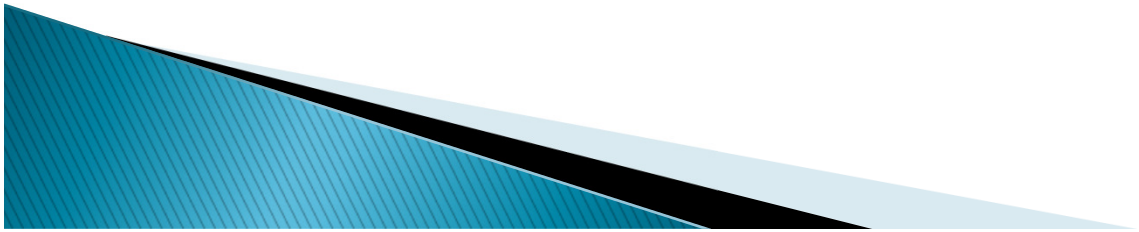
Because ISO 9001:2015 is an interpretive document…

- It is important to recognize that all of the requirements within ISO 9001:2015 are intended to be interpreted.
- None of these requirements has a "perfect" method for implementation.
- It is up to each individual organization to determine a methodology for implementation of the requirements.
- The auditor's role is to review the organization's methodology and exercise their judgement as to whether or not the methodology represents a true fulfillment of the requirement.



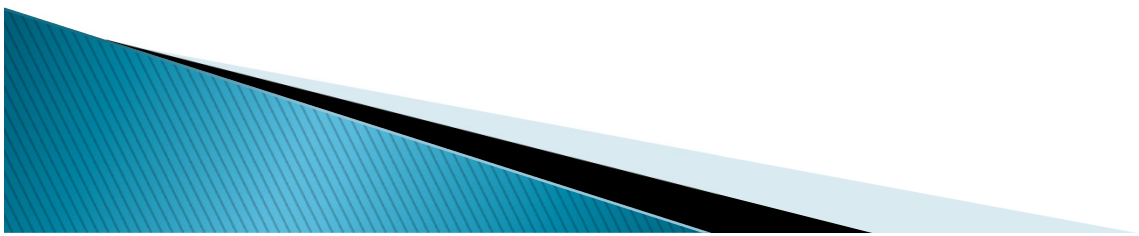
Impact of Procedures and Work Instruction

- One of the more interesting changes in the 2015 revision of ISO 9001 was the elimination of all procedural requirements.
  - ISO 9001:1987/1994 – 16 required procedures
  - ISO 9001:2000/2008 – 6 required procedures
  - ISO 9001:2015 – 0 required procedures
- However – if an organization chooses to have a procedure or work instruction (for any activity) the content of that procedure can be cited in the context of an audit. This is due to the definition of "Audit Criteria" as appears in ISO 9000:2015.
  - Audit Criteria – "*Set of policies, procedures, or requirements used as reference against which objective evidence is compared.*" – ISO 9000:2015 definition 3.13.7



The song remains the same…

- ISO 9001:2015 has been in print an unbelievable three years.
- ISO 9001 has been in print an even more incredible 30 plus years.
- Despite this tenure – it seems many of the same things continue to be cited in ISO 9001 audits year after year.



Data Sampling Disclaimer/Methodology

- In early October 2018 – PJR conducted a data mining exercise using approximately 350 audits from a period of time roughly covering the previous 12 months.

- Among the audits that resulted in nonconformances, the following five general areas were the most commonly cited (ordered by frequency of issuance):

  1. Management Review Meetings
  2. Internal Audit
  3. Quality Objectives
  4. Calibration/Verification of Monitoring and Measuring Resources
  5. External Provider Approvals

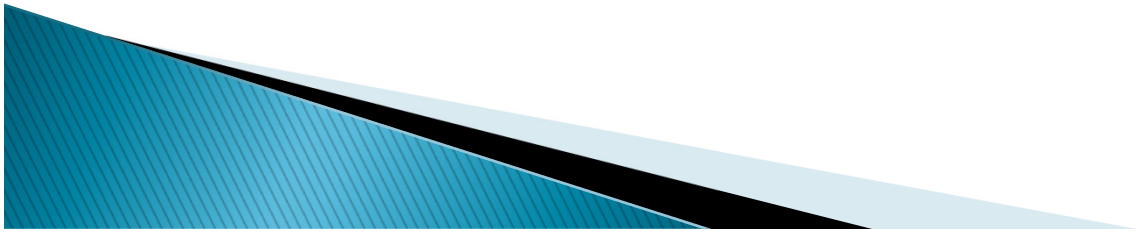
- It is interesting to note that three of these items (Management Review, Internal Audit, and Calibration) are all "legacy" requirements that have been included in the ISO 9001 standard since the first version was published in 1987.

Clarification of an interpretive document

- Recognizing that PJR cannot advocate specific methodologies for implementation of any requirement from ISO 9001:2015 (or any other standard) – it is proposed that PJR can attempt to provide some clarity on what these various requirements are **commonly interpreted to mean** and how they are **commonly fulfilled**.

- The content of the next several slides should not be taken as an official PJR endorsement of approach and cannot be used as justification for any circumstance cited by an auditor within an official nonconformance.

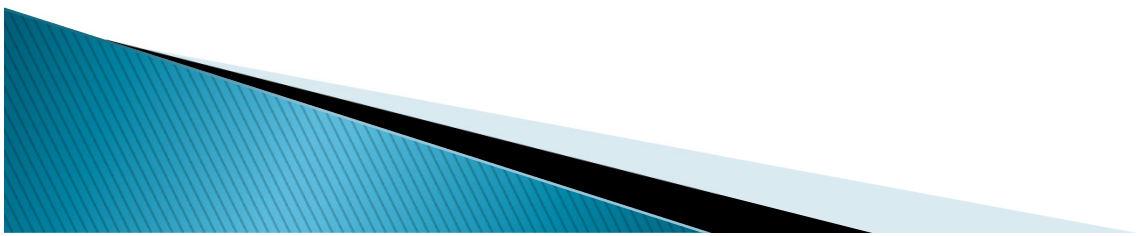
  - Details regarding how to request an impartial resolution of disputed nonconformances will be given later in this presentation.



