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Quality Management System Manual Revision E

Compliant with AS9100 Revision C



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# 1 Introduction to the Quality Management System Manual

This quality management system manual has been designed by Witco Inc. hereafter referred to as Witco, for the implementation of customer supplier quality requirements and the requirements of AS 9100. This manual contains:

- The scope of Witco's quality management system
- The sequence and interaction of the quality management system processes
- Justification for any exclusion from AS 9100, ISO 13485 or ISO 9001 in the quality management system
- Includes references to the following procedures which are required by AS 9100, ISO 13485 or ISO 9001:
  - o <u>Document Control</u>
  - o <u>Records Control</u>
  - o <u>Control of Nonconforming Product</u>
  - o Internal Auditing
  - o <u>Corrective Action</u>
  - o <u>Preventive Action</u>
- Descriptions of the processes in the quality management system including where applicable;
  - the objectives and measurables of the process;
  - the records required by the process;
  - rules that apply to users of the process;
  - o process instructions necessary for the successful function of the process
- A list of the authorities approving this Quality Management System Manual
- A brief description of revisions made to this document throughout its lifetime

## 1.1 Quality Management System Scope

This Quality Manual provides guidance and establishes requirements for Witco Inc. to remain compliant to the AS9100 Quality Management System. Witco's Quality Management System is tailored to meet the following AS9100 requirements:

## Precision CNC Machining for Commercial and Aerospace Industries

Situations where partial or no compliance is required will be exceptions and specifically designated in the contract or product work instruction.

## **1.2 Quality Policy Statement**

The mission of Witco Inc. is to provide complete customer satisfaction by successfully employing resources, striving for continuous improvement, and by utilizing our quality management system to assure a sustainable advantage over our competitors through our dedication, skill, and effort.



# 1.3 Exclusions from AS 9100, ISO 13485 or ISO 9001 and Justification for Exclusion

Clause from Standard	Торіс	Justification Statement
7.3 of all 3 Standards	Design Control	Product design is not required by our customers and not performing this process does not adversely affect compliance with statutory or regulatory requirements. Customer satisfaction is unaffected by excluding the design control process.

## **1.4 Approvals**

The approvals indicated below are for the approval of this revision of the Quality Management System Manual

Name	Title	Name	Title

## **1.5 Revision History**

Letter	Date	Brief Description
Α	10-07-09	Initial Release of document for management review prior to implementation
В	02-01-10	Clarification revisions throughout, enhancement of risk assessment and configuration management sections, addition of section numbers to all headings, rewritten preventive action procedure. Enhancement of document control, nonconforming product and records control procedures. Record retention times increased to meet general aerospace requirements.
С	03-05-10	Clarification of revisions throughout. Removed Risk Drivers Section, updated gages selection, and redefined the manner in which scrap will be handled.
D	06-03-10	Update Quality Manual Scope, update process interaction with outsourced processes, clarify records retained at supplier, clarify OK to Proceed disposition, and clarify actions taken when CAR is not effective.
E	07-02-10	Updated internal auditor competency requirements, defined individual having approval/disapproval authority for suppliers, and defined the process for approving personnel for dispositions of non-conforming material.



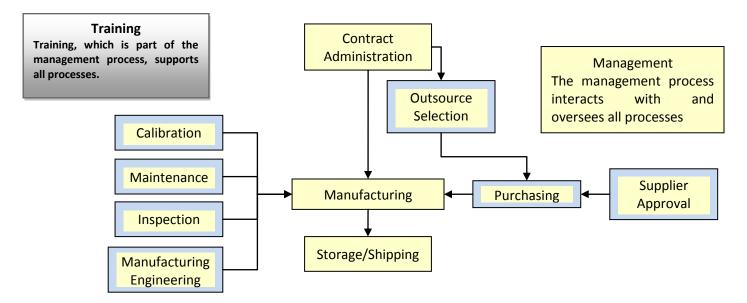
# 2 **Process Sequence and Interaction**

The **management process** is responsible for oversight of all processes, tracking and analyzing customer satisfaction, management review and the administration of the training process through the Human Resources department.

The **contract administration process** is responsible for the preparation of quotations, contract review, procurement of materials and services and planning of product realization.

The **manufacturing process** is responsible for producing and inspecting the product. They support these processes with maintenance and calibration.

The storage and shipping process is responsible for packaging product for inventory or immediate shipment.



## 2.1 Interaction of Procedures with Processes

## 2.1.1 Document and Records Control

Document and Records Control procedures are applied to all processes and all procedures.

## 2.1.2 Internal Audit

The internal audit procedure is applied to all primary processes and the supporting processes are audited as part of the primary process that they support. Internal audit results are reviewed in the management process. The management process administrates the internal audit procedure.

## 2.1.3 Control of Nonconforming Product

The nonconforming product procedure applies primarily to the purchasing, manufacturing and shipping processes. It provides review data to the management process.

## 2.1.4 Corrective and Preventive Action

The corrective and preventive action procedures are administered by the management process and applied to other processes as directed by the management process.



# 3 Management Process

This is the process by which Witco manages the quality management system to ensure that its various departments and employees remain focused on the customers.

## 3.1 Management Process Objective(s) and Measurement(s)

**Customer Satisfaction** – Customer satisfaction is measured by the number of customer complaints and by monitoring the data that affects customer satisfaction; Delivery Performance and Customer NCM's.

**Employee Competency** – Employee competency is measured by monitoring the number of issues with a resolution on the Issues Log of training or employee error.

## 3.2 Management Process Records

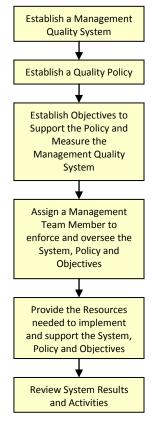
The records listed below are those necessary for the management process and may not be an exhaustive list. These records are controlled in accordance with the <u>Records Control Procedure</u>.

Record Type	Record Format	Minimum Retention Time	Maintenance Responsibility
Management Review	Issues Log	3 Years	Management Rep.
Employee Training	Training Records & Training Matrix	Length of Employment +1 Year	Office Manager

## 3.3 Management Process Rules

- 1. Control all documents created by management and providing instruction per the <u>Document Control Procedure</u>
- 2. Communicate all relevant quality management system, customer, product, statutory and regulatory requirements to the appropriate departments and personnel within Witco and where appropriate, to customers and suppliers
- 3. Establish, communicate and maintain Witco's <u>quality policy</u> in accordance with section 5.3 of the standard
- 4. Ensure that objectives, consistent with the quality policy, are established to ensure the effectiveness of the quality management system processes and the conformance of products to their requirements.
- 5. As a minimum, product conformity and on time delivery performance shall be measured to give evidence of customer focus.
- 6. Ensure that all process objectives are assigned target values that are consistent with the goals of Witco and will maintain customer satisfaction.
- 7. Assign at least one member of the management team with the authority and organizational freedom to perform the duties outlined in sections 5.4.2 and 5.5.2 of the AS 9100 standard as the management representative for quality
- Establish and maintain an organization chart that identifies key management functions within Witco, including the management representative discussed in rule 7, with the names of the managers and supervisors for the functions. The chart shall be a controlled in accordance with the <u>Document Control Procedure</u>.
- 9. Conduct management reviews at least once each year in accordance with the <u>Management Review Instruction</u>.
- 10. Ensure that all employees are competent to perform their assigned tasks.
- 11. Ensure that Witco's infrastructure and work environment is maintained to achieve conformity with product and customer requirements.







