



AS9100D Matrix

AS9	100D/ ISO 9001:2015	4.1	.34	4.4.1	4.4.2	5.1.1	5.2.1	5.2.2	5.3	6.1.1	6.1.2	6.2.2	6.3	7.1.1	7.1.2	7.1.3	7.1.4	7.1.5.1	7.1.6	7.2	7.3	7.4	7.5.1	7.5.2	7.5.3.1	7.5.3.2	81	8.1.2	8.1.3	8.1.4	8.2.1	8.2.2	8.2.3.1	8.2.3.2	8.2.4	8.4.1	8.4.1.1	8.4.2	8.5.1	8.5.1.1	8.5.1.2	8.5.1.3	8.5.2	8.5.4	8.5.5	8.5.6	8.6	8.7.1	8.7.2	9.1.1	9.1.3	9.2.1	9.2.2	9.3.1	9.3.2	9.3.3	10.1	10.2.1	10.2.2
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Scope, Policies

## Scope:

The manufacture and assembly of precision machined products for a diverse base of customers to including the aerospace, defense, and medical industries.

### Location:

2 Debush Ave, Unit A8, Middleton, MA 01949.

## Non-Applicability:

- Design and development of products and services.
- Post-delivery activities except for returns, complaints, etc.

### **Interested Parties:**

• The following entities have been identified as interested parties; customers, employees, suppliers.

### **Document Structure:**

The QMS structure will comprise this Quality Manual that shows the interaction of processes, a
description of the processes and links to other documents. In addition, this manual will be
supplemented by additional procedures and work instructions, either called out, linked to or available
to personnel. Knowledge of the availability of additional procedures will be covered through employee
awareness training. Knowledge of critical procedures or work instructions will be documented in the
training records.

## **Configuration Management:**

• Component configuration will be controlled through the document control process, review of customer requirements and traceability through production.

## **Management Representative:**

• The role of management representative is assigned to the Quality Manager. The Management Representative acts as the single point of contact for the QMS, however, responsibility for the QMS is shared between all managers, and, where documented through responsibilities, procedures and work instructions, etc., to all employees in the company.

## **Processes Requiring Validation:**

• There are no processes requiring validation in use within the organization.

## **Outsourced Processes and Purchases:**

• Outsourced processes comprise – certain machining, finishing, heat treating, chemical processing. All outsourced processes are managed using the purchasing process. The supplier is responsible for validating processes. Certs, Reports, training records etc. are required where applicable.

## Risk Management:

• Risk management is managed through the entire business process. Risk assessment is part of Sales, Purchasing, and Production. See each process for details – Clicking on highlights risk aspects. In addition, Management Review will be used to highlight risk in any of the agenda items, in particular

'Changes that Affect the QMS.' A strategic risk management spreadsheet is maintained to show system level risks. The matrix will be reviewed during management review.

### **Performance Evaluation:**

 KPIs (Objectives) will be set and reviewed as part of management review. Data is analyzed through all stages of the operation. Product conformity, customer feedback and supplier performance will be analyzed through the Nonconformance process, reviewed at Management Review.

## **Continuous Improvement:**

• Opportunities for improvement/ Risk mitigation will be identified at management review, as outputs of corrective action and as part of strategic business planning.

## **Counterfeit Material:**

 All materials and components will be purchased from US approved mills, distributors and component distributors. Certificates of origin as well as material certificates will be maintained. Certificates from outsourced processes will be maintained.

## Cybersecurity:

Good cyber security and information security practices will be maintained through
 FOD:

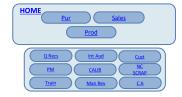
• FOD is practiced throughout the facility. Areas requiring FOD are identified, all employees training in the requirements of FOD.