Management Review

- Let's begin with an examination of the ISO 9001:2015 clause most typically cited for concerns pertaining to Management Review (9.3.)

- Clause 9.3 has three sub-clauses (which we will refer to in "parts.")



Management Review Requirement Part 1

- *Top management shall review the organization's quality management system, at **planned intervals**, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.*

Key Points

- The key portion of this requirement is "planned intervals."
- This statement intends for the organization to have some manner of controlling the frequency and content of the management review meetings.
  - As with all other requirements within ISO 9001, the actual controls established for this requirement are at the discretion of the organization. Acceptable controls observed in past audits for this requirement have included internal schedules, procedural stipulations, and automated reminders.

Management Review Requirement Part 2

- *The management review shall be planned and carried out taking into consideration:*
  - *The status of actions from previous management reviews;*
  - *Changes in external and internal issues that are relevant to the quality management system;*
  - *Information on the performance and effectiveness of the quality management system, including trends in:*
    - *1) customer satisfaction and feedback from relevant interested parties;*
    - *2) the extent to which quality objectives have been met;*
    - *3) process performance and conformity of products and services;*
    - *4) nonconformities and corrective actions;*
    - *5) monitoring and measurement results;*
    - *6) audit results;*
    - *7) the performance of external providers;*
  - *The adequacy of resources;*
  - *The effectiveness of actions taken to address risks and opportunities (see 6.1);*
  - *Opportunities for improvement.*

Management Review Requirement Part 2 – key points

- Each of the content items on the previous page is considered mandatory, but it is not a requirement that every item be included in every management review.
- Many organizations find it helpful to prepare a PowerPoint presentation or other presentation of relevant content.
  - Note that this is not mandatory
- Many organizations utilize a standardized agenda format to ensure no required topic is missed.
  - Note that this is not mandatory

Management Review Requirement Part 3

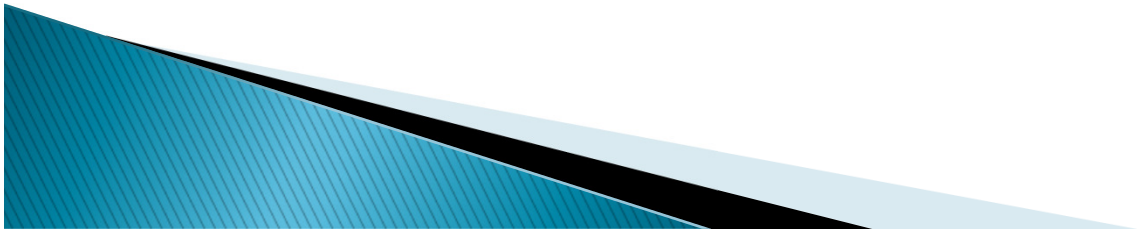
- *The outputs of the management review shall include **decisions and actions** related to:*
  - *opportunities for improvement;*
  - *any need for changes to the quality management system;*
  - *resource needs.*

- *The organization shall **retain documented information** as evidence of the results of management reviews.*

Key Points

- It is important to remember that the Management Review is supposed to be productive (note the highlighting of "decisions and actions" above.) It should not simply be a churn of information.

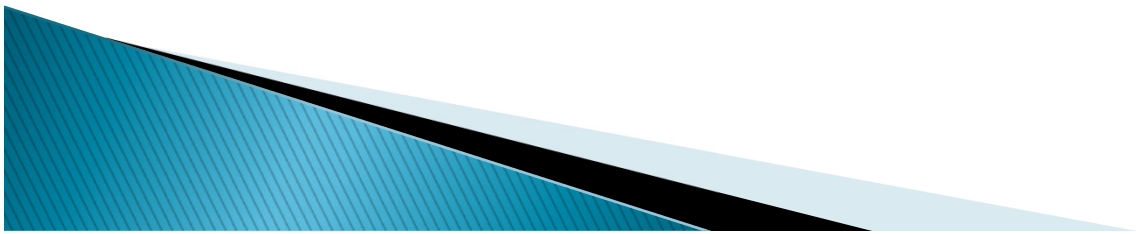
- Our auditors need to be able to confirm objective evidence of these "decisions and actions" in order to ensure that organizations are "retaining documented information" pertinent to management review.



Internal Audit

- Let's continue with an examination of the primary clause for Internal Audit, clause 9.2

- This requirement is split into two sub-clauses.

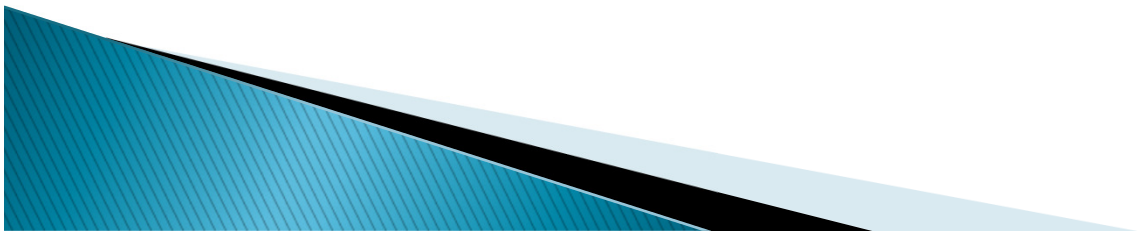


Internal Audit Requirement Part 1

- *The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system conforms to the organization's own requirements for its quality management system (as well as) the requirements of this International Standard (and if the quality management system) is effectively implemented and maintained.*

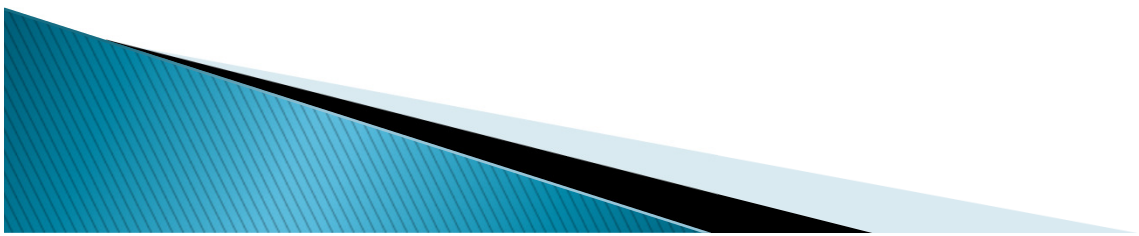
Internal Audit Requirement Part 1 Key Points

