

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

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 make time for as many questions as possible at the conclusion of this presentation.

# Overview of Topics

- Background
- ISO 9001:2008 related requirements
- 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

# 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 17021:2011.
- 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 begin issuing nonconformances to clients who have an IOP that does not identify processes in an appropriate manner.

# ISO 9001:2008 related requirements

- The below requirements are most often cited as mandating that organizations identify their processes and demonstrate their interaction:
- *4.1A – (The organization shall) determine the processes needed for the quality management system and their application throughout the organization;*
- *4.1B – (The organization shall) determine the sequence and interaction of these processes;*
- *4.2.2C – The organization shall establish and maintain a quality manual that includes a description of the interaction between the processes of the quality management system.*

# 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;
  - Marketing;
  - Purchasing;
  - Production;
  - Shipping;
  - Design and Development;
  - Production Control.
- 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?

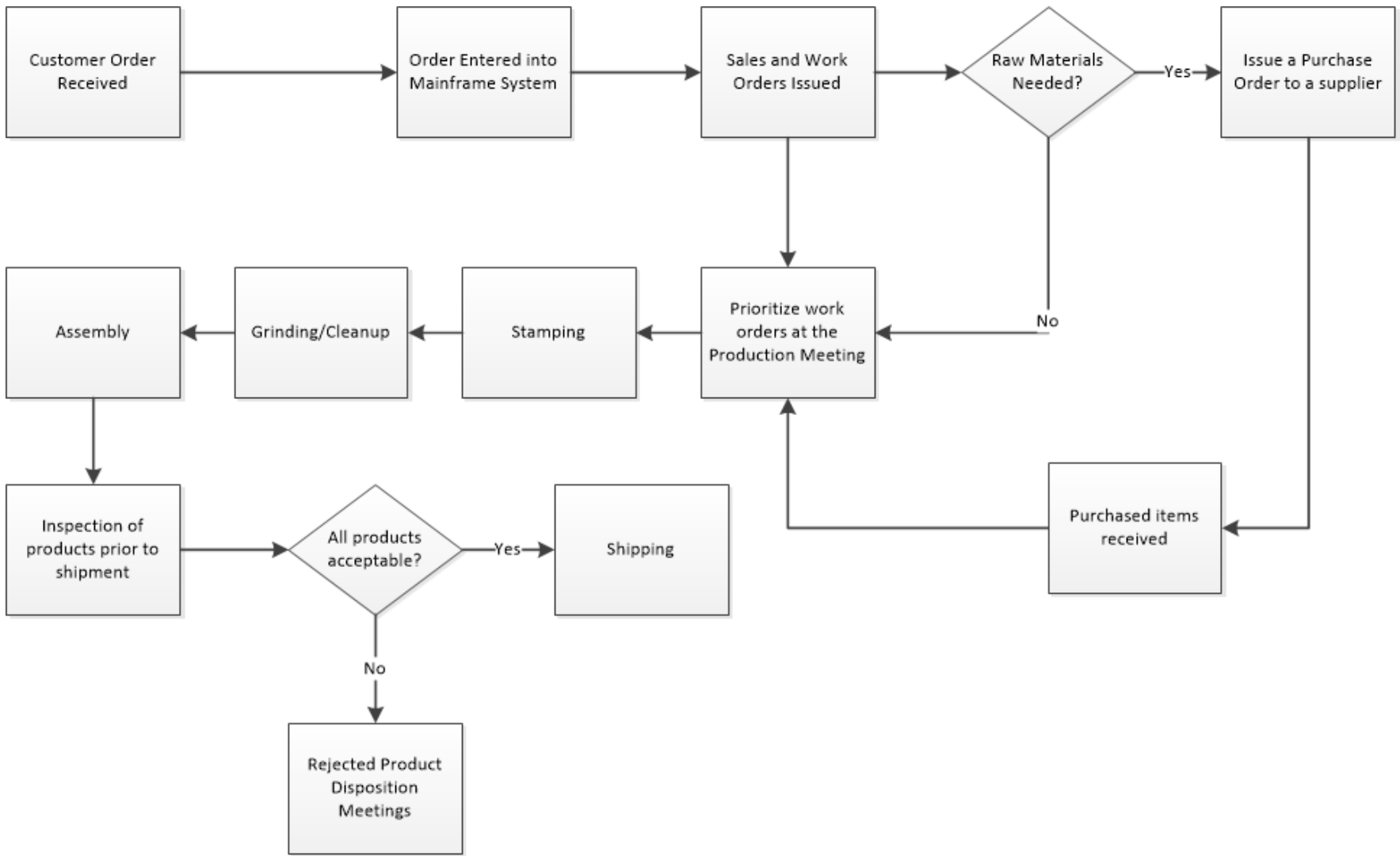
- Typically, the IOP documents that get rejected most often are those that present steps within a single process.
- Examples of such designations include:
  - Create work order;
  - Issue production schedule;
  - Complete work order
  - Package product;
  - Ship product.
- In the preceding example, it is conceivable that all five of these steps are part of a single process, but they are not processes by themselves.
- An 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.