## **Document Control/ Control of Customer Drawings/and Specifications:**

- All quality management documents are reviewed and approved by the Quality Manager for suitability
  and adequacy. Documents of external origin will be controlled by the relevant manager. Where
  documents are available electronically, they will be stored and controlled on the network. All
  employees will have access to all relevant documents at point of use. Placing the documents on the
  protected server is considered sufficient review and approval. Quality Records will be maintained.
- Customer documentation will be maintained on the server by Customer Name, Part Number and Revision. Customer specifications (such as quality requirements) will be obtained from the customer site on an as-needed basis or will be revision controlled if maintained on the server.
- Documents of external origin will be controlled on the network with access control. Documents will be periodically reviewed for revision status

## **CNC and CMM Inspection Programs:**

 Programs will be uniquely identified in the program library by customer name, part number and drawing revision.



RESPONSIBILITIES Quality Policy

# **Quality Policy**

Intellicut Inc. is committed to providing products and services while meeting or exceeding the requirements of our customers and interested parties. We comply with statutory and regulatory requirements and will continually improve our quality management system and business processes while setting objectives and measuring performance.



**RESPONSIBILITIES** 

# **QMS Approvals**

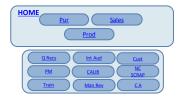
Revision	Approval Date	Approved By	Approved By	Change Description
1	10/10/2022	Armenak Chavushyan	Scott Winder	Initial release of Process Map based QM



