

# The Interaction of Processes and its importance to a successful audit

Presented by:

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- 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.
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- 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

- Background
- ISO 9001:2015 related requirements
- What is a process?
- What is not a process?
- Strategies for meeting the requirement with minimal changes to your existing documentation
- The impact of outsourced processes

# Background

- In 2014, Perry Johnson Registrars was faced with a mandate from our Accreditation Bodies to take a harder line on our assessments of client Interaction of Process (IOP) documents.
- Among the many requirements that PJR is held accountable to are those found in ISO 17021:2015.
- This standard includes a clause that reads (in part):
  - *“An audit program for the full certification cycle shall be developed to clearly identify the audit activity(ies) required to demonstrate that the client’s management system fulfills the requirements for certification...”*
- PJR is expected to ensure that our auditors perform and document their audits in such a way that they reflect the client’s management system.

# Where this gets difficult...

- Our policy is to adhere to the client's interaction of processes, and only the client's interaction of processes in completing the audit report.
- If these documents do not do an effective job of identifying the processes, the auditor's job is exceedingly difficult.
- We have instructed our auditors to issue nonconformances to clients who have an IOP that does not identify processes in an appropriate manner.

# ISO 9001:2015 related requirements

- The below requirements are most often cited as mandating that organizations identify their processes and demonstrate their interaction:
- *4.4.1 – The organization shall determine the processes needed for the quality management system;*
- *4.4.1B (The organization shall) determine the sequence and interaction of these processes;*
- *4.4.2 – The organization shall maintain documented information to support the operation of its processes.*

# What is a process?

- ISO 9000:2015 defines Process as follows:
  - *“Set of interrelated or interacting activities that use inputs to deliver an intended result”*
- The key portion of this definition is *“interrelated or interacting activities.”* This establishes a key aspect of what a process is not.
- It is not a single step, but rather a series of activities focused on a shared goal.

# What is a process?

- The following are examples of items that represent acceptable process designations:
  - Sales;
  - Purchasing;
  - Production;
  - Shipping; and
  - Design and Development.
- Remember that the IOP must reflect what YOU think your processes are.
- If you understand your quality management system to be made up of four processes (Sales, Purchasing, Production, Support) it is completely acceptable for your IOP to reflect as much.