- Again a key point is “planned intervals.” Internal audits must be conducted according to some sort of scheduling mechanism. Whether that mechanism includes calendar triggers, audit plans, database scheduling, or a combination thereof is up to the organization.
- Organizations are also permitted to conduct the internal audit in “small bites” if they so desire.
- The inclusion of “the requirements of this International Standard” implies that the Organization is expected to ensure that all requirements from ISO 9001:2015 are included in the internal audit process.
  - A common mistake in this area is not including the internal audit process itself in the internal audit assessment. You are indeed required to “audit the audit.”



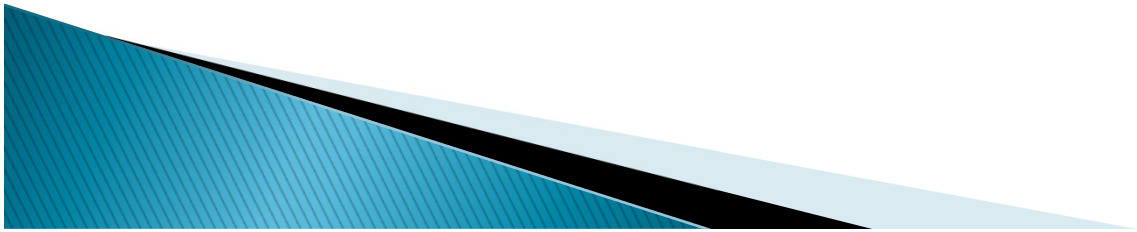
Internal Audit Requirement Part 1 Key Points (continued)

- The audit is expected to be performed against the "quality management system." Remember that ISO 9001 itself establishes that a quality management system is made up of processes.
  - *"The organization shall determine the processes needed for the quality management system and their application throughout the organization."* – ISO 9001:2015, clause 4.4.1, second paragraph
- Therefore – the organization is expected to structure their internal audits with respect to the processes that make up the quality management system (and **not** the clauses of ISO 9001:2015 itself.)



Internal Audit Requirement Part 2

- *The organization shall:*
- *plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;*
- *define the audit criteria and scope for each audit;*
- ***select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;***
- *ensure that the results of the audits are reported to relevant management;*
- ***take appropriate correction and corrective actions without undue delay;***
- ***retain documented information as evidence of the implementation of the audit programme and the audit results.***



Internal Audit Requirement Part 2 Key Points

- You will note that ISO 9001:2015 specifies no minimum requirements for auditor competency. Like all other tasks in the quality management system, the organization is expected to decide for itself what makes an internal auditor competent.
  - It is imperative that your internal auditor qualification records not just consist of a training signoff.
  - Remember that organizations are required to "*determine competency requirements*" per ISO 9001:2015 clause 7.2

Internal Audit Requirement Part 2 Key Points

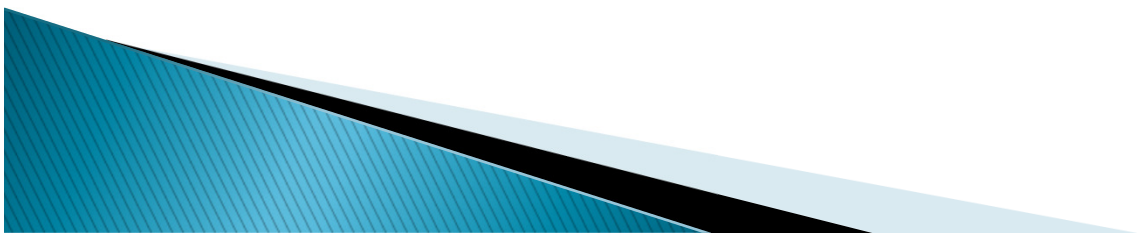
- A key issue that comes up frequently is a lack of responsiveness to internal audit nonconformances. These should be treated with the same seriousness afforded nonconformances issued by PJR or Customer Complaints. The requirements specifically mentions both Correction and Corrective Action in this context.

- Evidence (records) of the internal audit process at large are expected. The method of recording the internal audit (checklists, procedural printouts, etc.) are at the organization's discretion, but must be sufficiently detailed to give confidence that the entire quality management system was included.

  - This should include recording evidence of conformity in addition to recording evidence of nonconformity.

Consultants – a KEY point

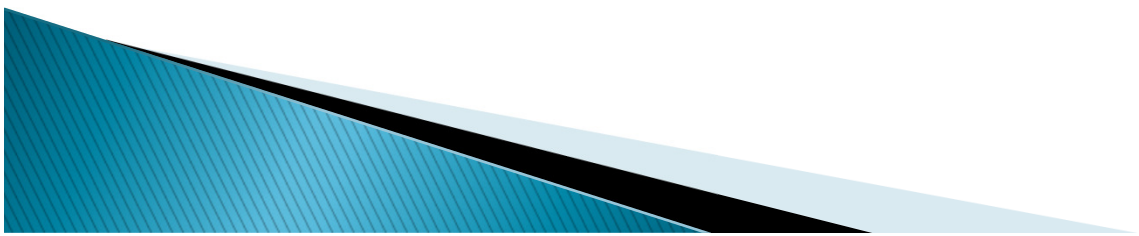
- Several of PJR's clients choose to outsource their internal audit program to a consultant.
- Such organizations must remember that regardless of who performs the audit, the overall responsibility for the internal audit program (scheduling of audits, maintenance of audit records, responding to nonconformances, etc.) belongs to the organization and not to their consultant.
- The organization should be able to speak confidently about their internal audit process and how it is controlled.