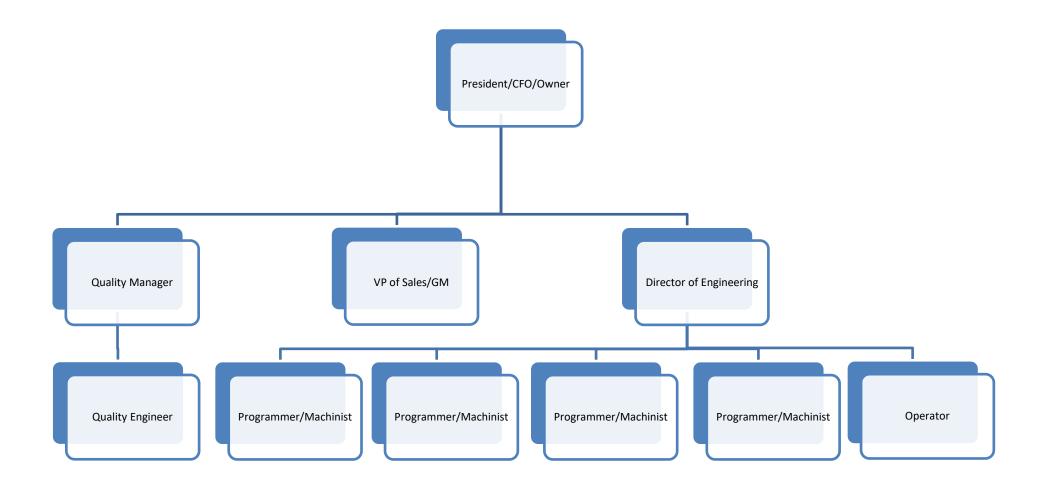
<u>RESPONSIBILITIES</u>

Certifications

Placeholder for Certs



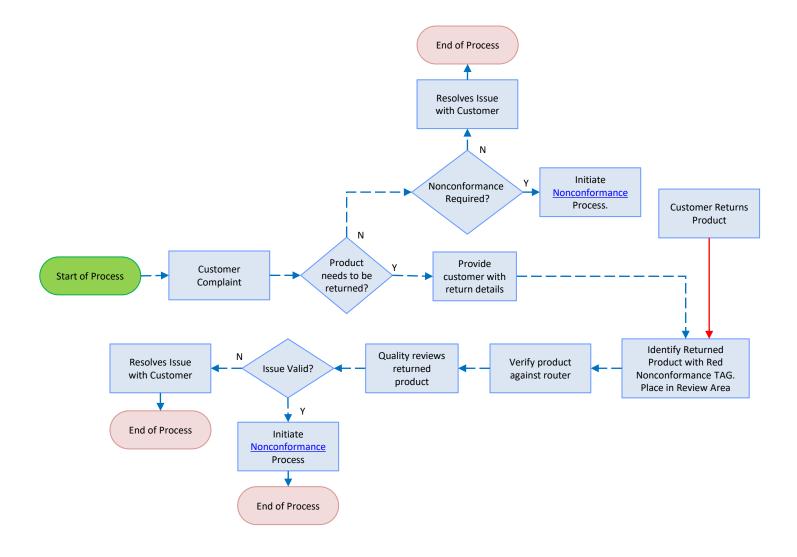
# **Organizational Chart**

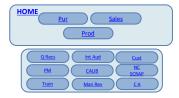




**RESPONSIBILITIES** 

## **Customer Communications**

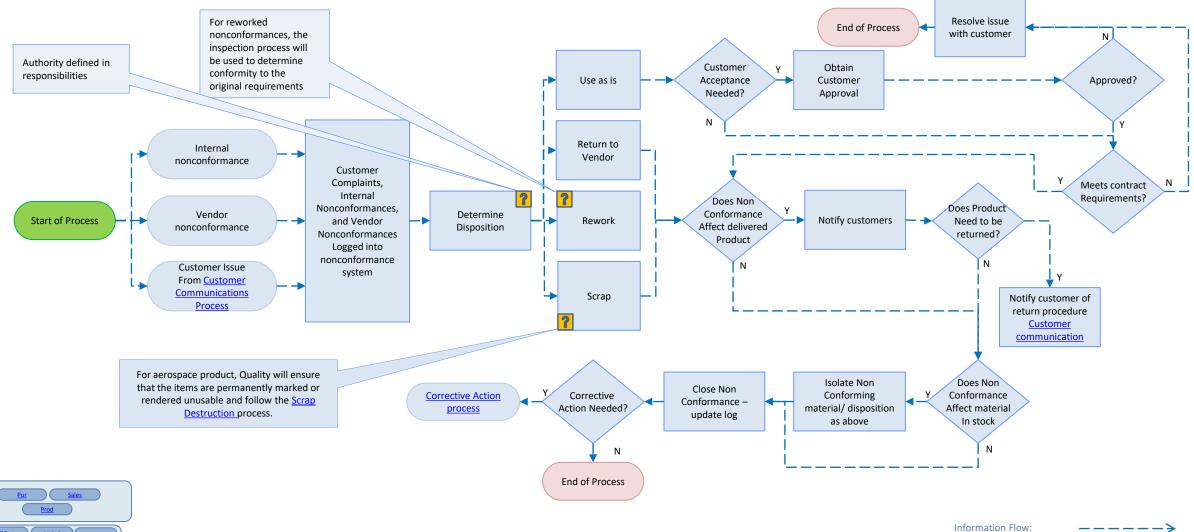




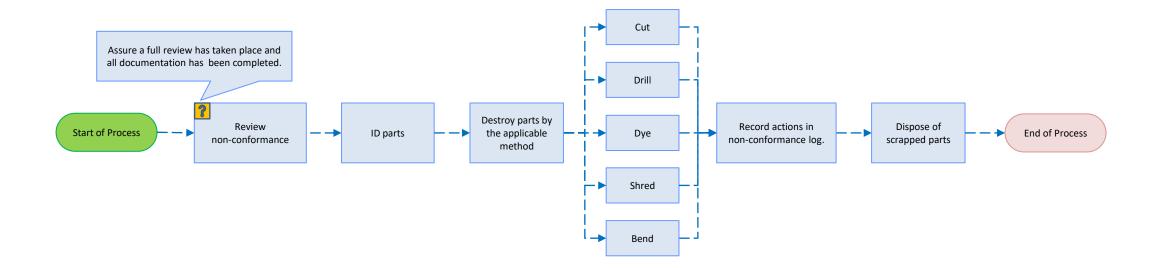
RESPONSIBILITIES Nonconformance

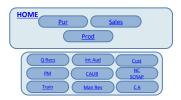
Identification of nonconforming product: All nonconforming product will be identified immediately by attaching a red nonconformance tag identified with the nonconformance number from the log as a minimum. Other data fields on the label should be completed with available information. Other means of identification can include, where appropriate; direct marking of the item, identification of the container, location in a nonconformance area, or other positive identification. Nonconforming material must never be left unidentified to prevent escapes.

