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 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

- 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 <u>the client's management system.</u>

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.

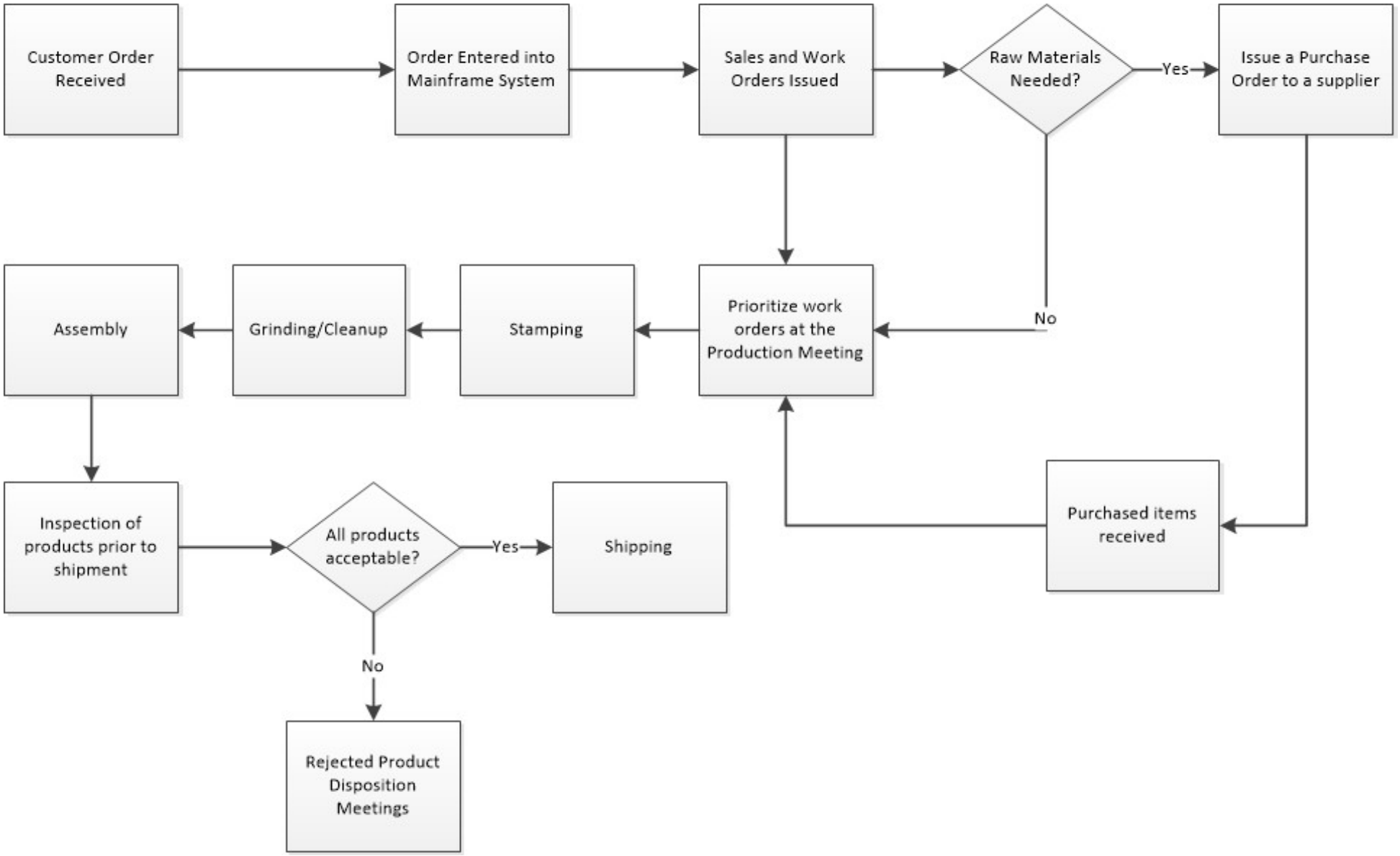
- Accordingly, we feel that for many of you, a few tweaks are all that will be needed to meet the requirement in a more effective way.

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.