Quality Objectives

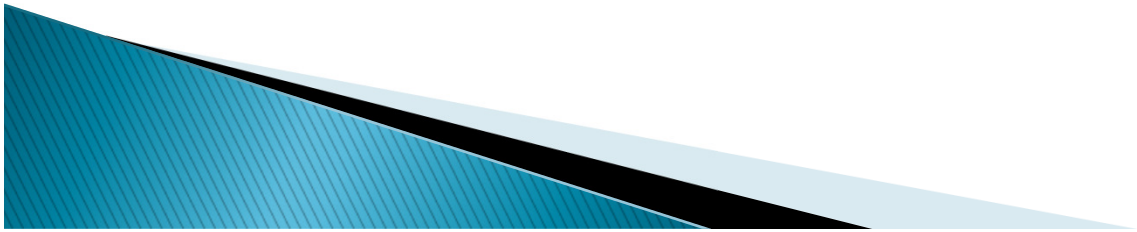
- Let's continue with an examination of the primary clause for Quality Objectives, clause 6.2

- This requirement is split into two sub-clauses.



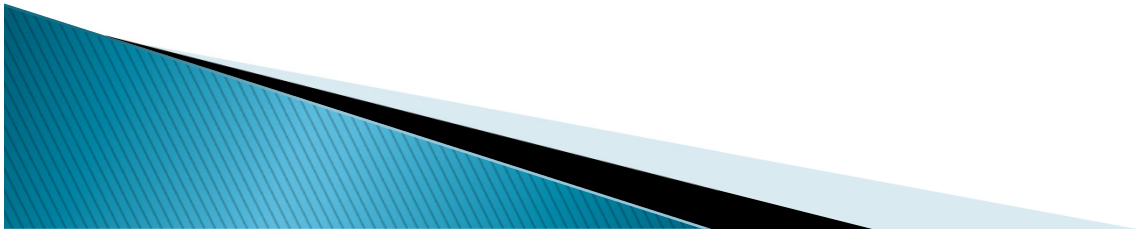
Quality Objectives Requirement Part 1

- *The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system. The quality objectives shall:*
  - *Be consistent with the quality policy;*
  - ***Be measurable**;*
  - *Take into account applicable requirements;*
  - ***Be relevant to conformity of products and services and to enhancement of customer satisfaction**;*
  - ***Be monitored, communicated, (and) updated as appropriate.***



Quality Objectives Requirement Part 1 – Key Points

- All quality objectives must be “measurable.” Without measurability there is no reliable way to determine if the objective was met.
  - While variable measurement type objectives are most common, attribute type objectives are also considered acceptable.
- Relevancy to customer satisfaction and products/services was a new requirement when ISO 9001:2015 was published. It is important to note that objectives rooted in areas such as profitability, safety, etc. are not forbidden, but an organization must ensure that other objectives exist that meet this requirement.
- Quality Objectives are a topic that everyone in a quality management system audit is expected to demonstrate knowledge and awareness.
  - Organizations must consider what measures are needed to ensure this is accomplished (placards, meetings, etc.) No specific methodology for ensuring awareness of Quality Objectives is mandatory.

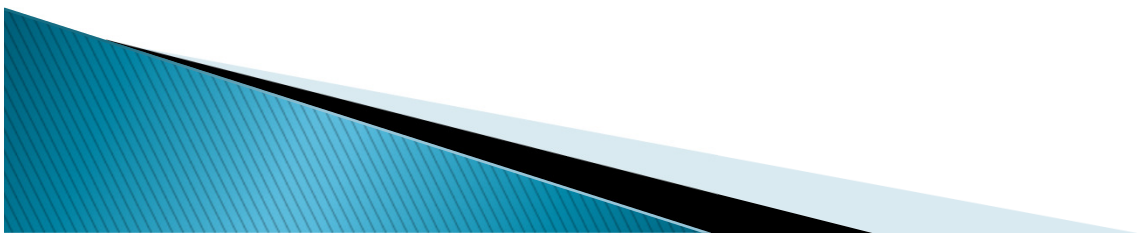


Quality Objectives Requirement Part 2

- *When planning how to achieve its quality objectives, **the organization shall determine what will be done**, what resources will be required, who will be responsible, when it will be completed, (and) how the results will be evaluated.*

- ISO 9002 offers an interesting point of clarity as it pertains to "*what will be done.*"

  - *"The organization should determine the actions that need to be implemented to achieve its quality objectives."* – ISO 9002, clause 6.2.2A



Quality Objectives Requirement Part 2 – Key Points

- The key overall takeaway from part 2 of the requirement is that it is not enough to simply have established quality objectives.
- The organization must track progress achieved towards quality objectives
- The organization must also (in the case of underperformance) take necessary action to improve quality objectives performance.
- “Necessary action” means an appropriate response. It may not necessarily mean formal corrective action.

Monitoring and Measuring Resources

- This requirement is typically referred to as “Calibration.”
- Monitoring and Measuring Resources refers to any device, tool, gage, meter, scale, or similar item used to perform monitoring and measurement of outputs (most typically referred to as inspection and/or testing.)
- The primary clause from ISO 9001:2015 that applies here is 7.1.5, which includes two sub-clauses.

Monitoring and Measuring Resources Requirement Part 1

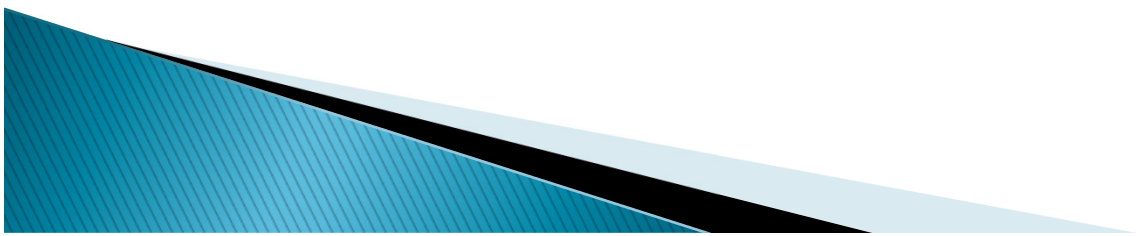
- *The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.*