**Responsibilities:** The Responsibilities Matrix will define who has the Authority to approve dispositions. Approval will be documented in the NC Databases.

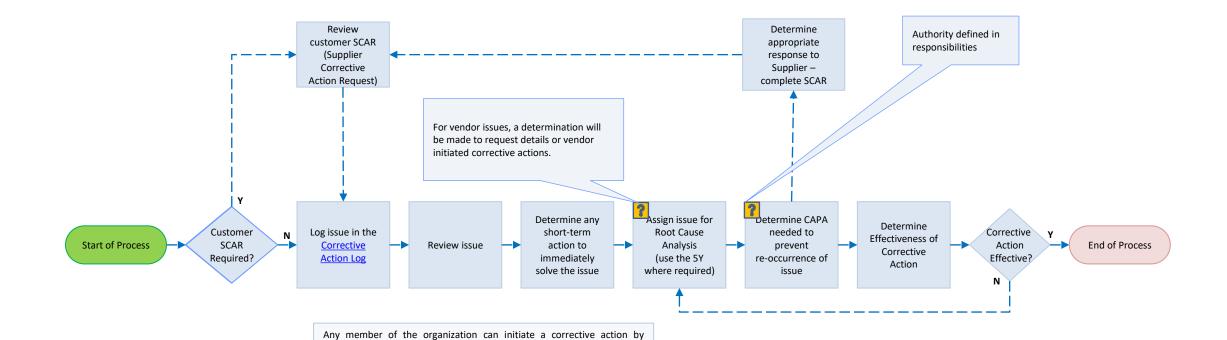


Scrap Destruction





RESPONSIBILITIES Corrective Action

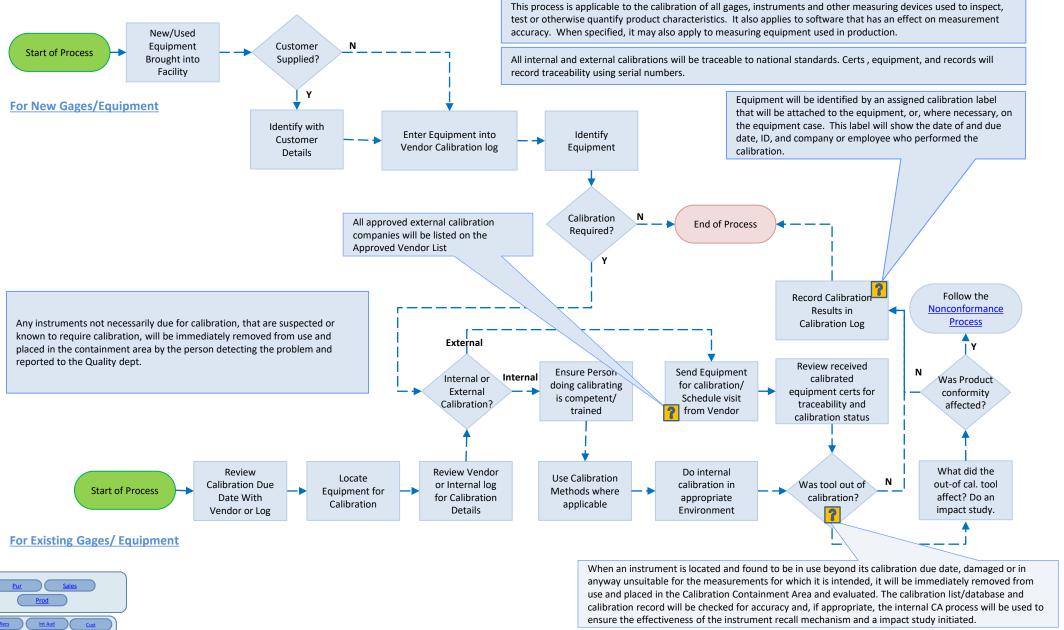


contacting the Production Manager. The Production Manager will be responsible for updating details onto the Corrective Action Log.