# 3.4 Management Process Instructions

## 3.4.1 Management Review

Management reviews may be conducted by one of two methods. The management representative will maintain a checklist of review inputs to ensure that all inputs receive a management review at least once each year.

The first method would be to review a log or document to determine if a <u>review input</u> indicates that a management action should be assigned. The record of this type of review would be initials or other indication of the managers that reviewed the input and the date of the review. This may be accomplished by circulating an email with the input data attached and requiring a response from all reviewers which could be saved as evidence of review. If any manager feels an action is necessary the second method (meeting) will be used to discuss and assign this action.

The second method would be to schedule and conduct a meeting with management personnel to discuss <u>review</u> <u>inputs</u> and determine if a management action should be assigned. The record of this review would be meeting minutes that indicated the managers attending, the topics discussed and the actions assigned.

Actions assigned should indicate the nature of the action, an individual responsible for coordinating the action, a due date for the completion of the action, and/or progress reporting intervals for the action. The nature of the action may be for:

- The correction of a problem (see <u>Corrective Action Procedure</u>)
- The prevention of a problem (see <u>Preventive Action Procedure</u>)
- The improvement of the effectiveness of the quality management system and its processes
- The improvement of Witco product
- The development or procurement of needed resources

## 3.4.1.1 Review Inputs

**Issues Log** – This document will provide information on product conformity, corrective action, preventive action, internal audits, customer feedback, supplier problems and internal issues that can affect process performance. A review of this log also provides evidence of the effectiveness of employee training by reviewing the nature and number of employee caused issues.

**Documents referenced in the Issues Log** - Documents referenced in the log are filed by type and issue number.

**Objective Measurement Charts** – These charts will provide information on process performance to the objectives targeted by management.

**Open Assigned Actions** – These are actions assigned from previous meetings. They are reviewed to determine if they have been completed and effectively accomplished their purpose.

**Changes that could affect the quality management system** – This would include revisions to the management quality system standards upon which Witco has designed its system. It would also be a review of customer supplier quality requirement changes or additional requirements from new, prospective or existing customers.

**Improvement Recommendations** – These are suggestions made from various sources both internal and external and are reviewed for feasibility and benefit.



## 3.5 Use of the Issues Log

Any manager or authorized employee may make an entry in the Issues Log. It is the management representative's responsibility to monitor and maintain the log and to assign corrective actions in accordance with the <u>Corrective</u> <u>Action Procedure</u>, as necessary.

The Issues Log is used to gather information on product non-conformances found internally, customer complaints, failure to meet the customer's delivery requirements, product returns related to problems caused by Witco or its supplier, non-conformances caused by a supplier, equipment failures and other issues deemed worthy of record by the management representative.

Each log entry is sequentially numbered. The issue number is used as the control number for documents generated to request actions related to the log entry. (I.e. Corrective Action Request, Supplier Nonconformance Reports, etc.)

The Issues Log is the key management tool for recording and reviewing activities both positive and negative in the quality management system.

## 3.6 Resource Control

The two primary resources to be controlled by this instruction are human and infrastructure resources. They are controlled to the extent necessary to achieve conformance with customer and quality requirements as they relate to products and services provided by Witco.

## 3.6.1 Human Resources

## 3.6.1.1 Competency Requirements

The education, skills, training and experience requirements shall be established and documented for each position at Witco that has an impact on product quality. A checklist or job description shall be prepared from these requirements to be used as a training guide.

## 3.6.1.2 Training

The competency requirements are used by the trainer as a guide to the employee's training. When all training is completed, the area supervisor or manager reviews the trainee to determine the effectiveness of the training. Effectiveness may be measured by observation, oral or written testing or other types of examination. The results of all training are documented in a training record.

The supervisor, the trainer (if not the supervisor) and the trainee sign the training record to indicate agreement with the record. The record is filed as a training record and retained in accordance with the Management Process Records table in this document.

Group training may be documented through the use of a sign in sheet attached to an outline of the training topic.

The effectiveness of training is monitored through <u>management review</u> of the Issues Log by analyzing issues that could be attributed to insufficient or ineffective training. It is also monitored thru the use an employee review system conducted between the employee and the area supervisor/manager.

## 3.6.1.3 Training Matrix

The training matrix serves as a master record of employee training by indicating the functions for which each employee is trained and the level of training. Levels include: Able to Substitute, Fully Competent, and Able to Train Others



## 3.6.2 Infrastructure Resources

Witco maintains infrastructure resources and a work environment necessary to achieve conformity with product requirements. A preventive maintenance program is administered through the manufacturing process to maintain infrastructure resources.

## 4 Contract Administration Process

This is the process by which Witco determines the feasibility and risk of compliance with customer, contract, product, statutory and regulatory requirements and establishes a price for the effort. This is also the process by which contracts are reviewed for requirements that need to be established and communicated.

## 4.1 Contract Administration Process Objective(s) and Measurement(s)

It is the objective of this process to ensure that all customer requirements, including risk, are understood prior to acceptance of the contract. This objective is monitored through on-time delivery, cost of non-conformances, and customer complaints.

## 4.2 Contract Administration Process Records

Record Type	Record Format	Minimum Retention Time	Maintenance Responsibility
Quotation	Quote Form and Notes	6 Months	Sales Manager
Contract Review	Copy of Reviewed Order	Length of Job + 7 Years	Sales Manager

## 4.3 Contract Administration Process Rules

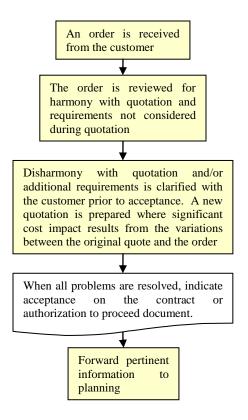
- 1. Witco effectively communicates with the customer about information relating to request for quotation, contracts or authorizations to proceed, including amendments. If the customer requires a specific proposal format, that format will be used to submit the proposal.
- 2. All customer requirements must be considered including delivery and post delivery activities.
- 3. If the customer does not provide a clear description of the product or requirements, Witco will, confirm the customer's requirements on key characteristics prior to acceptance.
- 4. If requirements cannot be met, attempt to resolve with the customer or decline the offer to quote.
- 5. Records of the results of the review and actions arising from the review will be maintained.
- 6. Customer feedback, including customer complaints are provided for management review
- 7. When required planning documents are prepared in a format required by the customer.
- 8. Planning must communicate acceptance criteria
- 9. Planning must identify key and critical characteristics
- 10. Planning must be clear and understandable to the user
- 11. When planning documents refer to drawings, work instructions or specifications they must also reference their engineering change level
- 12. All product requirements must be documented



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# 4.4 Contract Administration Process Instructions

## 4.4.1 Contract Review Instruction



## 4.4.2 Risk Assessment

As part of reviewing a contract risk factors must be considered. Risk factors include but are not limited to:

- The number of key or critical characteristics
- Characteristic Tolerances
- Material Requirements
- New Processes or Instructions
- Delivery Requirements
- Outsourced Processes

The estimator considers these risk drivers to determine if there is risk. High risk projects may require extraordinary measures to ensure that customer requirements are met. These requirements will be communicated to the planning process for incorporation into appropriate scheduling and manufacturing instructions.