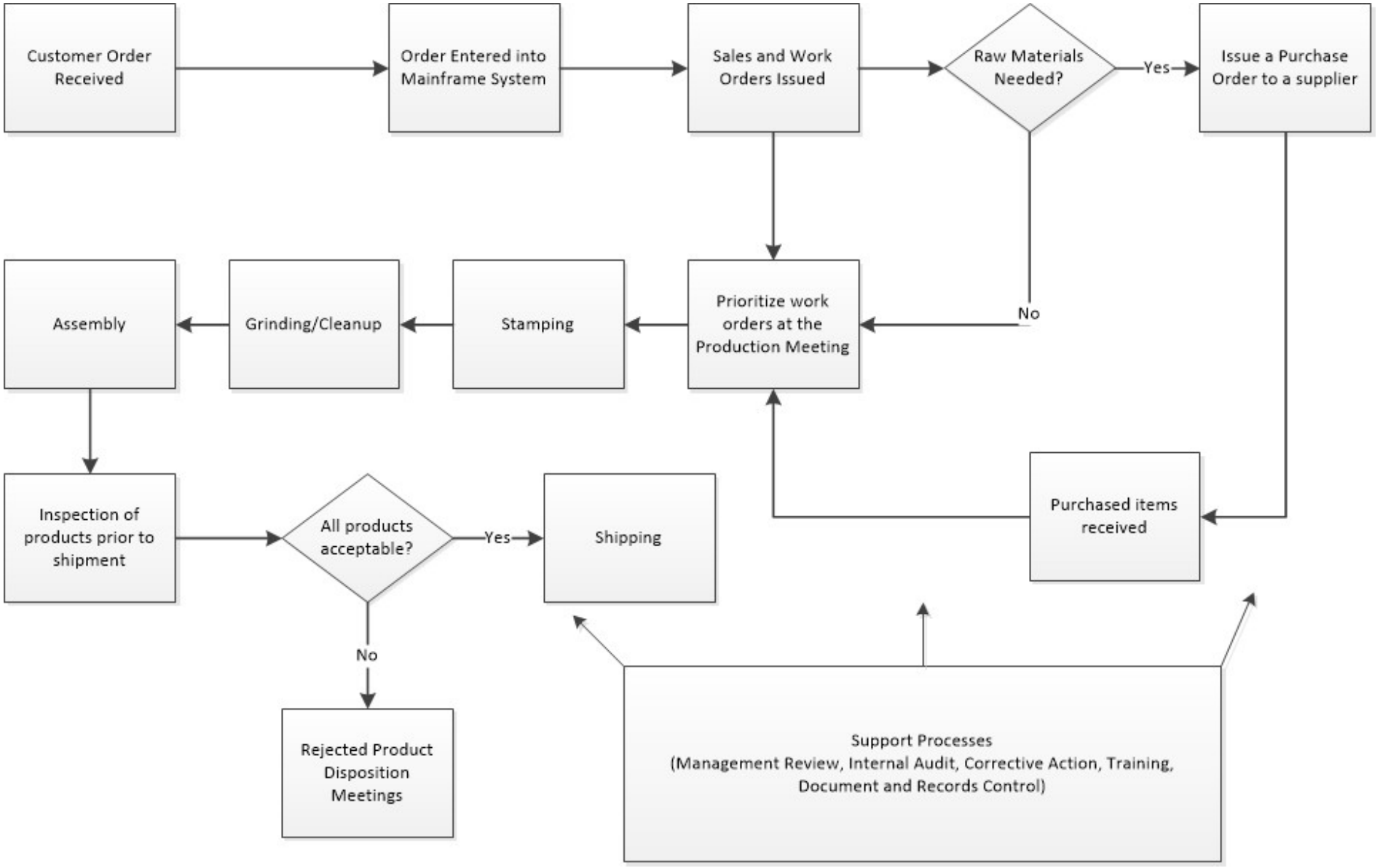
- Let's begin by reviewing the raw interaction of processes.

- Please note that this example is not reflective of any particular PJR client and was created solely for the purpose of this presentation.