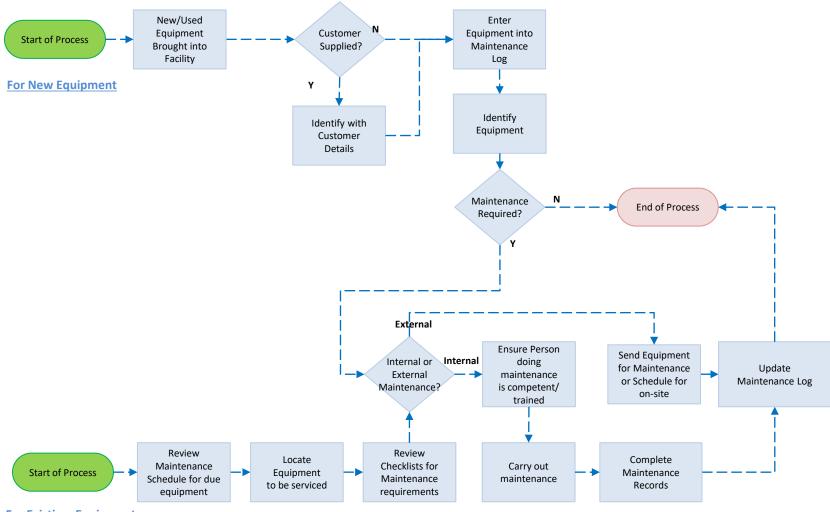


<u>RESPONSIBILITIES</u>

Calibration



Planned Maintenance



For Existing Equipment



<u>RESPONSIBILITIES</u>

Purchasing

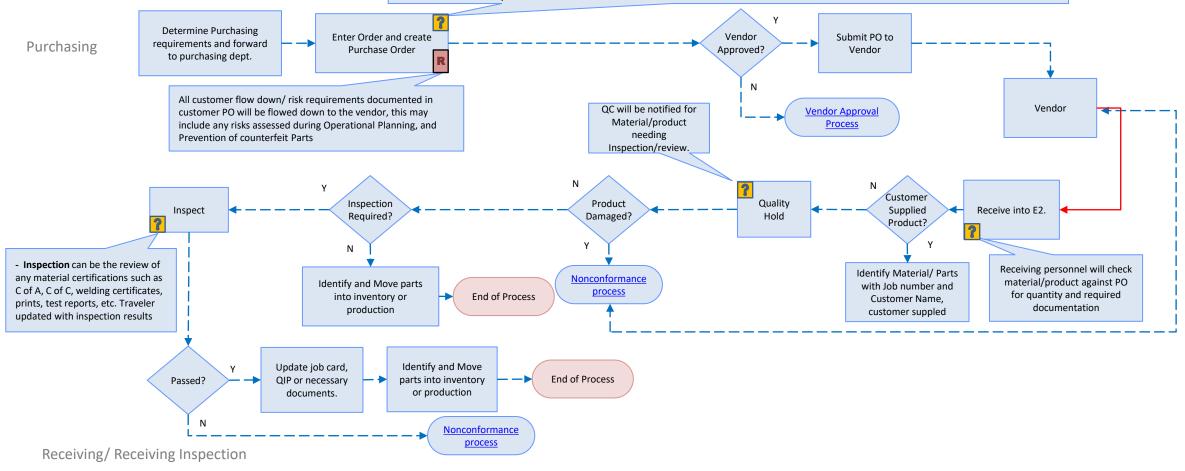
**Customer Supplied Property:** This can include material, gages, IP. Material will follow the process below. Gages will be identified with the customer's name. The gage will be calibrated as part of the calibration process.

### Flow down Requirements:

Where requirements for controlling documented information created by and/or retained by external providers differ from our internal Records List , such requirements will be flowed down on purchase orders.