#### 4.4.3 Risk Management

Risk is assessed by the sales department and forwarded to planning for incorporation into planning documents. Risks are identified even if "No Risk" is the identifying communication. If after accessing the risk drivers it is determined that measures are needed to mitigate the risks, mitigation methods should be documented and communicated.



#### 4.4.4 Configuration Management

Witco is not the design authority for products produced. Engineering change levels shall be verified as part of contract review.

#### 4.4.4.1 Identification

The engineering change status of the product, the assembly and sub assemblies shall be maintained throughout processing.

All documents and records that make reference to the part number shall also make reference to the engineering change status of the part or assembly. As a minimum this includes:

- Inspection Records
- Inventory Records
- Shipping Documents
- Product specific work instructions

If manufacturing drawings are produced from customer drawings, the engineering change level of the customer drawing shall be referenced on the manufacturing drawing, specification or instruction.

All product or assembly labels shall make reference to the engineering change status of the product or assembly.

## 4.4.4.2 Software Controlled Manufacturing and Inspection

Programs created from software for the control of manufacturing and/or inspection operations shall be controlled in accordance with the document control procedure. The identification of these programs shall also reference the engineering change status of the product for which it was created.

## 4.4.4.3 Configuration Changes

Configuration changes must be approved by the customer.

If a configuration change is approved to be implemented after production has begun or while product of the previous configuration is in inventory, the affected product should be processed in accordance with the procedure for the control of nonconforming product.

## 4.4.4.4 Configuration Audits

Quality control personnel shall audit documentation and identification at each inspection point to ensure configuration identification is correct and maintained.

Configuration identification shall be audited as part of the internal auditing process for product in process and in inventory.

## 4.4.5 Planning Instruction

- 1. Review Contract Administration Process records, customer requirements, customer drawings and specifications. (Process Input)
- 2. Verify customer documents are clear and understandable convert to English, as needed.
- 3. Determine any special tooling, gauging or equipment requirements.
- 4. Determine characteristics to inspect and inspection frequencies with, "out of the ordinary" controls placed on key characteristics
- 5. Determine the operations to be performed and the sequence, if vital, that the operations shall be performed.



- 6. Identify the non-standard measuring devices and/or if imperative, the specific standard device to be used in measuring inspection characteristics.
- 7. Determine special set up requirements
- 8. Identify programs and revision levels needed at each computer controlled operation
- 9. Identify special handling instructions, if any, such as, the use of gloves or masks when handling product.
- 10. Identify any other special requirements such as customer designated special characteristics
- 11. Create the Shop paper and schedule to meet delivery requirements. (Process Output)

# 5 Purchasing Process

This is the process that purchases products and services necessary to realize a product in compliance with customer, product and process requirements. This process is also used to purchase services to support compliance with quality management system requirements. The process assesses product and service compliance with purchasing requirements.

# 5.1 Purchasing Process Objective(s) and Measurement(s)

The objective is to procure quality products and services in time to meet scheduling requirements. This objective is measured by measuring supplier quality and delivery performance.

Record Type	Record Format	Minimum Retention Time	Maintenance Responsibility
Supplier Approval	er Approval Supplier Profile and/or QMS Registration Certificate		Sales Manager
Approved Supplier List	Approved Supplier Registry	Ongoing	Sales Manager
Corrective Action Request	CAR and Issues Log	3 Years	Management Representative
Receiving Inspection	Initials on Packing Slip and/or Supplemental inspection Report or Test Certificate from Supplier	7 Years	Sales Manager

## 5.2 Purchasing Process Records

# 5.3 Purchasing Process Rules

- 1. All suppliers must complete a Supplier Profile every three years, as a minimum
- 2. Suppliers must be on the Approved Suppliers List and be monitored in accordance with instruction
- 3. Purchase documents must clearly describe the product or service to ensure the correct product or service is provided
- 4. When the purchase order references another document it must also reference its engineering change status
- 5. All suppliers must allow access(with reasonable notice), to areas where our product is processed or stored, to our customers or regulatory agencies
- 6. Where applicable, customer requirements must be flowed down on Witco's purchase order to its supplier.
- 7. All defective products or services shall be recorded in the Issues Log and an NCM will be initiated. The Management team will review the NCM and determine if a CAR is necessary. If a CAR is initiated it will be flowed down to the supplier. A late delivery as defined in this process is the same as a defect.
- 8. All suppliers on the approved supplier list shall be monitored for quality and delivery performance.



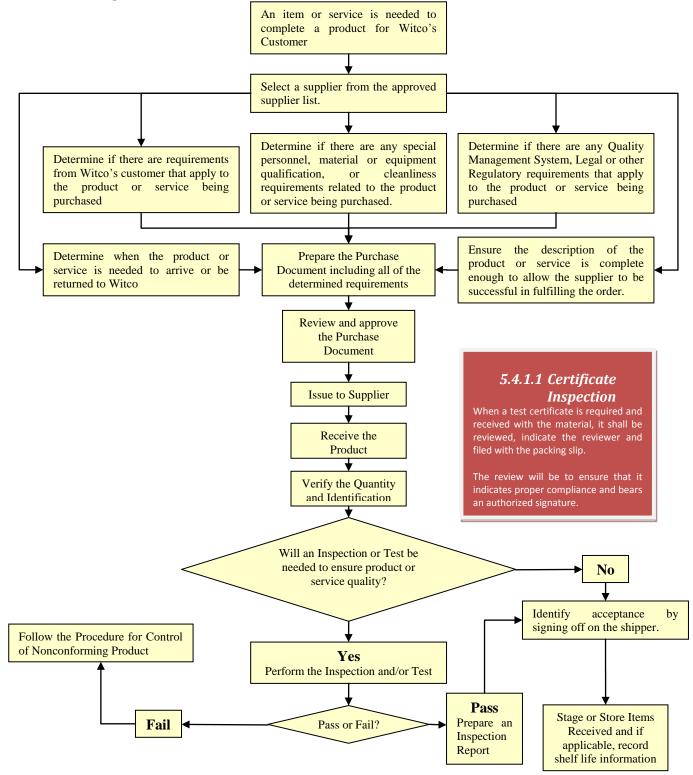
- 9. Failure to meet performance requirements will be cause for corrective action. Continual failure will make the Supplier subject to being placed on "Inactive" status and a search for a replacement supplier will begin.
- 10. Suppliers that refuse to respond to a Corrective Action Request are subjects for "Inactive" status and eventual replacement.
- 11. Items with a shelf life shall be clearly identified.
- 12. The use of a customer designated supplier does not absolve Witco from enforcing compliance with its purchasing process requirements
- 13. If records of quality are required to be retained by the supplier, record control and retention requirements shall be clearly defined
- 14. No purchased product or material shall be released without the completion of required verification activities



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## 5.4 Purchasing Process Instructions

#### 5.4.1 Order Preparation and Product Verification Instruction





## 5.4.2 Raw Material Control Instruction

Raw materials are inspected upon receipt and identified upon acceptance. Mixing of heat lots is only prohibited if it is a requirement of the customer. In that case, material will be identified with the heat lot number from the certification and may not be mixed in the same location.