Customer Order Received
Order Entered into Mainframe System
Sales and Work Orders Issued
Raw Materials Needed?
Yes
Issue a Purchase Order to a supplier
No
Prioritize work orders at the Production Meeting
Stamping
Grinding/Cleanup
Assembly
Purchased items received
Inspection of products prior to shipment
All products acceptable?
Yes
Shipping
No
Rejected Product Disposition Meetings

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.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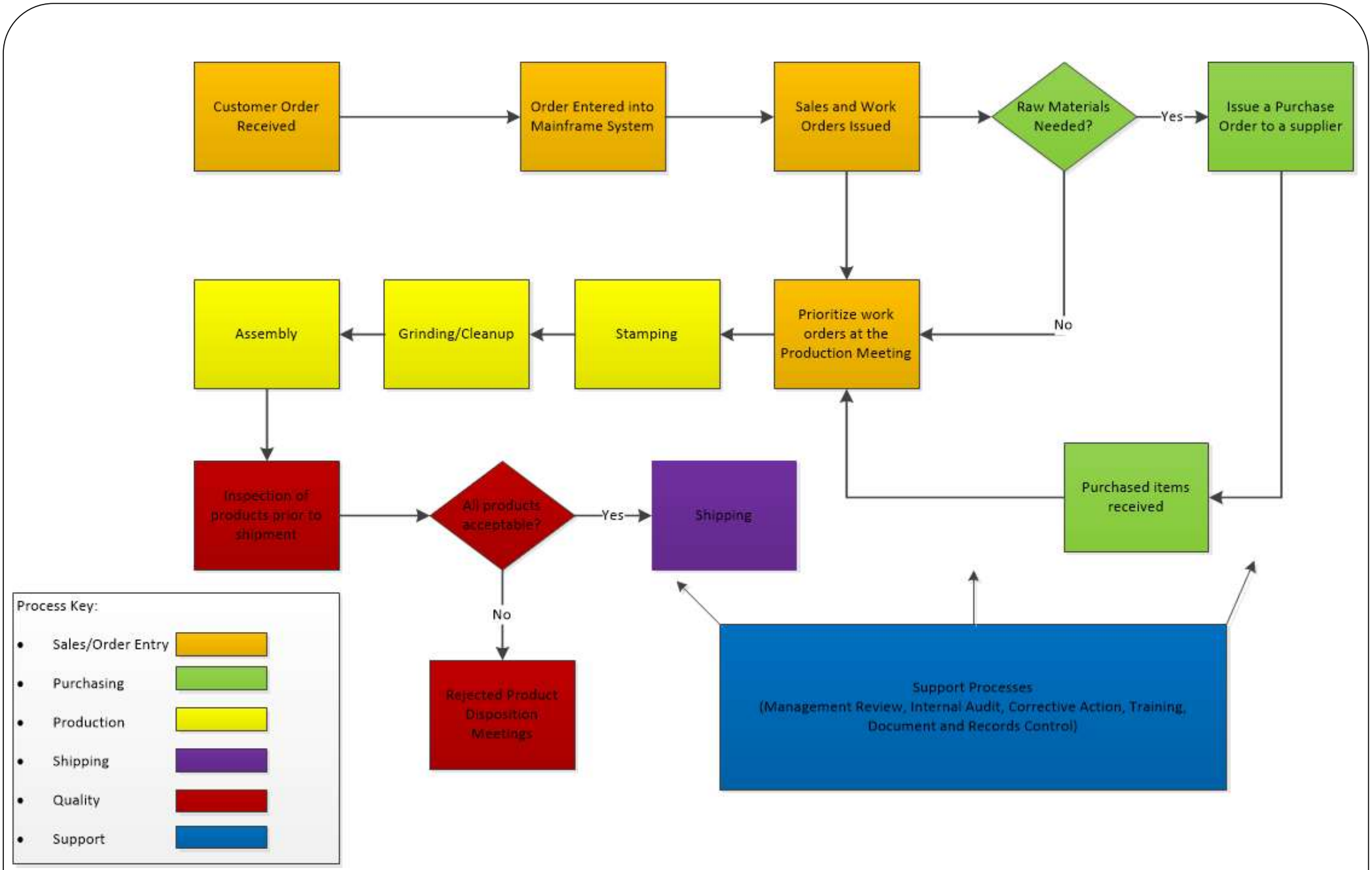
Sales and Work Orders Issued
Raw Materials Needed?
Yes
Issue a Purchase Order to a supplier
No
Prioritize work orders at the Production Meeting
Stamping
Grinding/Cleanup
Assembly
Purchased items received
Inspection of products prior to shipment
All products acceptable?
Yes
Shipping
No
Rejected Product Disposition Meetings
Support Processes
(Management Review, Internal Audit, Corrective Action, Training, Document and Records Control)

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.