All Purchase Orders will include, where required;

- Appropriate description of Product or service,
- Requirement's that external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met.
- Requirements for approval of product,
- · Requirements for qualification of personnel or Quality Management System,
- Requirements such as C of C or C of A, NADCAP
- Print numbers and revision.
- · Terms and Conditions/ Flow Down



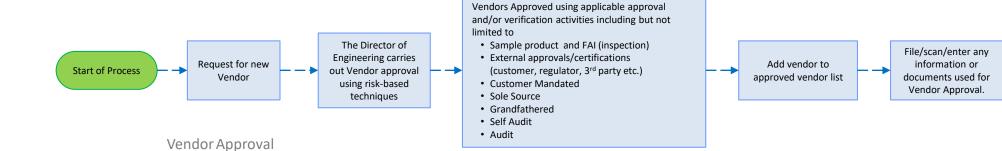


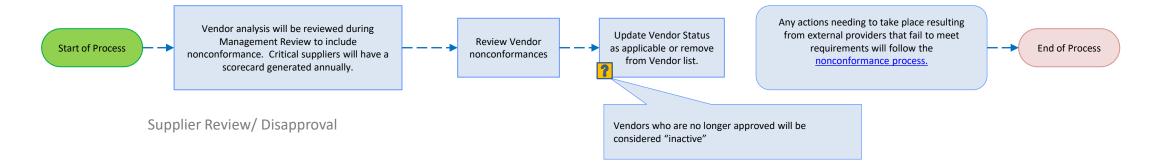
<u>RESPONSIBILITIES</u>

Vendor Approval

### Vendor Approval:

All vendors will be classified as critical or non-critical. Approval and re-approval criteria will be determined and documented in the approved vendor list. Supporting documentation will be maintained.







**End of Process** 

## **Production**

Follow

nonconformance

process

Update traveler,

identify product and

place on the

nonconformance shelf

Passed

Inspection?

### **Product Identification**

Product and materials will be identified and accounted for at all times to show status, Inspection status (pass/fail, requires inspect, etc), qty's and configuration using The traveler, Identification tags, designated areas or by direct marking. This includes property belonging to customers and/or external providers.

When traceability is a requirement, the methods and documented information necessary will be identified during planning and flowed down as necessary enabling traceability.

**Post delivery activities** are limited to Customer returns. When problems are detected after delivery, actions, including investigation and reporting will follow the . Customer Communication process.

### Preservation

Preservation of outputs during production; cleanliness, FOD, handling and storage will be controlled as necessary. Specific requirements will be called out on the traveler or related instructions.

All personnel involved in production and handling of product will be trained in FOD. Areas subject to FOD will be clearly identified. This includes ensuring previous jobs are purged from the work area .

When sampling is deemed necessary as a means of product acceptance, sampling plans will be justified using recognized statistical principles that are appropriate for use or as stated by the customer.

### Nonconformance

All nonconforming product and materials will be identified with a Red Tag. Where disposition is re-work, product will follow the same process outlined below. For aerospace product, repair will not be an option. This includes any property belonging to customers and/or external providers.

Intellicut does not perform any process(s) where resulting output cannot be verified by subsequent monitoring or measurement. In the case for outsourcing, Intellicut will verify certs, test reports and monitor supplier performance to control these process(s).

Outsourced

product received

passed to QC for

inspection

### FAI

For jobs requiring first article approval by the customer, or first piece inspection, the Quality Inspection Plan will be used to record/document inspection data. This process shall be repeated when changes occur that invalidate the original results (e.g., engineering changes, manufacturing process changes, tooling changes).

Depending on customer requirements and Traveler, print or specifications may be used at this review for planning as well as any identified planning flow downs.

Quality planning will also be underway during this review.

Review with

Production Control.

As applicable, programmer/ machinists will be responsible for obtaining and verifying;

- Materials
- Tooling
- Fixturing
- Purchased/Customer supplied Material
- Software software/ programs
- Gages

g and

Operators set up and

follows job in

accordance with the

job card.

Components, traveler passed to shipping

Shipping reviews

requirements,

checks PO, ships

to vendor

Outsourced processes?

End of Process

Inspections carried out as per quality plan. QIP and traveler updated

Completed product

shipped or put into

inventory

Production/ Quality
Documentation
reviewed, approved

write protected

Shipment Preparation
- check router for completeness, any

special packaging.

Production package will include any risk identified and documented during planning.
Package can also include, (where necessary):

Production package

Prepared.