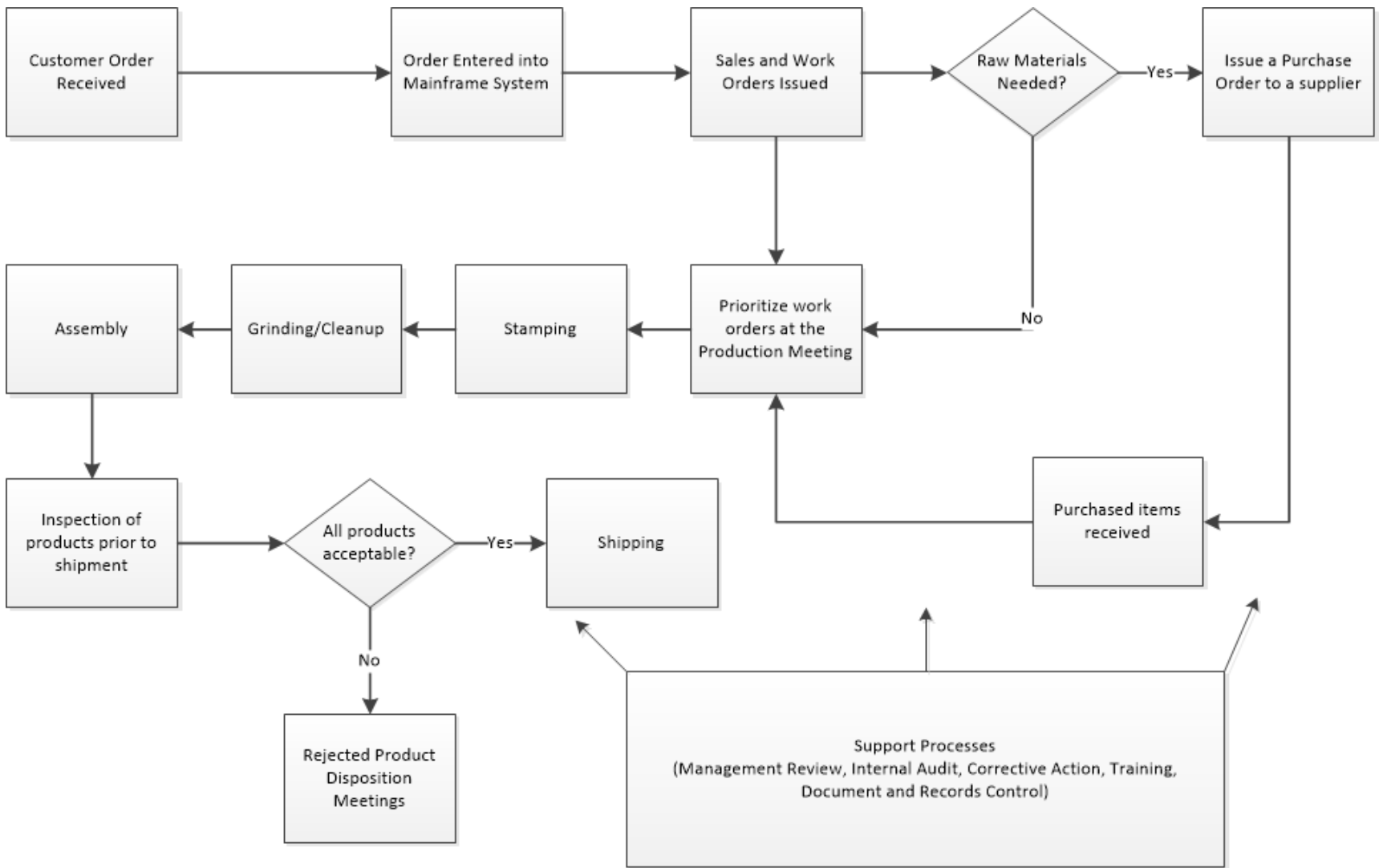
# Let's improve an example of an interaction of processes