Customer Order Received
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Prioritize work orders at the Production Meeting
Stamping
Grinding/Cleanup
Assembly
Purchased items received
Insoection of products prior to shipment
All products acceptable?
Yes
Shipping
No
Rejected Product Disposition Meetings
Support Processes
(Management Review, Internal Audit, Corrective Action, Training, Document and Records Control)
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:

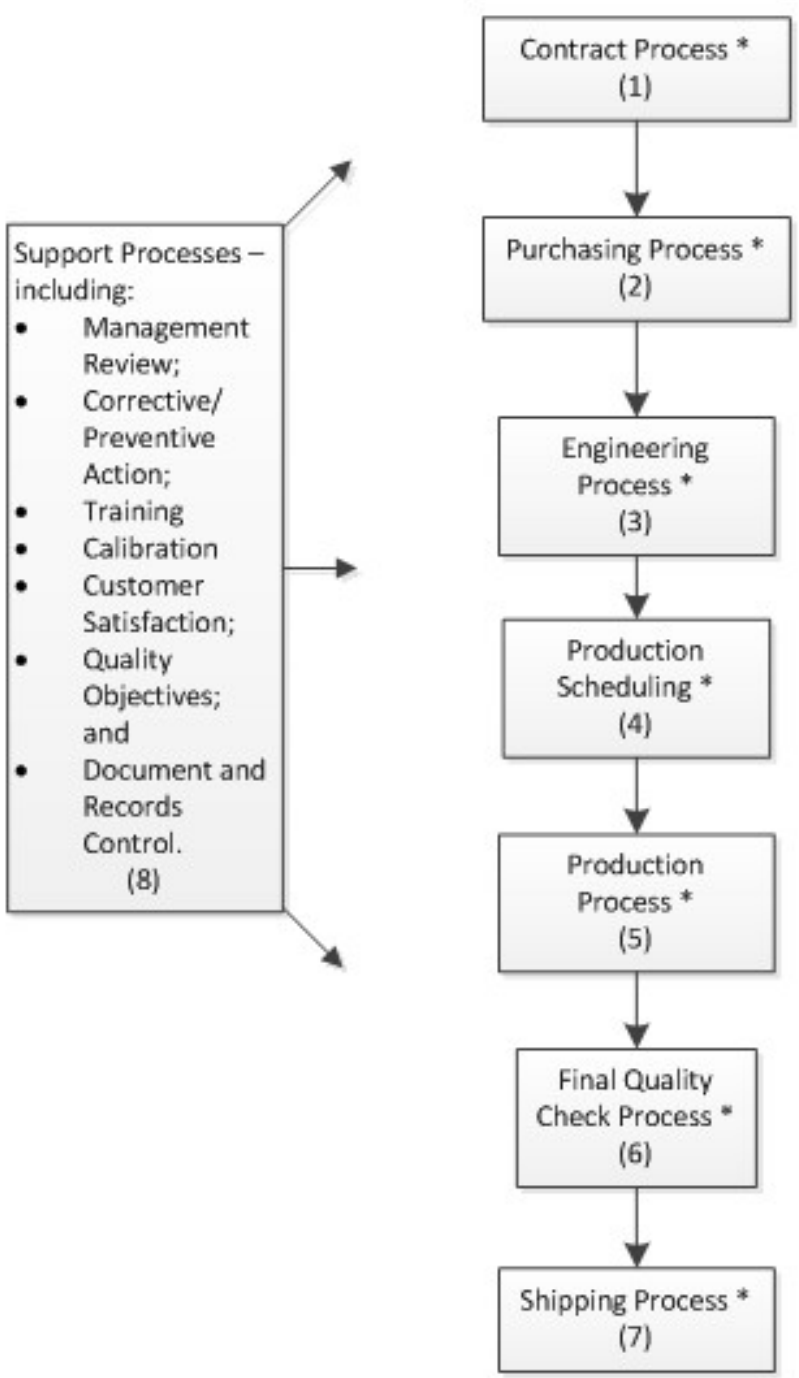
  1. The IOP now identifies what the company's processes are; and
  2. The IOP now reflects support processes.