- Traveler
- Inspection
- Print
- Additional instruction sheets

Consideration specific requ

Production planning

distributes production

package based on delivery

dates, machine availability

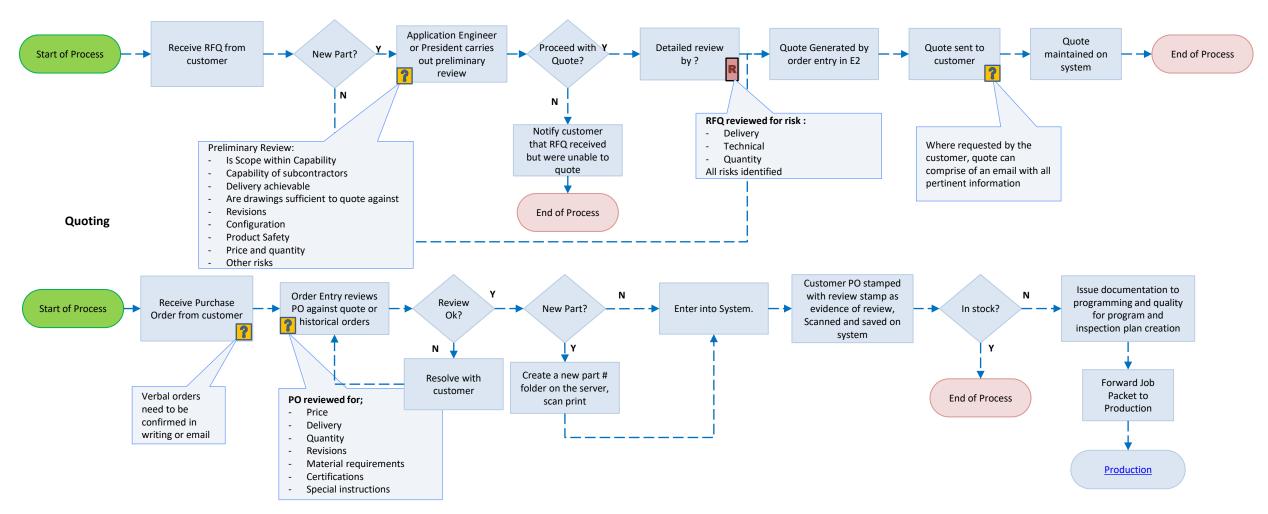
Consideration will be given for the skill and any specific requirements needed when assigning to programmer/ machinists