#### 5.4.3 Supplier Approval and Monitoring Instruction

This process is only performed for suppliers manufacturing or servicing product or raw materials used by Witco which adds value to the product Witco is supplying to its customer(s).

Suppliers identified as providing a product or service that adds value to the finish product must complete the new supplier paperwork (Supplier Profile, Non-Disclosure Agreement, ITAR Compliance Letter, and the Terms and Conditions Acknowledgement). They must also be approved by the manager of purchasing or a Management Representative prior to the issuance of a purchase order except as noted in 5.4.3.2.

The manager of purchasing and Management Representatives has the ability to disapprove or inactivate a supplier at any time and for any reason.

## 5.4.3.1 Customer Designated Suppliers

If Witco is required to choose from a list of suppliers prepared by our customer or a supplier required by our customer and the supplier has not been approved by Witco by this process, we will use those suppliers for that customer only.

#### 5.4.3.2 Emergency Purchase

An emergency purchase is defined as a purchase of an item from a source which has not been approved because the evaluation process would cause a critical delay in the product or service which is not available from an approved supplier. The evaluation process must commence with the initiation of the purchase. Only one purchase is permitted without approval of the Management Representative and no purchases can be made after 30 days from the emergency purchase without completion of the evaluation process. Disqualified suppliers may not be used for emergency purchases.

#### 5.4.3.3 Evaluation Criteria

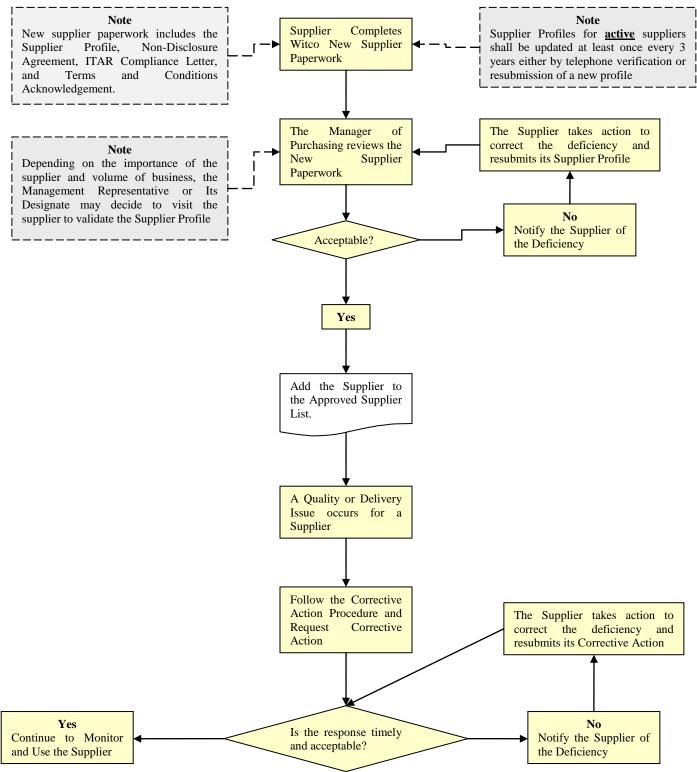
Suppliers are evaluated continually and may be placed on "Inactive" status at any time at the discretion of the Management Representative. All nonconformances including late deliveries (as defined in the box on this page) are documented on a Corrective Action Request. 5.4.3.5 Definition of Late A supplier is considered late if delivery is past their quoted delivery date.

Suppliers will also receive Corrective Action Requests for poor performance. If a supplier is issued more than 3 CARs in a month or more than 10 in a year, they will be issued a Corrective Action Request for poor performance. Inadequate responses or failure to respond may result in being placed on "Inactive" status.



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#### 5.4.3.4 Evaluation Flow





# 6 Manufacturing Process

This is the process that creates the finished product and monitors its compliance with customer, contract, product, process, statutory and regulatory requirements.

## 6.1 Manufacturing Process Objective(s) and Measurement(s)

It is the objective of this process to effectively and efficiently meet customer requirements for quality and delivery. These objectives are measured by Witco's internal and external cost of non-conforming material and on-time delivery.

## 6.2 Manufacturing Process Records

Record Type	Record Type Record Format		Maintenance Responsibility
In Process Inspection	In Process Inspection In Process Inspection Sheet		Sales Manager
Final Inspection	Final Inspection Report	7 Years	Sales Manager
Process Verification	Final Inspection Report or First	Life of Active	Sales Manager
	Article Inspection Form	Part	Sales Mallager
Equipment Maintenance	Maintenance Log	Life of	Engineering
	Maintenance Log	Ownership	Manager
Device Calibration	Device Calibration Calibration Certificate		Quality Manager
Customer Satisfaction	Management Issues and Action Log	3 Years	Management Rep

## 6.3 Manufacturing Process Rules

- 1. All customer supplied items are checked for damage and adequacy upon receipt
- 2. All customer supplied items shall be clearly identified to indicate ownership
- 3. Issues with customer supplied items shall be reported to the customer for disposition
- 4. All measurements for planned inspections shall be taken using calibrated measuring devices
- 5. Operators are responsible for monitoring the quality of their work
- 6. Process instructions will be accessible to all employees that use them
- 7. Inspection results will be recorded as directed
- 8. Production equipment used will be maintained in accordance with the maintenance instruction
- 9. Non-conformances shall be handled in accordance with the procedure for the <u>Control of Nonconforming</u> <u>Product</u>
- 10. All employees have the authority to stop production and contact supervision when ongoing product quality is questionable
- 11. All employees are responsible for maintaining the identity of product in process as it moves from step to step. This includes, where applicable, lot traceability identifications.
- 12. Employees are responsible for maintaining a clean and safe work area.
- 13. The shelf life of product and processing materials shall be verified as unexpired prior to use in manufacturing.
- 14. Sampling shall be done in accordance with a recognized statistical-<u>sampling plan</u>.
- 15. All processing agents, oils, debris, etc. shall be removed from product prior to shipment, unless specified by customer.



## 6.4 Manufacturing Process Instructions

## 6.4.1 Production Process Verification (First Article)

Production process verification shall be performed as required by customer on a completed product from the first production run. If a change is made to the equipment, material, process, work instruction or supplier used to perform the production process verification, new process verification shall be performed. Changes to programs used to perform computerized operations should be reviewed for impact and may require new production process verification. The results will be documented in either Witco's format or a format required by the customer. As a minimum, all records shall indicate the customer, part number and engineering change level.