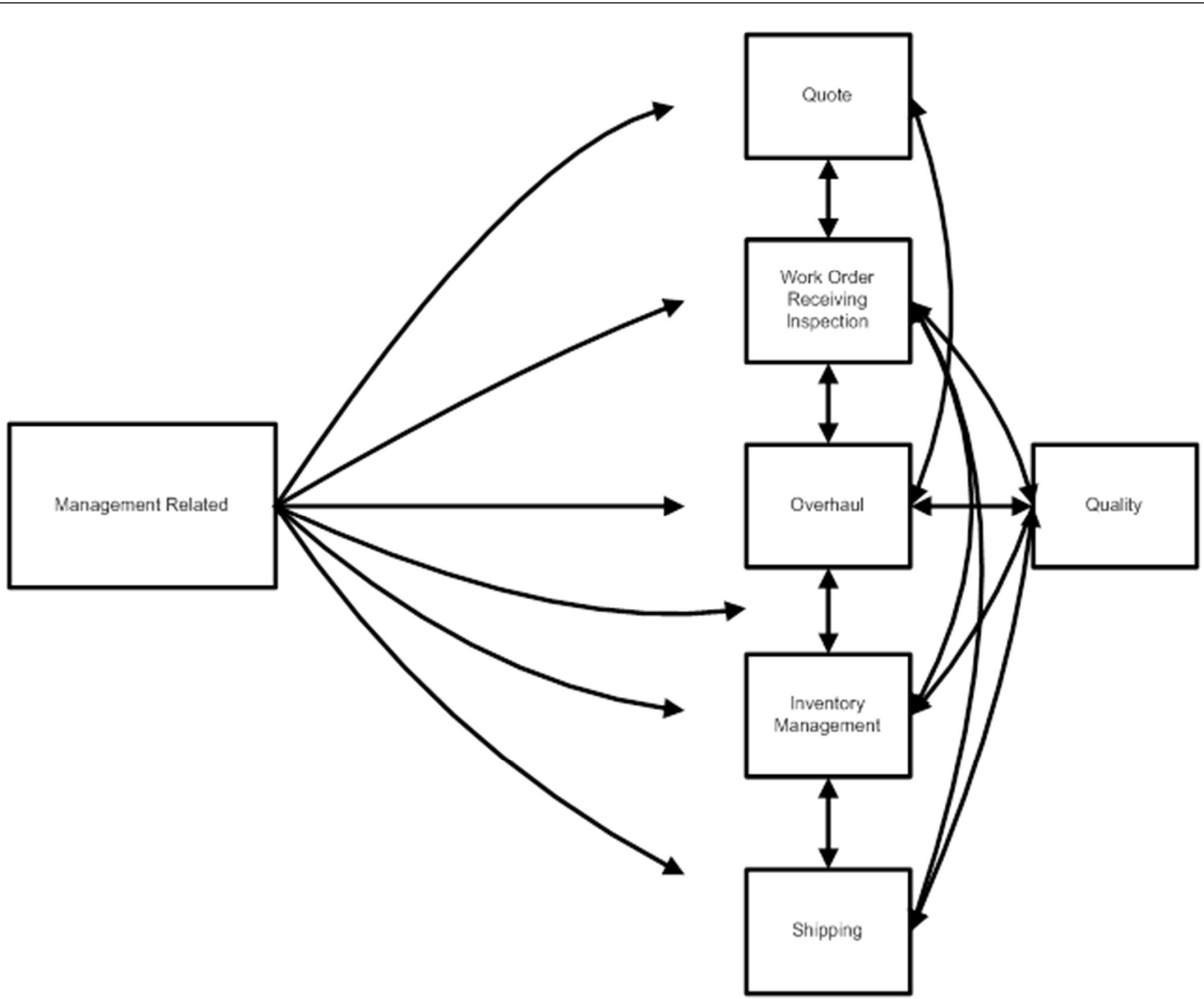
- This IOP is ready for audit assessment!