## Production

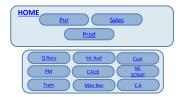
**Start of Process** 



## **Quoting and Sales**

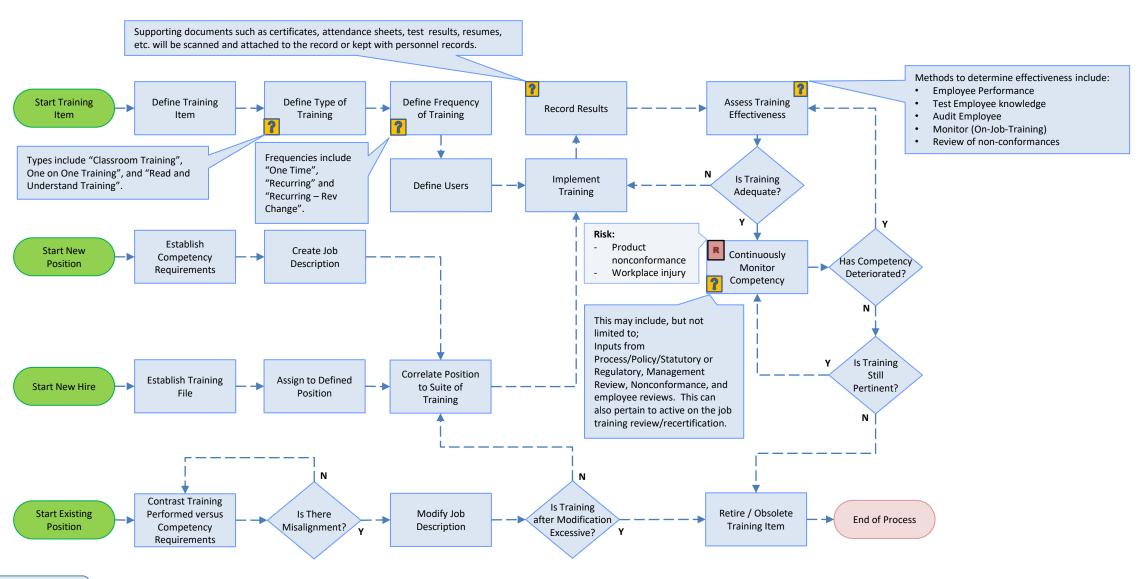


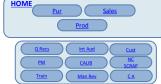
Sales - Order Processing



<u>RESPONSIBILITIES</u>

Training





**Quality Records** 

Quality Records provide evidence that Quality Management System processes are being followed. Examples of Quality Records include minutes from meetings, completed forms, databases, and other documents proving an occurrence.

The following would be considered Quality Records:

**Purchase Orders** 

Travelers

Inspection records

All employees will be responsible for ensuring records are collected according to procedures, are clear and concise, and are stored appropriately.

For retention period set by customer that supersede our retention policy, records will be maintained and managed separately with clear indication of the retention requirements





Information Flow: —————>

Material Flow: ——————

Approved By Management Team – Revision 1

**Management Review RESPONSIBILITIES** 

Management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Management review Meeting Attendees shall include at a minimum:

- President & CEO
- **Operations Manager**
- Quality Manager
- Sales Manager

Key Process Data Input Data from

Management

Quarterly **MRM AGENDA** Monthly Semi-**Annually** Annually **Previous Minutes Review of Open Acton Items** Χ **Internal Audits Quality Policy Process/Product Conformity** Х **Corrective Actions KPI's/Objectives Supplier Analysis** Resources Χ **Plant & Equipment Production Environment Training / Human Resources Changes that affect the QMS Continuous Improvement Risk Management Internal Factors that affect QMS** Χ **External Factors that affect QMS** 

**Document Management** Review Outputs;

Action Items

Meeting

**Output Data** 

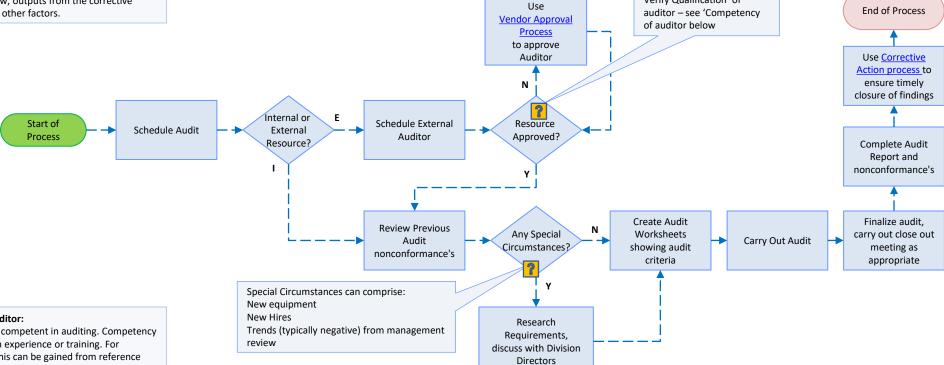
- Goals and objectives
- Corrective Actions
- Continuous Improvement

Communicate objectives, performance, actions to appropriate personnel and workforce

RESPONSIBILITIES Internal Auditing

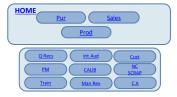
### Internal Audits:

A schedule will be maintained to show when audits will be carried out, and what processes will be covered. At a minimum, audits will be carried out once a year, however, the actual frequency will be determined by the schedule, outputs from management review, outputs from the corrective action process and other factors.



## Competency of Auditor:

All auditors will be competent in auditing. Competency can be gained from experience or training. For external auditors this can be gained from reference (Resume) or certificates of audit training. For internal auditors, auditors will be recruited from staff who have previous documented experience or staff will be sent out for training. All auditors shall have documented competency in the relevant standards being audited.



Verify Qualification of