- *The organization shall ensure that the resources provided are suitable for the specific type of monitoring and measurement activities being undertaken and are maintained to ensure their continuing fitness for their purpose.*

- *The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.*

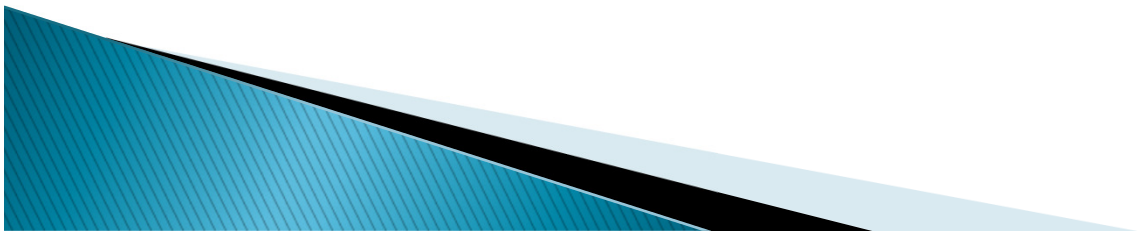
Monitoring and Measuring Resources Requirement Part 1 Key Points

- The primary requirement that gets emphasized during audits is the last paragraph, where "retained documented information" demonstrating "fitness for use" is required.
- For most organization, this will manifest in calibration/verification records for all measurement devices.
- The content of such records is influenced by the 2nd part of the requirement.



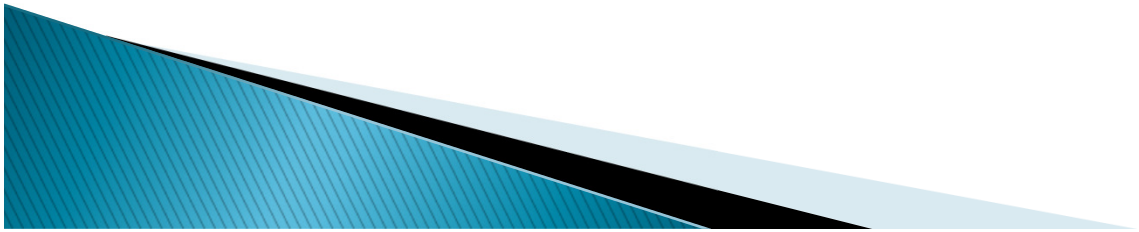
Monitoring and Measuring Resources Requirement Part 2

- *When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:*
  - *Calibrated or verified, or both, at specified intervals, or prior to use, **against measurement standards traceable to international or national measurement standards**; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;*
  - ***Identified in order to determine their status**;*
  - *Safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.*
- *The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary.*



Monitoring and Measuring Resources Requirement Part 2 Key Points

- The two most oft violated aspects of this requirement are:
  - The required traceability to “national or international standards.”
    - In most cases (in the United States) this is going to be the National Institute of Standards and Technology (NIST.)
    - In situations where an NIST traceable method is not available (note that this is rare) it is typically acceptable for calibration to be performed by the device manufacturer.
  - Consistent and reliable device “identification in order to determine status.”
    - One of the more common misconceptions is that this requirement automatically means “calibration stickers.” This is actually not the case.
    - So long as there is some form of device identification that permits traceability to the calibration records any approach is acceptable.



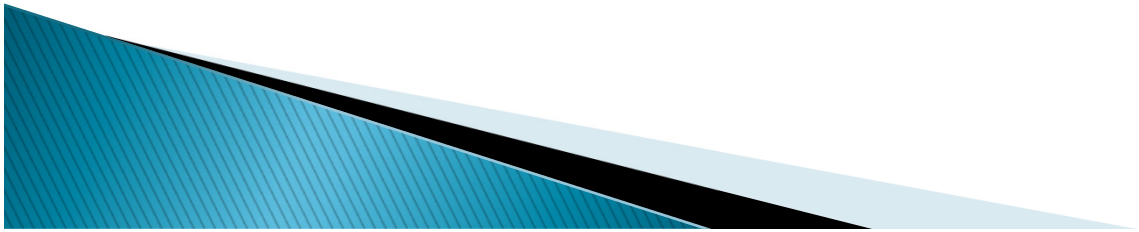
External Provider Approvals

- In the older versions of ISO 9001 the following terms (among others) were used:
  - Suppliers;
  - Subcontractors;
  - Outside Partners;
- In some cases the requirements associated with these parties resided in separate parts of the standard.
- All of these terms were merged under the collective term “External Provider” in the 2015 version.
- However – the requirement to approve these parties is not new. It currently resides in the third paragraph of clause 8.4.1.

External Provider Approvals Requirement

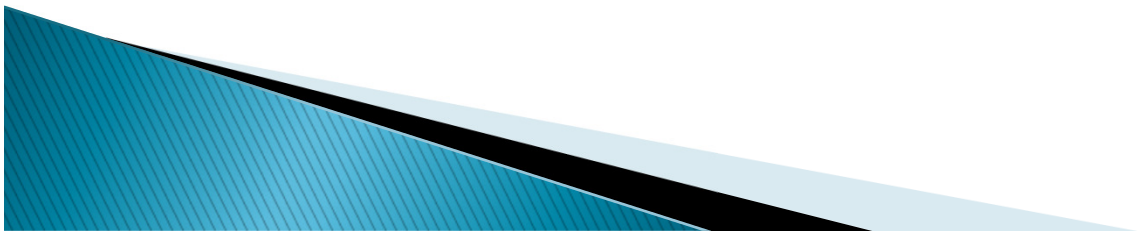
- *The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements.*

- *The organization shall retain documented information of these activities and any necessary actions arising from the evaluations.*



External Provider Approvals Requirement Key Points

- The organization is required to establish a methodology for external provider approval.
- What that methodology is and whether there are alternatives to that methodology are strictly at the organization's discretion.
- It is also key to note that the requirement calls for monitoring and re-evaluation.
- Finally, organizations should note that the "retained documented information" requirement specifies that "these (evaluation) activities" are to be 'on the record.'
  - This means that having the External Provider's name on a list is not sufficient evidence of evaluation on its own, as it does not constitute a record of the evaluation "activity."