# What is not a process?

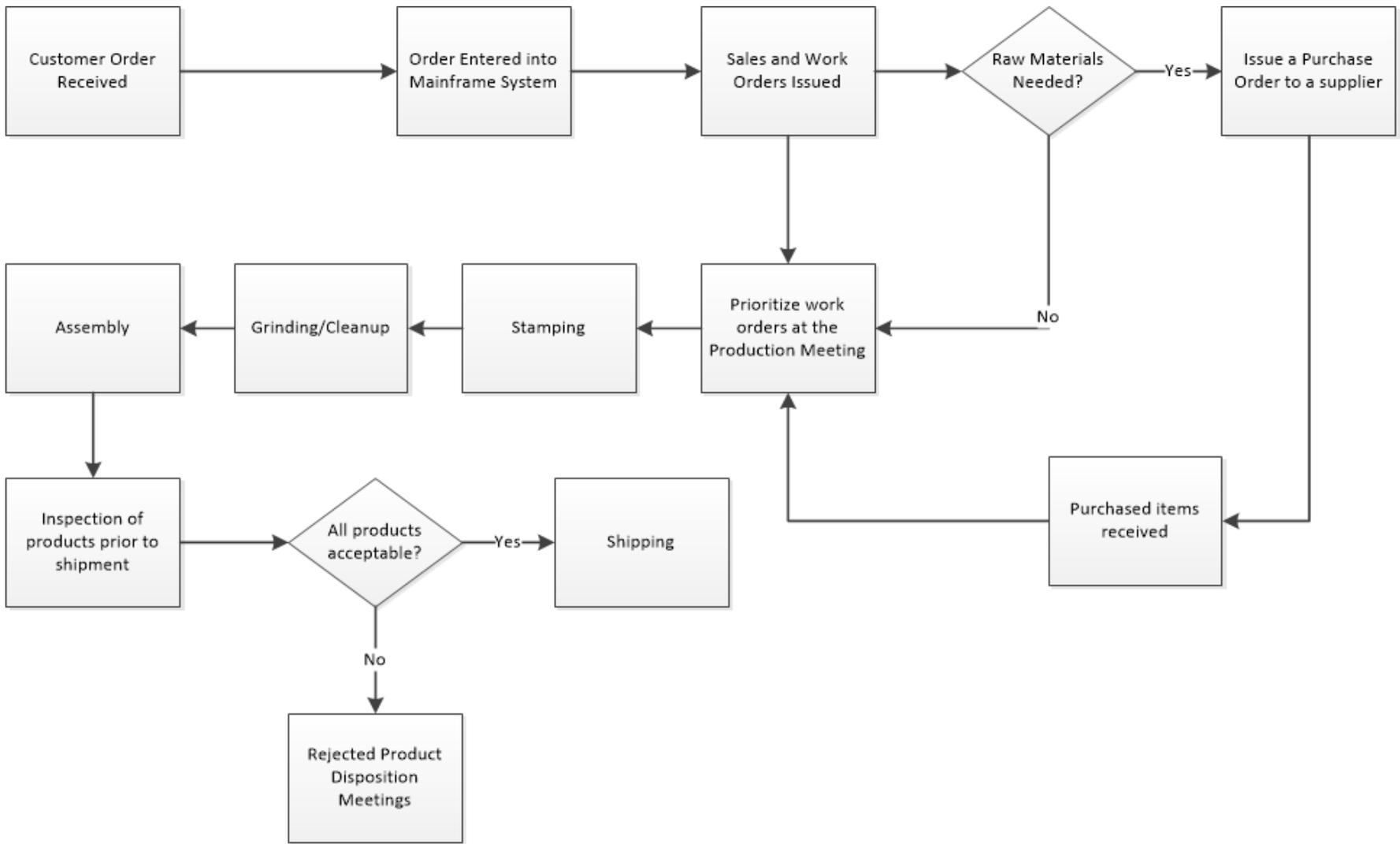
- The IOP documents that get rejected most often are those that present steps within a single process.
- Examples of such designations include:
  - Create work order;
  - Issue production schedule;
  - Complete work order
  - Package product;
  - Ship product.
- In the preceding example, it is conceivable that all five of these steps are part of a single process, but they are not processes by themselves.
- An IOP that presents sections from the applicable standard as the organization's processes should also be regarded with concern. How many organizations actually have a process that they call “*Resource Management*”?
- An interaction of process document that bears such items as processes should result in a nonconformance being issued during the audit.

## Strategies for meeting the requirement with minimal changes to your existing documentation

- PJR recognizes that for many of our clients, a lot of careful thought and consideration went into the development of the IOP.
- We also are well aware that for many of our clients it is somewhat disconcerting to be told that a portion of your quality system that passed audit assessment for many years is now “suddenly” unacceptable.
- Accordingly, we feel that for many of you, a few tweaks are all that will be needed to meet the requirement in a more effective way.