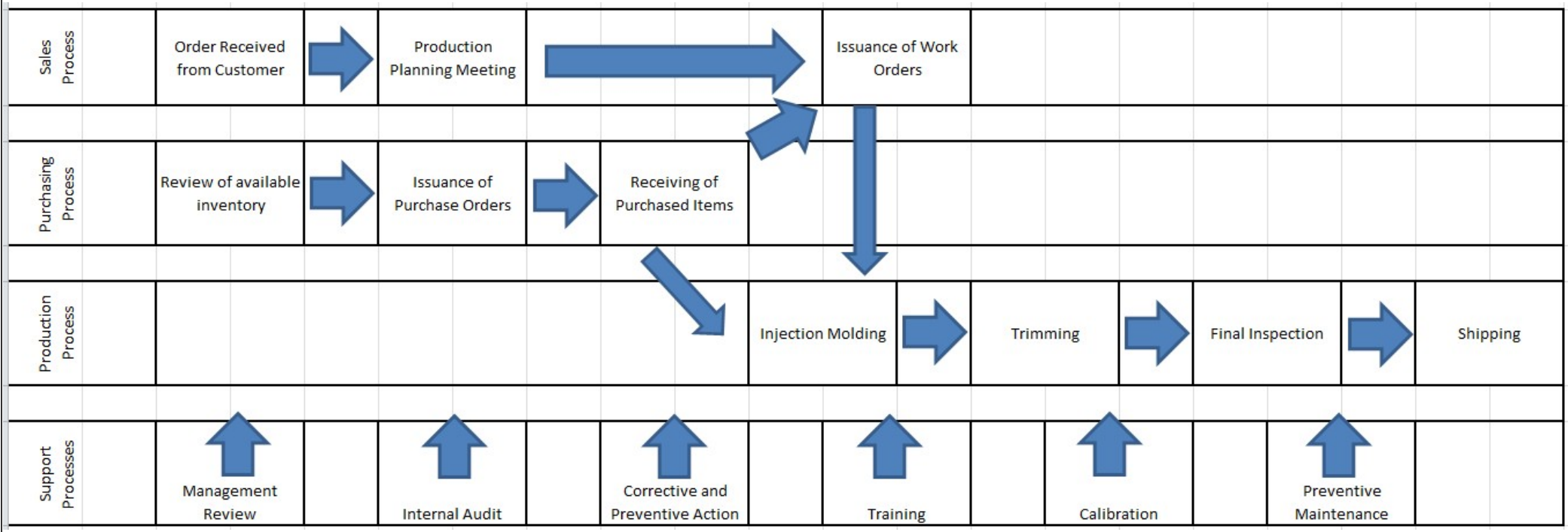
There's more than one way to accomplish this!