- 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

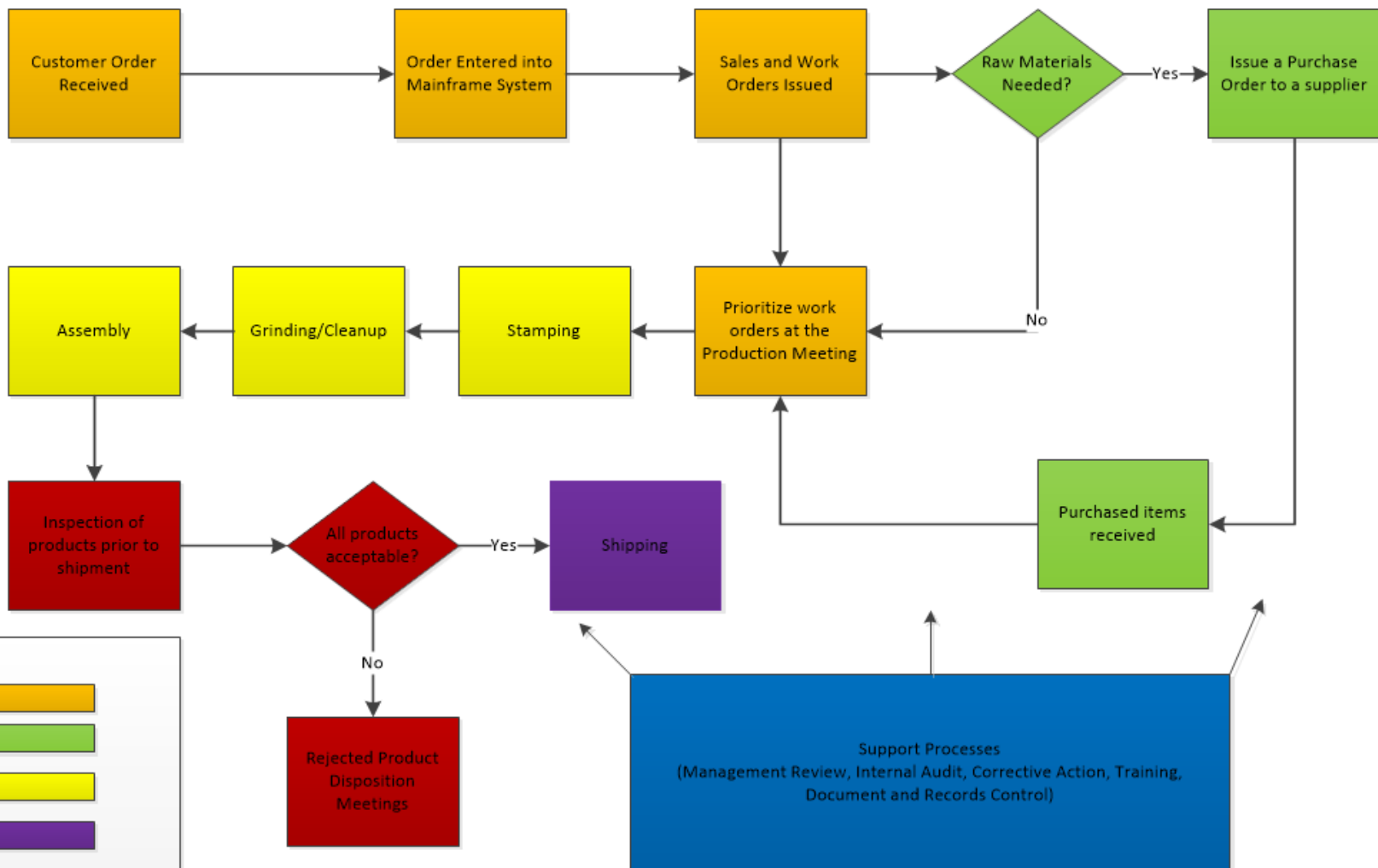
- Some of the IOP documents that get rejected lack a specific place to identify what many companies consider to be “support” processes.
- It is important to note that ISO 9000 and ISO 9001 do not draw any particular distinction between classifications of processes. Nevertheless, the concept of key/core 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:**