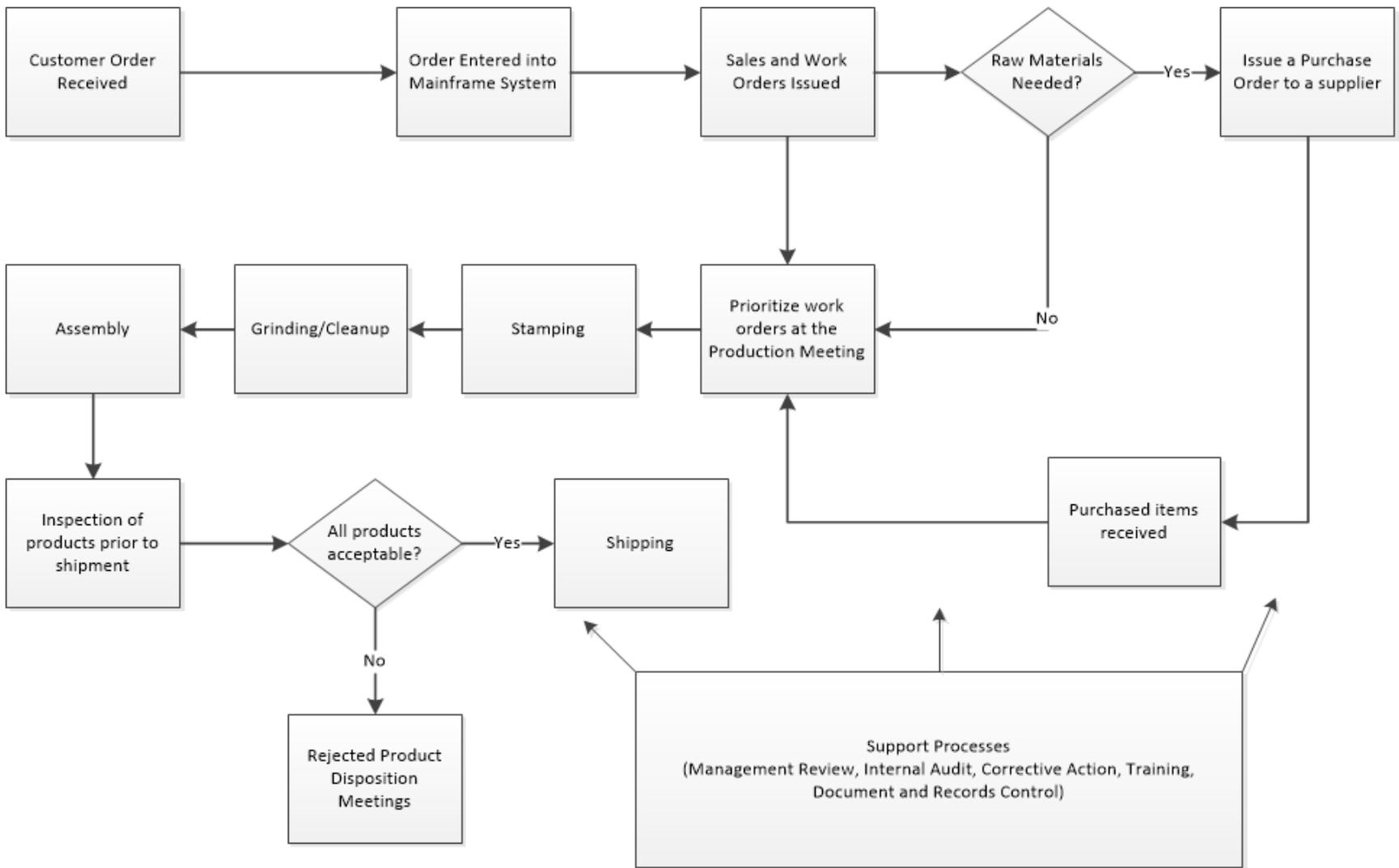
# Let's improve an example of an interaction of processes

- We're going to review a sample of an interaction of processes and improve it in two key ways.
- Let's begin by reviewing the raw interaction of processes.
- Please note that this example is not reflective of any particular PJR client and was created solely for the purpose of this presentation.