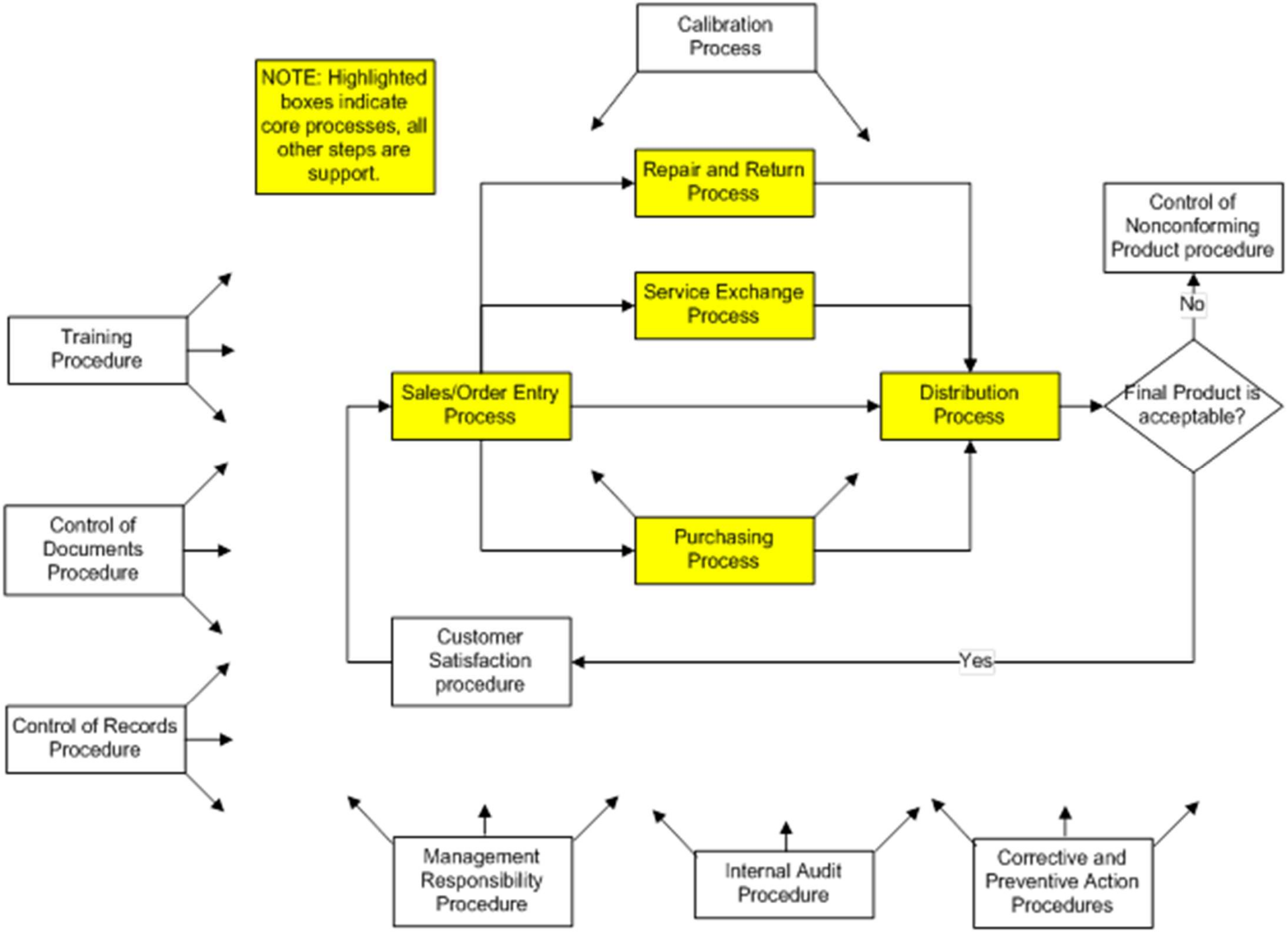
- It is important that you understand the wide variety of methods PJR has seen and accepted over the years in fulfillment of this requirement.

- 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.


Contract Process * (1)
Purchasing Process * (2)
Engineering Process * (3)
Production Scheduling * (4)
Production Process * (5)
Final Quality Check Process * (6)
Shipping Process * (7)
Support Processes – including:
Management Review;
Corrective/ Preventive Action;
Training
Calibration
Customer Satisfaction;
Quality Objectives; and
Document and Records Control.
(8)


Quote
Work Order
Receiving
Inspection
Management Related
Overhaul
Quality
Inventory
Management
Shipping


Sales Process
Order Received from Customer
Production Planning Meeting
Issuance of Work Orders
Purchasing Process
Review of available inventory
Issuance of Purchase Orders
Receiving of Purchased Items
Production Process
Injection Molding
Trimming
Final Inspection
Shipping
Support Processes
Management Review
Internal Audit
Corrective and Preventive Action
Training
Calibration
Preventive Maintenance


NOTE: Highlighted boxes indicate core processes, all other steps are support.
Calibration Process
Repair and Return Process
Service Exchange Process
Sales/Order Entry Process
Distribution Process
Purchasing Process
Customer Satisfaction procedure
Control of Nonconforming Product procedure
No
Final Product is acceptable?
Yes
Training Procedure
Control of Documents Procedure
Control of Records Procedure
Management Responsibility Procedure
Internal Audit Procedure
Corrective and Preventive Action Procedures

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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