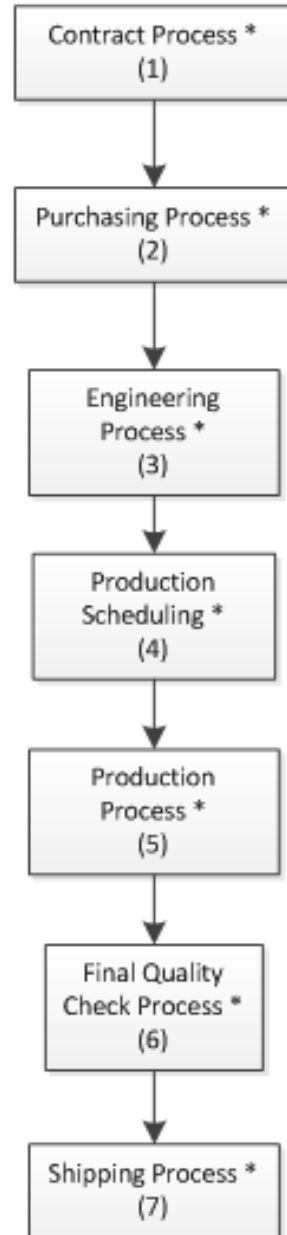
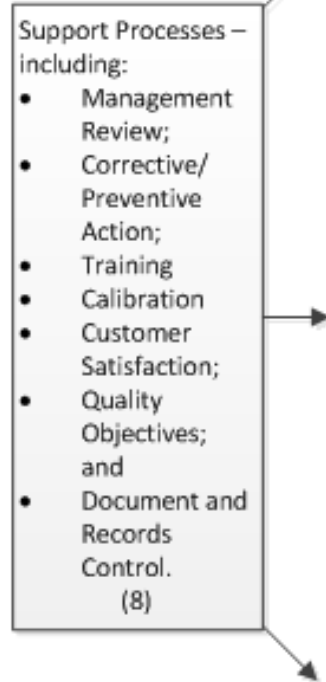
- Sales/Order Entry
- Purchasing
- Production
- Shipping
- Quality
- Support

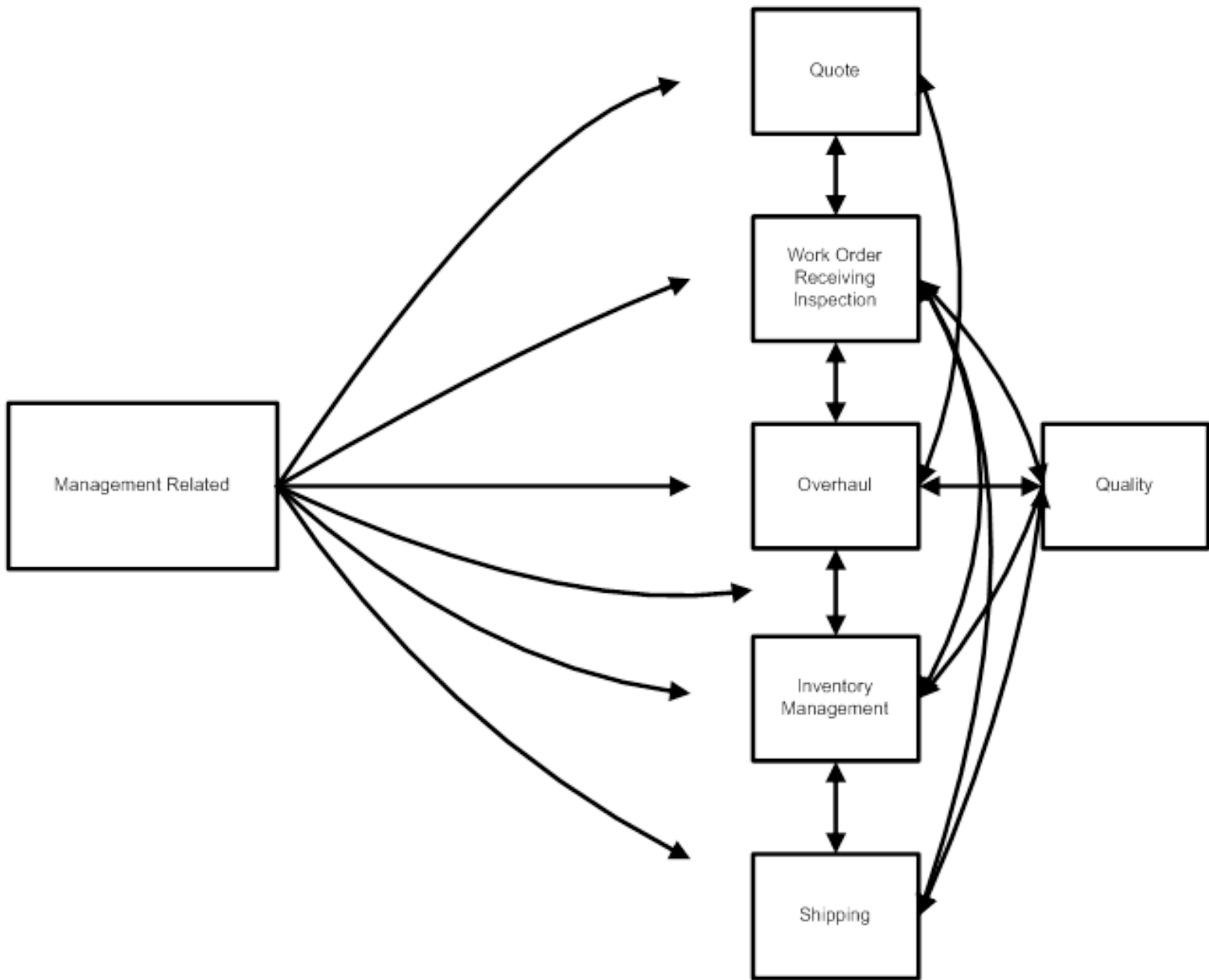
# Now we've got something!