Two additional key areas

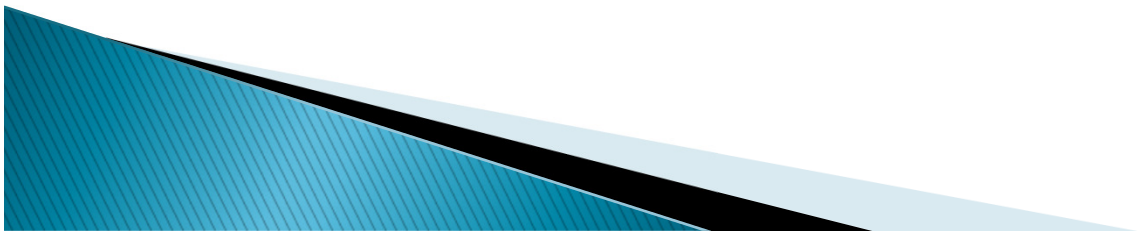
- PJR's initial analysis of ISO 9001:2015 included an identification of the key "new" requirements.

- Two areas stood out in our analysis as having the most pronounced impact on our clients and the overall auditing process.

  - Risk
  - Interested Parties

Risk

- The term “risk” is used 16 times in the auditable portion of the ISO 9001:2015;
- Identification and management of risk is being viewed as a new system wide strategy in much the same light that Continual Improvement was when ISO 9001:2000 was published.
- A formal/documented Risk Management Process is NOT specifically required.
- Expands the idea of Risk aversion to one that affects all of the various areas of the Quality Management System.
- ISO 9002 discusses key risks including *“the failure of processes, products, and services to meet their requirements, or the organization not achieving customer satisfaction.”*



Risk

- Clause 6.1.1 of the ISO 9001:2015 standard states:
  - *When planning for the quality management system, the organization shall consider the issues referred to in 4.1* (meaning those that come from inside and outside the organization) *and the requirements referred to in 4.2* (meaning those that come from internal and external interested parties) *and determine the risks and opportunities that need to be addressed to:*

    a) give assurance that the quality management system can achieve its intended result(s);

    b) enhance desirable effects;

    c) prevent, or reduce, undesired effects;

    d) achieve improvement.

Risk

- Clause 6.1.2 of the ISO 9001:2015 standard states:
  - *The organization shall plan:*

    a) actions to address these risks and opportunities;

    b) how to:
    - *1) integrate and implement the actions into its quality management system processes (see 4.4);*
    - *2) evaluate the effectiveness of these actions.*

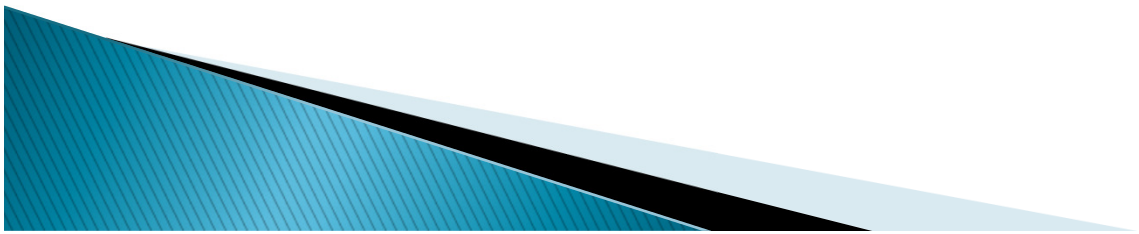
  - *Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.*

NOTE 1
- *Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.*

NOTE 2
- *Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new clients, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.*

What do they mean by “actions to address risks and opportunities”?

- ISO 9002 provides further guidance in this area, and identifies the following possibilities:
  - Risk avoidance – by no longer performing the process in question;
  - Risk limitation – such as establishment of procedures or work instructions to assist personnel and thereby reduce the risk; and
  - Risk sharing – such as working with customers to agree to advance/bulk purchasing of raw materials.
  - Risk transfer – maintaining insurance or other similar arrangements.
  - Risk acceptance – when all reasonable measures have been taken, a final acceptance that the remaining risk is acceptable.

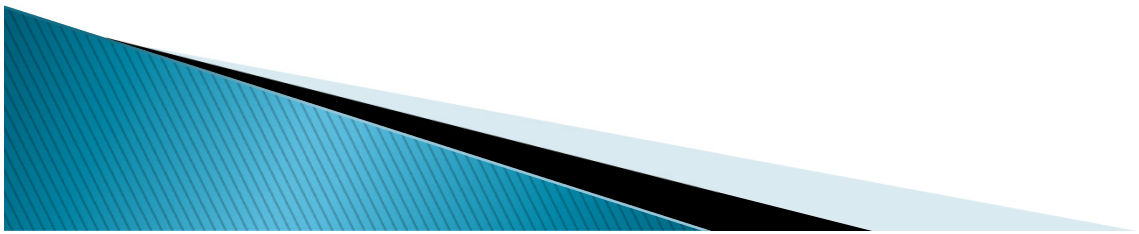


How is risk audited?

- Auditors have been directed to ask about Risk Management and are prepared to examine the various activities presented by the auditee.
  - We expect our clients to understand the concept and be prepared to explain what their approach has been.
- It is important to point out that there is only one requirement in ISO 9001:2015 that specifically mandates records pertaining to Risk Actions.
  - Clause 9.3.2E requires that "*the effectiveness of action taken to address risks and opportunities*" be included in management review.
  - Clause 9.3.3 requires that "retained documented information" of management review be kept.

Interested Parties

- The definition of "Interested Party" is as follows:
  - *"Person or organization that can affect, be affected by, or perceive themselves to be affected by a decision or activity."* Examples given include customers, owners, people within the organization, suppliers, bankers, unions, partners, and even competitors.
- Clause 4.2 requires that organization determine who their interested parties are, but emphasizes "relevant to the quality management system."
- The intention is that as an organization, you will ensure that your quality management system considers all relevant input requirements. The term "Interested Party" is intended to broaden the scope of who such requirements might come from.
- Ensuring that you are cognizant of all applicable requirements is simply good business.