#### 6.4.1.1 PPV Process

The process for performing production process verification is as follows:

- 1. Review the product specification and any specifications referenced on the top level specification
- 2. Sequentially number each item, including the notes, on the top level specification (part drawing)
- 3. Prepare an inspection report with numbers that correspond to those identified on the drawing
- 4. Select the appropriate device for the inspection of each characteristic
- 5. Perform the Inspection
- 6. Record the results and the measuring device used on the first article inspection form. The record must also indicate pass/fail for each characteristic.

#### 6.4.2 In-Process Inspections

#### 6.4.2.1 First Piece

The first piece of the production run shall be inspected by someone other than the process operator to verify that it complies with specification requirements. If the first piece fails to pass, the inspection will be performed again on the next part after the proper adjustments in the process have been completed.

The first piece inspection shall be performed again if the set up is broken down and reset up later or on another machine.

The first piece will remain identified and segregated until the operation run is complete. The approved first piece shall serve as a workmanship standard for visual inspections being performed in process.

First piece approval shall be documented on the shop paper and inspection report.

## 6.4.2.2 On Going Inspections

Additional inspections are performed by the process operator and documented in accordance with the instructions on the Inspection Report Verification of Measuring Devices

## 6.4.3 Verification of Measuring Devices

All dimensional inspections performed to evaluate the acceptance of a product shall be performed with a device that has current and identifiable calibration verification or must be verified prior to use. Gages identified as "Reference Only" cannot be used to accept or reject product.

Gage users are responsible for maintaining clean gages, storing them in a manner that prevents invalidation of the verification and reporting any suspect conditions. Suspect conditions include accidental impact such as dropping or bumping.



#### 6.4.3.1 Gage Selection

Gages selected for use must, at a minimum, meet the requirement of the 10:1 Rule.

- The gage chosen for inspection must have a resolution of 1/10<sup>th</sup> resolution of the total tolerance of the dimension being measured.
- Example: A part is being inspected which has a feature size of 1.000", with a total tolerance of 0.007" (+.003,-.004). These inspection criteria would require a gage that can discriminate to 0.0007".

If a gage is specially designed, its capability must be established using procedures compliant with ISO 10012.

## 6.4.3.2 Out of Tolerance Findings

If a measuring device may have allowed a nonconforming product to be shipped, the customer shall be immediately notified verbally and followed by a written notification (email, fax, etc.).

#### 6.4.3.3 Traceability

All measuring device verifications will be performed with devices or standards that have been verified and are traceable to the National Institute of Standards and Technology. Witco maintains records of this traceability.

#### 6.4.3.4 Records

Calibration records shall indicate:

- Equipment ID Number
- Calibration Date
- Identity of Calibration Technician or Laboratory
- Next Calibration Due Date

The verified device or its container is identified with its calibration status in a manner that is legible and visually apparent to the user.

#### 6.4.3.5 Verification Intervals

Verification intervals are based on history or adjustment, accuracy required and working environment.

#### 6.4.4 Equipment Maintenance

Production equipment essential to product quality and delivery receive preventive maintenance based on their type, importance, need, automated warning capability and disposable value.

Routine maintenance such as greasing fittings, checking oil levels, cleaning, etc. are considered part of the operation of the machine and do not require schedules or records of activity.

A list of equipment requiring scheduled maintenance activities is prepared along with a schedule for these activities.

Maintenance is performed by employees of Witco or outside suppliers with the capability of performing the needed tasks.

Records are retained for all scheduled activities indicating the date when the last activity was performed.

#### 6.4.5 Work Instructions

If work instructions are needed for general tasks or specific tasks related to the product, that are not included as part of the Shop paper, they shall be documented and controlled in accordance with the <u>Document Control Procedure</u>.



## 6.4.6 Sampling Inspection

The sampling table represents a C=0 sampling plan and shall be used when 100% inspection is not practical or required. Unless otherwise indicated, 1.00% AQL is used as a minimum for customer designated critical/key characteristics and 10.00% AQL is used for all general characteristics. In process inspections may be designated as a rate (i.e. "x per hour", "every 10<sup>th</sup> part", etc.). The rate should satisfy the sample size indicated in the sampling table.

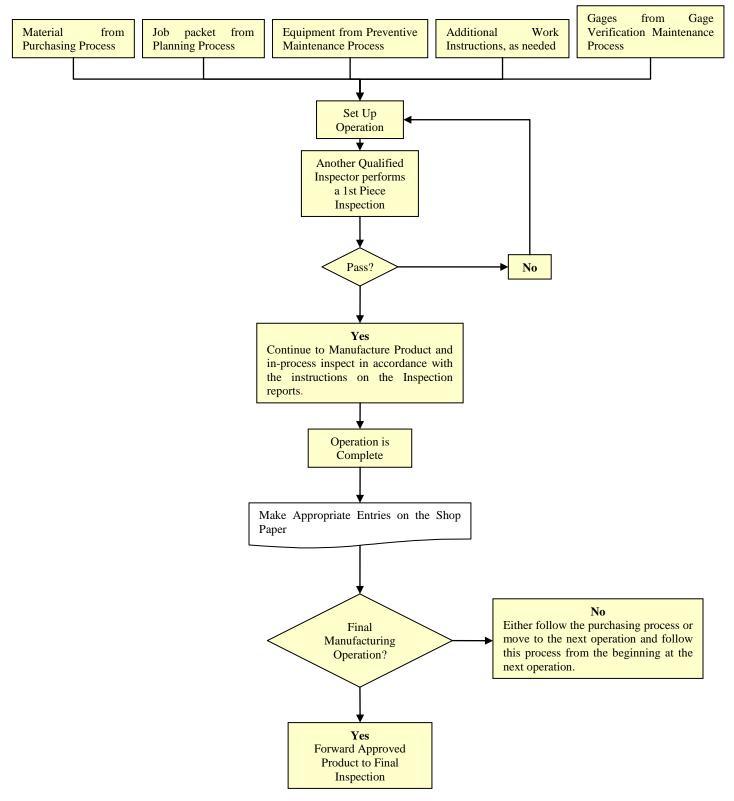
Customer requirements take precedent over Witco's sample designations.

#### 6.4.6.1 Sampling Table

	AQL Level							
Lot Size	0.65	1.00	1.50	2.50	4.00	6.50	10.00	S2N
2-8	All	All	All	5	3	2	2	2
9-15	All	13	8	5	3	2	2	2
16-25	20	13	8	5	3	3	2	2
26-50	20	13	8	5	5	5	3	3
51-90	20	13	8	7	6	5	4	3
91-150	20	13	12	11	7	6	5	3
151-280	20	20	19	13	10	7	6	3
281-500	47	29	21	16	11	9	7	3
501-1200	47	34	27	19	15	11	8	3
1201-3200	53	42	35	23	18	13	9	3
3201-10000	68	50	38	29	22	15	9	9
10001-35000	77	60	46	35	29	15	9	9
35001-150000	96	74	56	40	29	15	9	9
150001-500000	119	90	64	40	29	15	9	9
500001 and Over	143	102	64	40	29	15	9	9



#### 6.4.7 Manufacturing Process Flow





#### 6.4.8 Final Inspection

Final inspection is an audit of activities performed on each ship lot to ensure product quality and customer requirements have been met.

#### 6.4.8.1 Process Paperwork Review

The final inspector reviews the process paperwork to ensure all forms have been completely filled out and reviews the issues log to ensure that there has been no indication of an unresolved nonconformance that is applicable to the current final inspection.