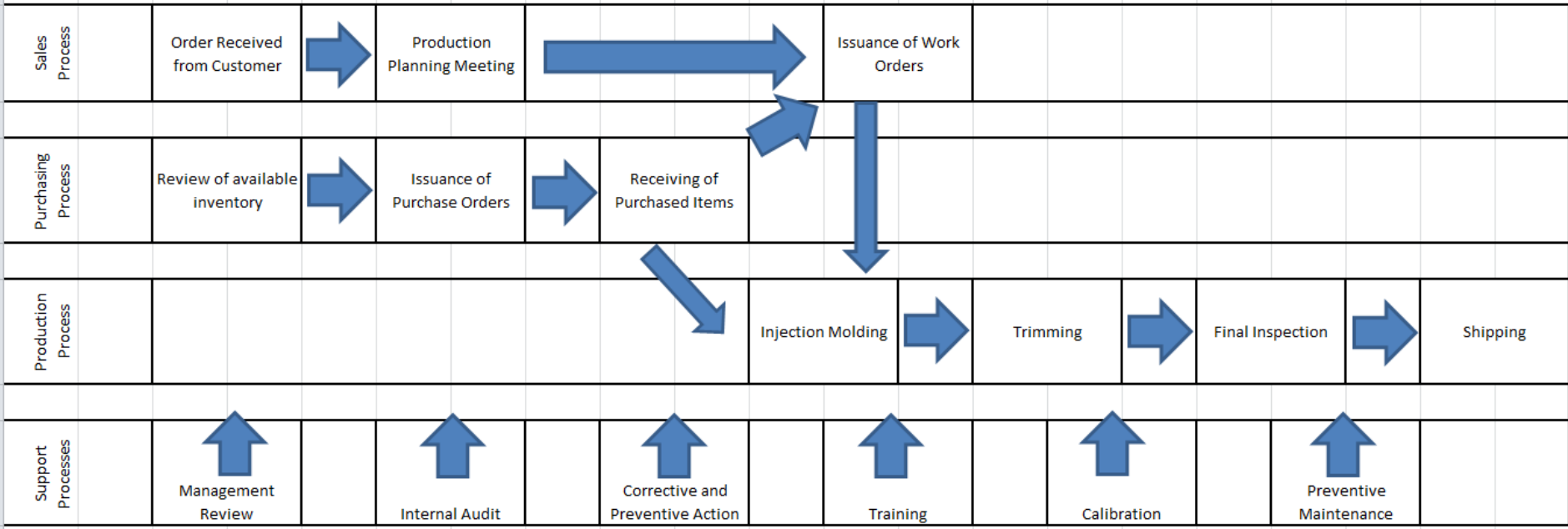
- By these two small adjustments, we've kept the content of the IOP as it was before, but we've accomplished two key goals:
  1. The IOP now identifies what the company's processes are; and
  2. The IOP now reflects support processes.
- This IOP is ready for audit assessment!