Not just customers

- One point should be emphasized. It is most likely inappropriate for an organization to conclude that their only Interested Party group is their customer base.

- If an organization says “customers only.”

  - The organization should expect to be asked about the process they employed to conclude that their customers are the only relevant interested party.

  - If the organization cannot provide evidence of a structured analysis having been performed, it is likely that the process by which interested parties were selected was flawed, and a nonconformance should be issued.

Who else might be an interested party?

- ISO 9002 includes an extensive list of potential interested parties:
  - customers;
  - end users or beneficiaries;
  - joint venture partners;
  - franchisors;
  - owners of intellectual property;
  - parent and subsidiary organizations;
  - owners, shareholders;
  - bankers;
  - unions;
  - external providers;
  - employees and others working on behalf of the organization;
  - statutory and regulatory authorities (local, regional, national or international);
  - trade and professional associations;
  - local community groups;
  - non-governmental organizations;
  - neighboring organizations; and
  - competitors.

How should an organization figure out what the interested parties want?

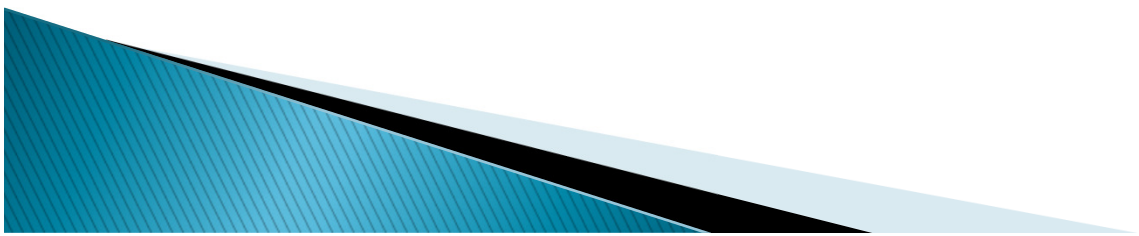
- Further guidance is provided in ISO 9002 on what an organization should be doing to ascertain the needs of their Interested Parties, including the following:
  - reviewing orders received;
  - reviewing statutory and regulatory requirements with compliance or legal departments;
  - lobbying and networking;
  - participating in relevant associations;
  - benchmarking;
  - market surveillance;
  - reviewing supply chain relationships;
  - conducting customer or user surveys; and
  - monitoring customer needs, expectations and satisfaction.

What nonconformances are most likely that pertain to Interested Parties?

- There are two circumstances where a nonconformance is likely appropriate:
  - If there is no evidence (or limited evidence) of an implemented process for monitoring and reviewing information – this would represent a violation of ISO 9001:2015 clause 4.2;
  - If there is no evidence that interested party feedback (not just customer feedback) is being discussed within Management Review – this would represent a violation of ISO 9001:2015 clause 9.3.2c1

One more thing to discuss…

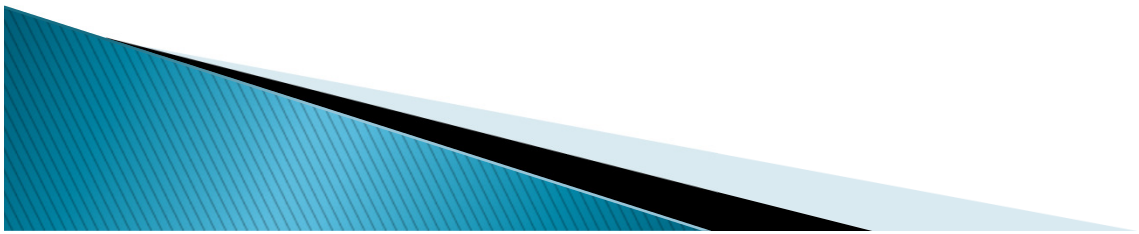
- ISO 9001:2015 (in section 5.1) has exacting and crucial requirements that pertain to Leadership.



How has PJR approached the concept of Leadership?

- Our audit report includes several targeted questions that auditors are expected to ask the management team, under the heading “Leadership Interview.”

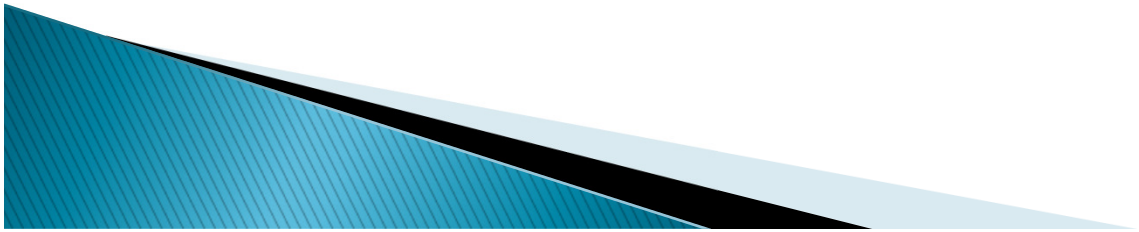
- The audit report also directs auditors to ensure that Leadership is directly involved in the management of the quality system.



Leadership Interview Questions

(content taken from PJR audit report)

- *What are you specifically doing to make yourself accountable for the effectiveness of the quality management system?*
- *How do you participate in the quality management system?*
- *Who are the primary interested parties of your organization?*
- *Do you have a process in place to monitor interested party requirements (including changes) and to respond to those requirements?*
- *What are some examples of current internal and external issues that you are attempting to address within your organization?*



Leadership means multiple persons in most cases

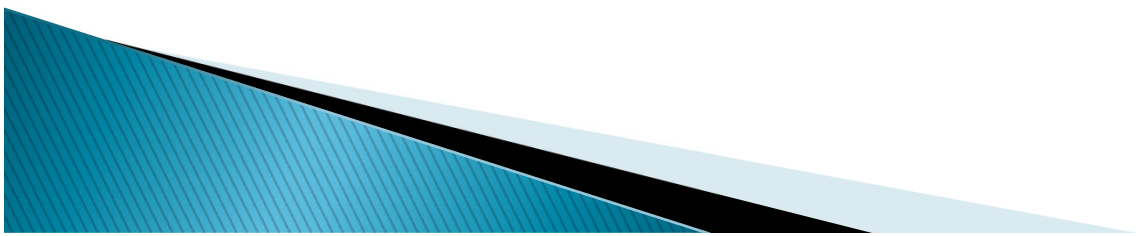
- In some cases, when PJR receives the completed audit report, we are noting only a single individual was included in the Leadership interview.