#### 6.4.8.2 Part Accountability

With each shipment from a job number, until it has been completely shipped, shipping verifies that the total number of parts started at the first operation have been accounted for. The sum of the parts being shipped plus the parts that have shipped plus the parts in process plus the parts scrapped plus the parts on hold must equal the total number of parts started.

#### 6.4.8.3 Foreign Objects and Debris

A visual inspection is made of the ship lot to ensure that parts are clean and free of dirt, debris, corrosion and foreign objects. Special attention is given to holes, threads and crevices in the part.

Employees will receive training on FOD control and awareness posters will be placed throughout the facility. The Shipping Department will audit finished goods to verify that they are clean and ready to ship and utilize appropriate packaging to prevent contamination.

#### 6.4.8.4 Critical and Key Characteristics

A sample of product in accordance with the C=O sample plan is inspected. As a minimum, the critical/key characteristics are inspected. The record must identify the inspector, the part number and engineering change level.



# 7 Storage and Shipping Process

This is the process for preparing the product for shipment and/or storage awaiting shipment.

## 7.1 Storage and Shipping Process Objective(s) and Measurement(s)

The objective of this process is to package a product in a manner that will prevent handling, storage and transit damage or degradation of product quality. It is also an objective of this process to indentify and/or label the product in accordance with customer requirements. The process is measured by monitoring the Issues Log for customer complaints or rejections due to handling damage, transit damage or labeling errors.

## 7.2 Storage and Shipping Process Records

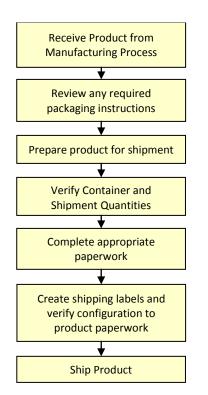
Record Type	Record Format Minimum Retention Time		Maintenance Responsibility
Shipping Paperwork	Shipper	7 Years	Sales Manager

# 7.3 Storage and Shipping Process Rules

- 1. Product labeling must include the engineering change level
- 2. Product will be stored and shipped in a manner that prevents contamination from foreign objects and debris
- 3. Product packaged for storage will be identified with a packaging date
- 4. Export documentation will be prepared in accordance with statutory and regulatory requirements

# 7.4 Storage and Shipping Process Instructions

## 1.1 Shipping Process Flow





# 8 Document and Record Control Procedure

Required by and Compliant with Section 4.2 of AS 9100 REV. C

## 8.1 Scope

## 8.1.1 Documents

The document control section of this procedure applies to all documents required by Witco's Quality Management System that provide instructions for the carrying out of tasks required by AS 9100 REV. C, Witco's Quality Manual, Quality Procedures and product work instructions. These include:

- The Quality Management System Manual
- Procedures and Instructions referred to in the Quality Manual, including all procedures required by AS 9100 REV. C
- Product Data, Instructions and Drawings used in manufacturing and/or inspection of product
- External documents that provide instructions necessary for compliance with customer, product, quality system and/or regulatory agency requirements

#### 8.1.2 Records

The records control section of this procedure applies to all records that provide evidence of conformance to requirements and effective operation of the quality management system. This includes all records required by AS 9100 REV. C.

#### 8.1.3 Forms

Blank forms are a special type of document until data is entered. After data is entered, they become records.

## 8.1.4 Electronic Documents

Electronic documents shall reside on a media that is accessible to all users. If a document is to exist in multiple electronic locations (hard drives, disks, etc.) it shall be controlled in the same manner as a paper document. A back up copy of the current issue of all electronic documents is required.

Either electronic documents are only available to those authorized to make changes or they must be protected from inadvertent edits as either read only or password protected documents.

#### 8.1.5 Paper Documents

Paper documents that are to be controlled must have a means of identifying where all of the controlled copies are located. They must be identified as controlled documents. Controlled copies must be issued from a master copy and may not be duplicated.

# 1.2 Control of Documents



Paper documents that do not require control may be used for reference only. Reference only documents cannot be used to make a final determination of product quality unless they are verified as current against the controlled master. A document that is not identified as controlled is considered reference only.

Printed copies of this manual or any page from this manual is considered uncontrolled for reference only unless accompanied by a serialized first page



## 8.1.6 Job Specific Documents

Documents being issued for a specific job such as Shop papers or Inspection Reports are controlled by a job number identification. These documents can only be used for identified job number. If the document is to be used for another job, it must be reviewed for adequacy and status and then identified with the new job number.

## 8.1.7 Externally Controlled Documents

The validity and status of externally controlled documents including customer drawings, is verified as part of contract review.

## 8.2 Document Control

All documents created by Witco shall have a unique title, a visually apparent revision status and identification of the approving authority.

## 8.2.1 Approval, Review and Update

As a minimum, all Quality Management System documents created by Witco shall be approved by at least one member of management. The approval can be by signature, initial or electronic application. The approval indicates that this manager has reviewed the document for adequacy and authorizes its implementation.

At least once every 5 years a document created by Witco shall be reviewed by Management. The review is to determine if the document is still valid or needs updating. The review may result in update or removal from use. If updated or left as is, the document will be reapproved by at least one member of Management. If removed from use the document will be handled as an obsolete document.

## 8.2.2 Availability and Maintenance

Only the most current revision of a document shall be available at its point of use. Available means that the user has unrestricted access to the document for the purpose of reading it. How close the document is to the workstation is based upon the user's need for uninterrupted flow of his/her work and the importance of the document to the task being performed.

Users must know where the documents are located and how to verify the revision status of the document they are using.

Users are responsible for the protection and care of the documents that they use and obtaining replacements for documents that are not legible or readily identifiable.

## 8.2.3 Obsolete Documents

If necessary for legal purposes or compliance with customer and/or regulatory agency requirements, obsolete documents may be retained as long as it is identified in a way that makes it visibly apparent and unmistakably clear to the user that the document is obsolete or void.

Obsolete documents cannot be used to make decisions regarding compliance for products produced after the document became obsolete.

## 8.2.4 Revision of Documents

- 1. Mark up a copy of the document with proposed changes
- 2. Present the marked up document to the approving authority for review. If required by contract or regulatory authorities, coordinate activities to include their notification and/or approval, as required.
- 3. The marked up copy may be used temporarily as long as each change is initialed by the approving authority
- 4. The master copy of the document will be revised with the approved changes
- 5. The revision status on the master document shall be updated to indicate changes have been made Printed copies of this manual or any page from this manual is considered uncontrolled for reference only unless accompanied by a serialized first page



6. Copies of the document will be made available to points of use and obsolete copies removed

## 8.3 Records Control

Records that provide evidence of compliance with product, Quality Management System, statutory, regulatory or customer requirements are controlled by this procedure.

Suppliers retaining records, on behalf of Witco Inc., that provide evidence of compliance with; component specifications, Quality Management Systems, statutory, regulatory, or customer requirements will be controlled in accordance with this procedure. Records stored by a supplier, on behalf of Witco Inc., must be readily available to Witco Inc. for a period of seven years after component completion.