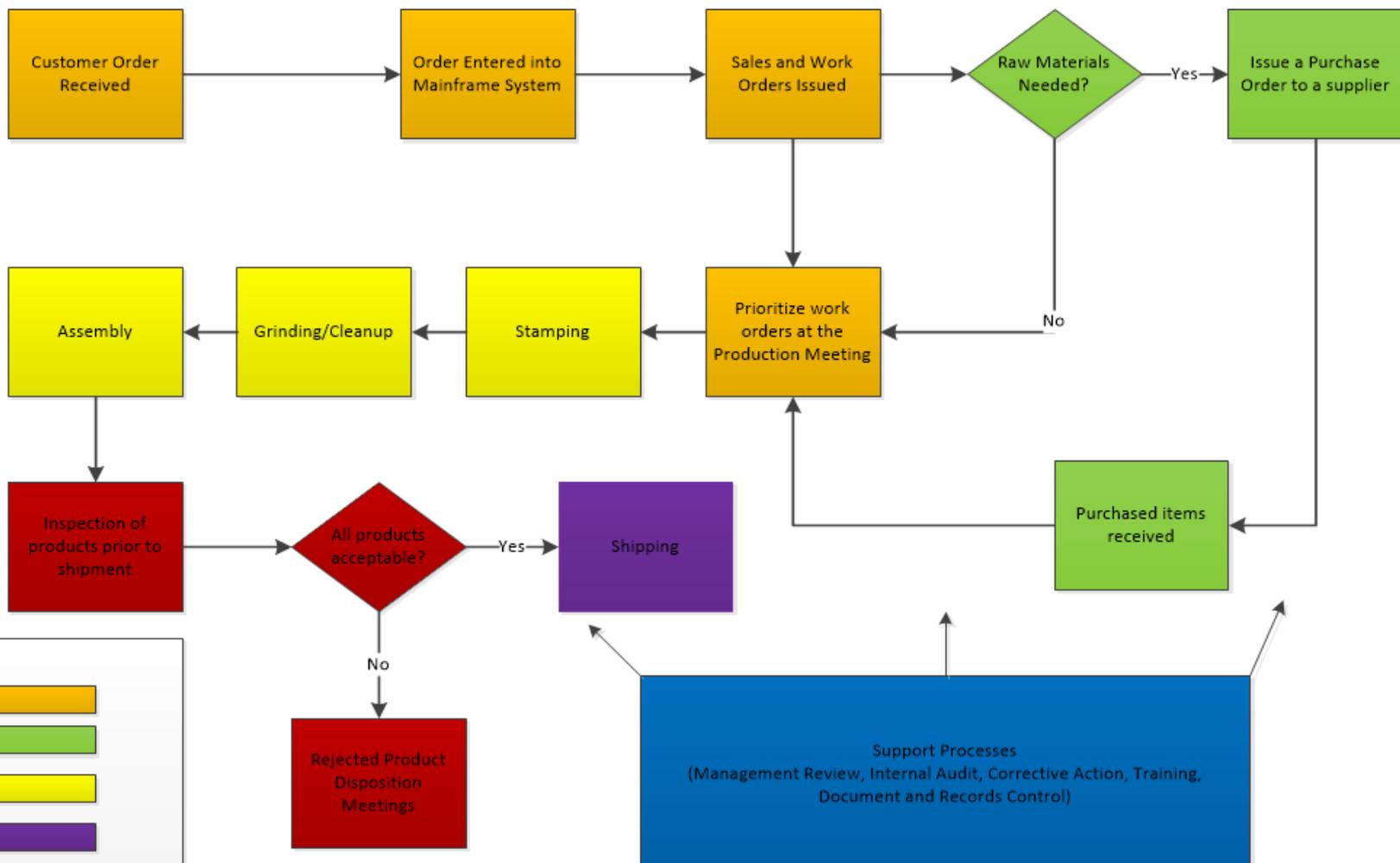
# Improvement 1: Identification of “Support” processes

- Some of the IOP documents that get rejected lack a specific place to identify what many companies consider to be “support” processes.
- It is important to note that ISO 9000 and ISO 9001 do not draw any particular distinction between classifications of processes. Nevertheless, the concept of key/core processes is a common one.
- As a result, many of the items that are characterized as support/management processes are left off of the IOP.
- Such items include, but are not limited to:
  - Management Review;
  - Internal Audit;
  - Training;
  - Corrective Action
- Let’s apply this improvement to our test model.