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

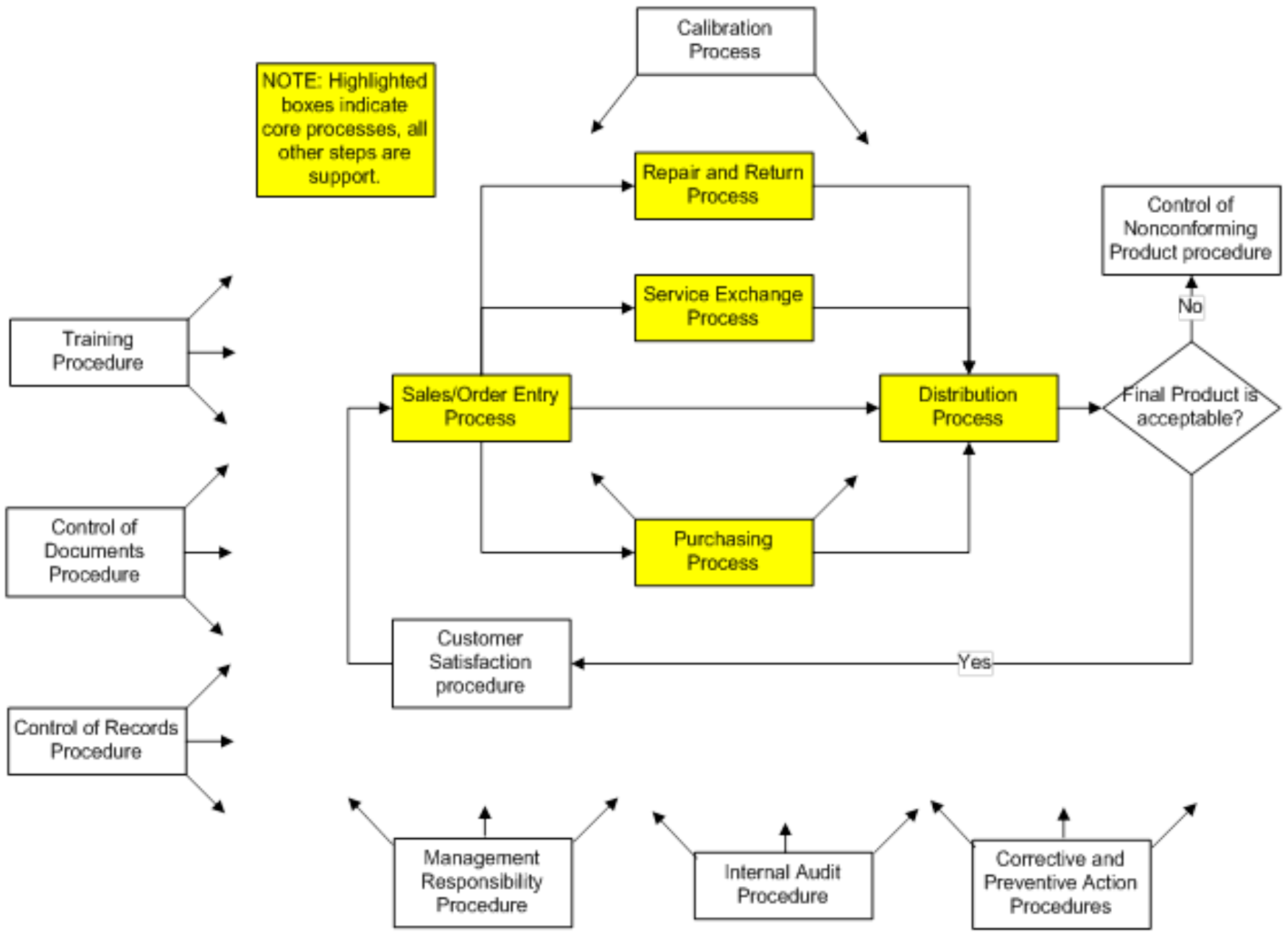
- It is important that you understand the wide variety of methods PJR has seen and accepted over the years in fulfillment of this requirement.
- We'd like to share some additional examples to give you some additional ideas as you prepare/revise your IOP to ensure it meets all applicable requirements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







NOTE: Highlighted boxes indicate core processes, all other steps are support.



# 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.



# Thank you!

- Questions?