## 8.3.1 Rules for Quality Records

- Records shall remain legible, readily identifiable, and retrievable. The records shall be stored in a manner that is indexed by a common theme. (Customer, job number, date, etc.)
- Records can be retained on paper or electronic medium.
- Records are available for review by customers and regulatory authorities in accordance with contract or regulatory requirements at our facility.
- Records will be stored in a manner that preserves their legibility
- Electronic records will be stored in an environment that receives regular back up to prevent loss.
- When required by the customer, their record format will be used in lieu of or in addition to Witco's format.

## 8.3.2 Records Control Matrix

Records control information is listed with the specific processes. The following matrix shows the control information for records that are not included with a specific process and may transcend several processes.

Record Type	Record Format	Record Responsibility	Creating Process	Retention Time
Internal Audit	Audit Report and Non- conformances	Management Representative	Management	7 Years
Corrective Action	Corrective Action Request	Management Representative	Any	7 Years
Preventive Action	Preventive Action Request	Management Representative	Any	7 Years
Nonconforming Product	Non-Conforming Material Report	Quality Control	Any	7 Years
Defective Customer Supplied Items	Emails, Faxes, Letters	Management Representative	Any	7 Years
Traceability	Per Customer Requirement	Various	Any	Life of Contract
Customer Satisfaction	Management Issues and Actions Log	Management	Any	7 Years

# 9 Internal Auditing Procedure

Required by and Compliant with Section 8.2.2 of AS 9100 REV. C

## 9.1 Internal Audit Scope and Purpose

The purpose of this procedure is to assess Witco's compliance with the standard and customer requirements and to look for opportunities for improvement or preventive actions.

This procedure covers all system, process and product audits performed at Witco.

## 9.2 Internal Audit Responsibilities

The management representative is responsible for coordinating the audit schedule and ensuring audits are conducted by qualified employees or agencies in an effective and timely manner.



## 9.3 Audit Planning

## 9.3.1 Process

To conduct a process audit the auditor needs a copy of the process being audited. The owner of the process and the measurable data for the process shall be defined and available prior to the start of the process.

Supporting Processes shall be audited as part of the core processes they support.

QMS procedures shall be audited as they apply to each process being audited.

#### 9.3.2 Schedule

All core processes should be included on a schedule that indicates the next planned audit of the process.

#### 9.3.3 Management Representative

The management quality representative (see management process) is responsible for coordinating the audit schedule and selecting the auditor for each process.

#### 9.3.4 Auditor Selection

Internal Auditors must have at least 6 months of experience at Witco Inc. and have received a certificate of completion from an ISO based internal auditing course. Internal auditors are required to complete at least one process or product audit per 12 month period between 3<sup>rd</sup> party surveillance audits.

An auditor cannot audit his/her own work. Preference should be given to an auditor that is familiar with the process being audited.

#### 9.3.5 Outside Agency

An outside agency can be contracted to perform the internal audits. They must be certified to an ISO standard at a minimum. The management representative will also review the audit report to ensure that it includes as a minimum:

- The identity of the process audited
- Notes of the audit
- The process' relationship to the standard
- Documentation of non-conformances found
- The audit scope and results

## 9.3.6 Audit Preparation

The auditor shall have access to all procedures, instructions and records applicable to the process being audited. The auditor should review these documents prior to conducting the audit.

## 9.4 Conducting the Audit

The audit is conducted using one of three methods; Observation, Document Review and/or interview.

#### 9.4.1 Observation

Auditing by observation requires observing the process in action and noting whether or not it is compliant, effective and efficient.



## 9.4.2 Document Review

Auditing by document review requires the examination of completed records and in-process records to ensure that they are being completed according to direction, with no spaces left blank. This is also a review to determine if the records being created, filed, and retained are in accordance with their associated procedure or instruction and the <u>Records Control procedure</u> in this manual.

## 9.4.3 Interview

This method is asking questions of employees in the process to ensure they understand the written requirements and have had sufficient training to meet their competency requirements. This method also assists in evaluating the effectiveness and efficiency of the process.

## 9.5 **Product Audits**

These audits are conducted at least twice a year. This involves tracking a completed product backwards from completion to quotation to ensure that all requirements were met as required.

## 9.6 **Documentation**

#### 9.6.1 Audit Report

The audit report summarizes the audit activity and highlights the findings for each process audited. The audit report is logged in the Issues Log.

#### 9.6.2 Audit Non-conformances

Audit non-conformances are documented in the Issues Log as issues. The person resolving the non-conformance enters the resolution in the Issues Log. The resolution should indicate systemic action.

#### 9.6.3 Follow Up

All non-conformances that have a CAR are followed up after the issue has been reported as resolved by an internal auditor. The auditor will add comments to the issue indicating the effectiveness of the actions taken.

## **10 Procedure for the Control of Nonconforming Product**

Required by and Compliant with Section 8.3 of AS 9100 REV. C and compliant with A-302.5 of the ASME QC System requirements

## **10.1 Non-Conforming Product Control Scope and Purpose**

This procedure covers product that is unexpectedly non-conforming. It does not include, with the exception of identity and segregation requirements, anticipated non-conformances such as set up scrap.

This procedure may not apply to non-conformances found and corrected in the process in which they were created.

## **10.2 Identification**

The product or its container shall be clearly identified as non-conforming. When identifying a container, the identification shall indicate the quantity of parts.

The identification shall usually be a Material Hold Tag that identifies the part number and where applicable, job or lot number of the non-conforming product.

Records must indicate the person, customer or outside agency that has classified the product(s) as non-conforming.

Product identified as scrap shall be permanently and conspicuously identified until it can be rendered unusable.



## **10.3 Segregation**

Nonconforming product shall be moved to a location where it cannot easily be mixed or confused with conforming product.

## **10.3.1 Containment**

When a customer or Witco places a product on containment, the following actions will apply:

- 1. Check for additional non-conforming product still in processes or inventory
- 2. Institute a 100% inspection requirement until the cause of the non-conformity can be eliminated

## **10.4 Disposition**

Dispositions can only be completed by approved individuals. The Witco AS9100 Document Matrix contains form number, QAF-90r – Non-Conforming Material Disposition Chart. This chart details positions that have the authority to complete a disposition depending on the situation (scrap, repair, rework, or OK to Proceed). Individuals in a position approved for completing dispositions per the QAF-90R can only disposition parts to which they are assigned. Employees in these positions must also sign a training sheet acknowledging their understanding of the QAF-90R form (either at New Hire Orientation or through additional continual improvement training).

## 10.4.1 Scrap

Product deemed scrap must be permanently and conspicuously identified, stored in a separate container, and accompanied with a Material Hold Tag (QAF-002 Red Tag). If a Scrap part can be used as a setup piece on a subsequent process it is acceptable to move forward and must be documented on the Shop Paper or the Parts Sign-Out Form (QAF-001A). Once a scrap part can no longer be used as a setup piece it should be rendered unusable.

At the completion of the process the part count must be verified and documented. Material Hold Tags will be removed from product rendered unusable, stapled to the back of the Shop Paper, and the scrap material must be disposed.