# Improvement 2: Creation of an IOP “key”

- By far, the most popular strategy that we have seen and accepted for this issue is to create a “key” that identifies what the processes are (usually by numbering/alpha characters.)
- This enables the IOP to stay as-is, but serves the quality system and audit process by naming the processes made up by the various process steps shown.
- Let’s make this additional improvement to our test model.



**Process Key:**

- Sales/Order Entry
- Purchasing
- Production
- Shipping
- Quality
- Support

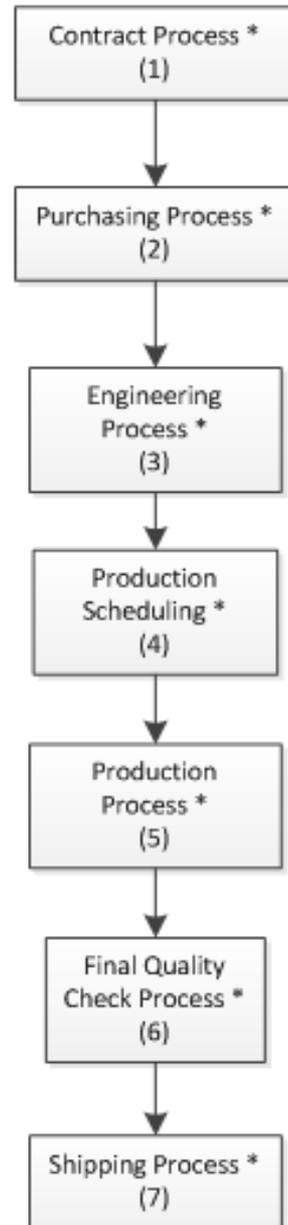
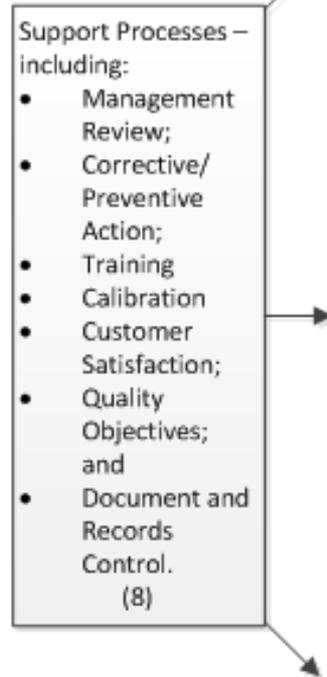
**Support Processes**  
 (Management Review, Internal Audit, Corrective Action, Training, Document and Records Control)