- While this is conceivable in a small (3-5 person) operation, it becomes less plausible in any situation with a higher employee count.

Guidance from ISO 9002 on Leadership

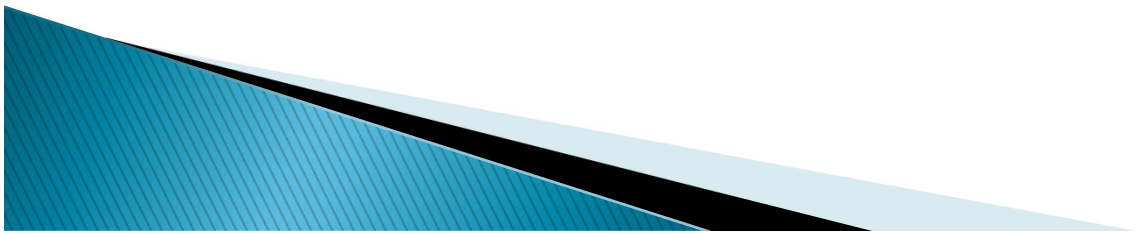
- ISO 9002 provides clarification on the role of Top Management. It states that *"although certain authorities and responsibilities can be delegated, the accountability remains with top management."*

- In other words, you can certainly still appoint a Management Representative, but you can no longer expect to have limited to no involvement in the quality management system.



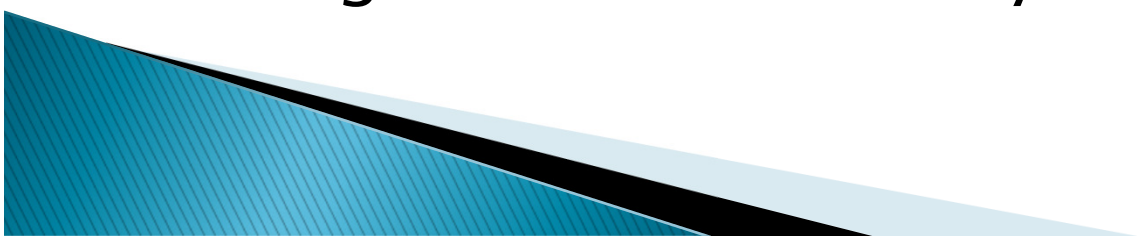
What happens if we don't agree?

- One of the more common questions the PJR Executive Committee gets from clients who have just completed an audit revolves around the concept of disputes.
- As an accredited certification body, PJR is required to provide a process for an impartial review of contested nonconformances.
- The process for filing a dispute request is explained in PJR's procedure PRO-10.
  - PRO-10 is available for download on our website under the link "Registration Document Download" (look to the bottom of the homepage.)
- <u>Per PRO-10 stipulations, all disputes must be received within 15 days of the end of the audit.</u>



Conclusion

- ISO 9001:2015 remains the world's most utilized standard (just over 1.3 million registered companies.)
- Many of the items cited in nonconformances are entirely avoidable and seem to come up time and again.
- PJR hopes the content of this presentation will leave you feeling more confident that things will go well on audit day!



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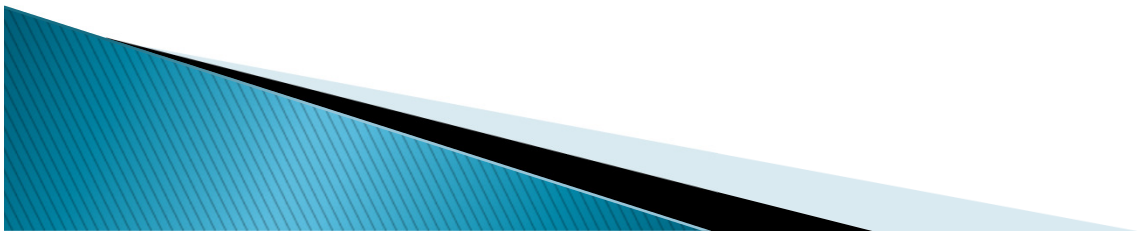
- *"Non-Applicable Clauses, Permissible Exclusions, Exemptions - Developing a better understanding of what can and what cannot be excused in an audit assessment"* is presented on a quarterly basis.
  - This webinar explores the critical topic of exemptions and the right approach to take in determining which apply to you.
- *"The Interaction of Processes and its importance to a successful audit."*
  - This webinar explores the crucial topic of processes and how to correctly understand them.
- We offer a variety of webinars on other topics including Corrective Action, Stage 1 Audits, AS9100, ISO 13485:2016, IATF 16949, and ISO 14001:2015.



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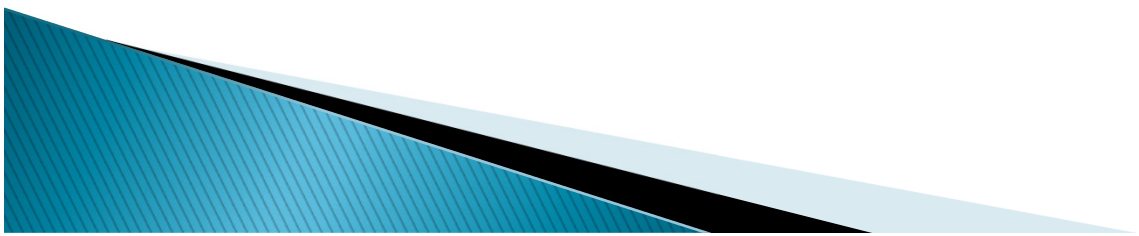

Thank you!

- Reminders:
  - 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."
- Questions?

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