All Material Hold Tags associated with scrap material must remain attached to the Shop Paper until the job is completed and all parts can be accounted for through all processes. When the job is closed and the total part count is reconciled, Material Hold Tags can be then be removed from the shop paper and discarded.

Customer supplied material will be handled per the customer's request.

## **10.4.2 Repair**

If the product is to be repaired, the customer shall provide an approved repair method to be employed by Witco. Repaired product should be given a unique package and identification during the shipping process.

## 10.4.3 Rework

Rework by definition is reprocessing the product in accordance with its approved work instruction in order to achieve conformance. Unless required by contract, the customer does not need to be notified of rework.



#### **10.4.4 Ok to Proceed**

OK to Proceed indicates that a non-conformance exists, but has been deemed inconsequential. Dispositions of OK to Proceed require the approval of the Design Authority. The Design Authority must be notified of the nonconformance and a waiver request initiated (If the non-conformance is on an internal process, a waiver request will not be initiated and OK to Proceed will be authorized either by engineering or quality assurance). Once the Design Authority has approved the waiver, the disposition can be completed and the parts can be moved to the next process.

## **10.5 Customer Notification**

Management may notify the customer of a non-conformance if it cannot be reworked by Witco. The customer may decide that the product is scrap, may be repaired in accordance with an instruction, can be used as is, or needs to be returned for further evaluation.

## **10.6 Issues Log**

Incidents that result in the creation of unanticipated non-conforming parts should be entered into the Issues Log for management evaluation.

## **10.7 Supplier Caused Nonconformity**

When it is suspected that nonconformity is caused by a supplier or subcontractor:

- 1. Identify the product and segregate it from conforming product
- 2. Notify management and the buyer of the nonconformity
- 3. Management will determine if the product is to be returned, evaluated by the supplier at Witco or other actions related to the retention or transport of the product
- 4. A request for corrective action may be issued to the supplier.

## **10.8 Customer Returns**

- 1. Identify the product and segregate it from conforming product
- 2. Notify management of the reported nonconformity and enter into the Issues Log
- 3. Evaluate the product to determine the validity of the claim
- 4. If the nonconformance is verified;
  - a. Determine the compensation to be made to the customer and execute
  - b. Handle the product using the procedure for internal nonconformance
  - c. Follow the Corrective Action Procedure
- 5. If the nonconformance cannot be verified or if it may have been customer caused, contact management for resolution with the customer and execute the resolution

## **10.9 Internal Nonconformance**

- 1. Identify the product and segregate it from conforming product
- 2. Notify management and enter into the Issues Log
- 3. Obtain a disposition
- 4. Execute the disposition

## 10.10 Records

Records of the nature of nonconformities and subsequent actions shall be retained in accordance with the Records Control Procedure.



# **11 Corrective Action**

Required by and Compliant with Section 8.5.2 of AS 9100 REV. C

## **11.1 Corrective Action Scope and Purpose**

The purpose of this procedure is to identify the causes of non-conformity and correct those causes to prevent the occurrence of similar non-conformities in the future.

This procedure will be applied to all customer returns. The procedure will be applied to other non-conformities at the discretion of Witco's management.

## **11.2 Corrective Action Responsibilities**

The management representative is responsible for coordinating corrective action activities.

## **11.3 Review Non-Conformances**

As part of the <u>management review process</u>, the Issues Log, which includes customer complaints, will be reviewed for potential corrective action activity.

## **11.4 Determine the Cause**

Methodologies such as 5 why may be used to find the root cause of a non-conformity. The root cause is usually not employee error. The root cause is usually related to human, material, measures, methods, equipment and environmental elements.

Another cause may be identified when investigating the root cause that is not the cause of the specific nonconformity being investigated. In this instance, the cause should be considered for preventive action.

## **11.4.1 Investigation**

The following questions may be asked in the investigation of the root cause of non-conformity:

- 1. Is employee training required?
- 2. Is there a material or supplier problem?
- 3. Are the work instructions clear?
- 4. Are the measuring methods adequate?
- 5. Is there evidence of an equipment problem?
- 6. Is the workspace where the non-conformity occurred conducive to a quality product?
- 7. Are there sufficient resources to produce conforming product?
- 8. Is Witco capable of producing conforming product?

## **11.5 Prevent Recurrence**

Once the root cause has been identified, Witco shall consider the value of taking actions to eliminate the root cause. Customer satisfaction shall be given extra weight in the consideration of value.



## **11.6 Corrective Action**

Action must be taken in potentially three different areas:

- 1. Action to correct the non-conformity
- 2. Action to correct the cause of the non-conformity
- 3. If the non-conformity was discovered by the customer, action must be taken to correct the problem with detection of the non-conformity prior to shipment.

If a supplier was the cause of the non-conformance, the corrective action activity may be flowed down to the supplier by initiating a corrective action request.

## **11.7 Time Limits**

A Corrective Action Request must be answered within 30 days of issuance. If additional time is needed it must be requested of and approved by a management representative.

## **11.8 Documentation**

All corrective action activities are documented on a Corrective Action Request form and entered into the Issues Log.

## **11.9 Review the Results of Actions Taken**

All CARs are entered into the Issues Log and are reviewed by the Management Team. The Management Team must approve the CAR resolution prior to the CAR being completed. Once a CAR has been deemed complete it is automatically entered onto the audit log with a timeframe for review established. The effectiveness of the actions taken may not be immediately apparent and significant time may be necessary to determine if the actions are effective. When the audit due date arrives an audit of the CAR is completed to verify its effectiveness. If it is determined that the CAR resolution was not effective then the audit is marked "Failed" and a new corrective action issue is automatically generated on the Issues Log.

## **12 Preventive Action**

Required by and Compliant with Section 8.5.3 of AS 9100 REV. C

## **12.1 Scope**

This procedure is used to prevent loss to Witco or eliminate the cause of potential nonconformity.

## **12.2 Evaluating the Need**

The need for preventive action may be identified from several sources which include but are not limited to:

- Management Review
- Internal Audit
- Customer Complaints
- Employee Complaints or Suggestions
- Design Review
- Changes in Customer Requirements
- Reduction of Resources



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# **12.3 Determining and Implementing Actions Needed**

Once a potential problem is identified, management should determine a course of action to prevent the occurrence of this problem. Actions may include but are not limited to:

- Monitoring and/or Measuring a New Objective
- Preparation or Revision of a Disaster Recovery Plan
- Clarification of Customer Requirements
- Mistake Proofing
- Development of Emergency Subcontractors
- Utilization of Temporary Employees
- Reduction or Removal of the Potential for Human Error

## **12.4 Review and Record**

• All Preventive Actions are entered into the Issues Log and are reviewed by the Management Team. The Management Team must approve the Preventive Action resolution prior to the Preventive Actions being completed. Once a Preventive Action has been deemed complete it is automatically entered onto the audit log with a timeframe for review established. The effectiveness of the actions taken may not be immediately apparent and significant time may be necessary to determine if the actions are effective. When the audit due date arrives an audit of the Preventive Action is completed to verify its effectiveness. If it is determined that the Preventive Action resolution was not effective then the audit is marked "Failed" and a new Preventive Action issue is automatically generated on the Issues Log.