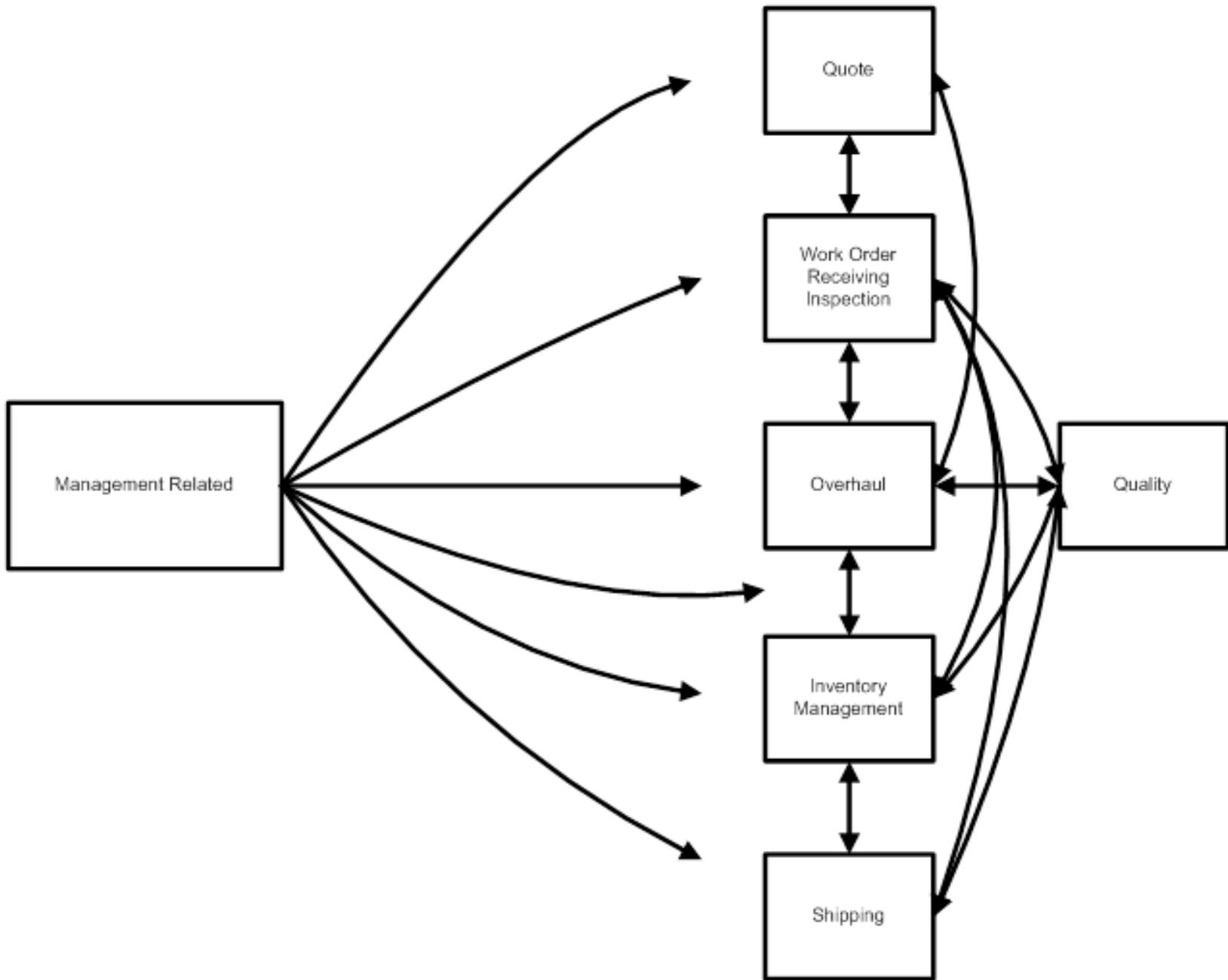
# Now we've got something!

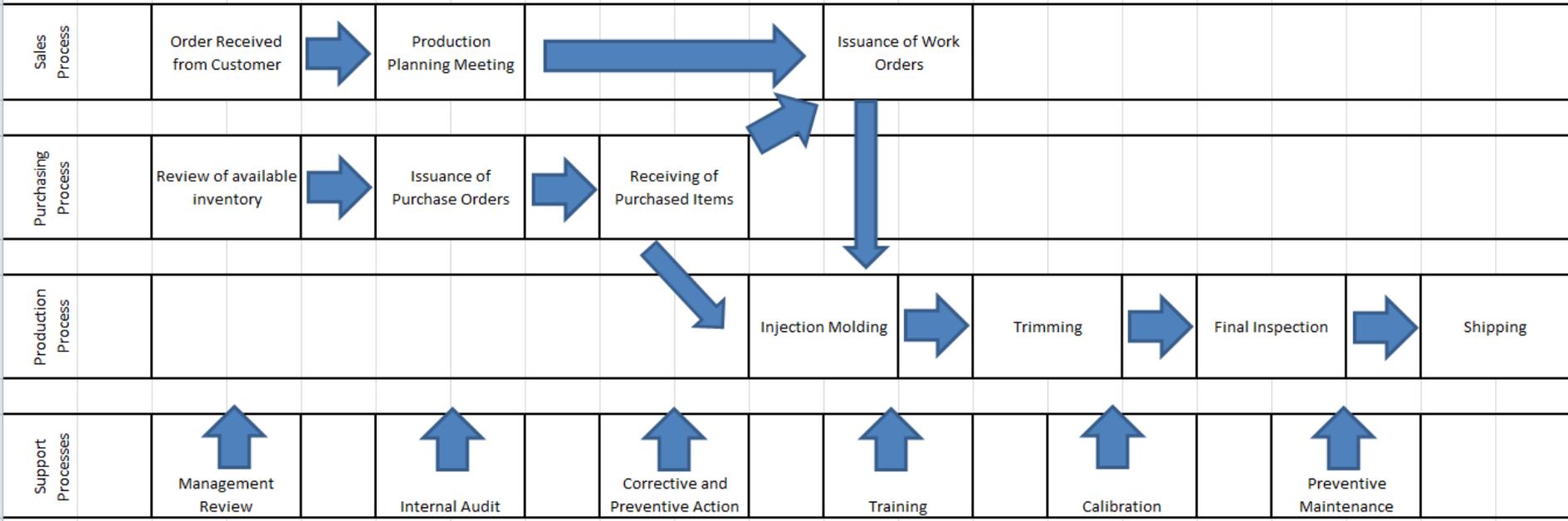
- By these two small adjustments, we've kept the content of the IOP as it was before, but we've accomplished two key goals:
  1. The IOP now identifies what the company's processes are; and
  2. The IOP now reflects support processes.
- This IOP is ready for audit assessment!

# There's more than one way to accomplish this!

- It is important that you understand the wide variety of methods PJR has seen and accepted over the years in fulfillment of this requirement.
- We'd like to share some additional examples to give you some additional ideas as you prepare/revise your IOP to ensure it meets all applicable requirements while adding the maximum value to your organization.









# Outsourced Processes – another layer of requirements

- Many organizations outsource a few or even several of their processes to external providers.
  - External Provider is defined as a “Provider that is not part of the Organization” – this is an inclusive terms and refers to subcontractors, partner companies, parent companies, etc.
- PJR has a whole separate webinar that addresses the topic of “Outsourcing” titled *Non-Applicable Clauses, Permissible Exclusions, Exemptions*.

# 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:
- 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.)

# How do Outsourced Processes factor into the IOP document?

- Let's revisit the applicable requirements from ISO 9001 that are in play:
  - 4.4.1 requires an organization to determine the processes that make up their quality management system.
  - 8.4.1 requires an organization to maintain control over any outsourced processes.
  - 4.4.2 requires documented information supporting the operation of the processes.
- Recent accreditation body feedback has reinforced PJR's position that this means the IOP must identify any outsourced processes.

# Examples of how to identify outsourced processes

- You might use a special font – for example:
  - Purchasing, Sales, Internal Audit, Shipping
- You might use bold, unlined text – for example:
  - Purchasing, Sales, **Internal Audit**, Shipping
- You may also choose to give the outsourced processes their own special place on the IOP.
- The approach taken is entirely up to you.

# Conclusion

- PJR wants to ensure that we provide our clients with a value added audit while meeting all applicable requirements.
- It is our hope that you will use the points of this presentation to develop an even better understanding of what your processes are.

# Please tune in for one of our other webinars

- *“ISO 9001:2015 – Knowing what to expect to ensure a stress free audit”* is presented on a semi-annual basis.
  - This webinar explores what some of the more common “issues” are in ISO 9001:2015 audits and what is typically expected for these areas.
- *“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 semi-annual basis.
  - This webinar explores the critical topic of exemptions and the right approach to take in determining which apply to you.
- We offer a variety of webinars on other topics including Stage 1 Audits, AS9100, ISO 13485:2016, IATF 16949, and ISO 14001:2015.

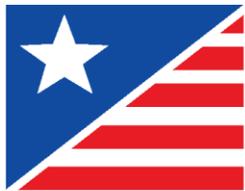
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